Nigeria: Inactivated Polio Vaccine (IPV) Introduction Plan

Version date: March 30, 2014

NOTE: This is a working document that will be revised based on ongoing feedback from the Nigerian IPV Core Group, Nigerian ICC, and Nigerian Stakeholders

Review Committee	Date reviewed	Date modified
NPHCDA (internal review)	**12 Feb 2014**	**14 Feb 2014**
IPV introduction team	**18 Feb 2014**	**21 Feb 2014**
Enlarged IPV Working Team review	**12 March 2014**	**15 March 2014**
In puts from stake holders consultations	**20 March 2014**	**25 March 2014**
ICC review and ratification	**27 March 2014**	**29 March 2014**
Submission to GAVI	**30 March 2014**	**30 March 2014**

Foreword

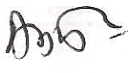
Nigeria's pledge to the world to rid itself of polio is fast becoming a reality. Already, wild polio virus type 2 disease has disappeared and since November 2012, wild polio virus type 3 disease has not been detected. In 2013, type 1 wild polio virus cases have been reduced by more than 50% and genetic clusters by 83%. The disease is boxed to the north east corner of the country where security challenge is hindering access to the children. This remarkable progress has put the country far ahead of the other endemic countries (Afghanistan and Pakistan). The triple benefits accruable from the use of inactivated polio vaccines (risk mitigation against wild polio type 2 disease, boosting immunity effect on types 1 and 3 disease and tackling the risk of cVDPV and VAPP) provides a leap frogging opportunity for Nigeria in the polio eradication end game strategy. The country therefore intends to seize this opportunity effectively by rapidly introducing the vaccine to end the polio game in the polio free areas and interrupt transmission in endemic areas.

Realizing that a strong routine immunization is the bedrock on which IPV introduction would be successful, the first ever National Routine Immunization Strategic Plan (NRISP 2013-2015) launched in 2013 by Mr. Gates and others clearly articulated strategies to be employed in getting sustainable high coverage levels for all antigens. Emphasis is placed on reaching every ward, accountability and health systems strengthening. Impressively, quick wins implementation resulted in a national penta 3 (DPT3 containing) coverage of 83 percent being achieved in 2013. Thus in 2014, on the eve of the MDGs it is very important for the nation to accelerate introduction of vaccines to reduce child mortality by tapping on our experience with penta. We envisage the planned PCV introduction in October would be less difficult and by extension the planned IPV in December will be a smooth sail. These introductions as carefully articulated in the strategic plan, would be more impactful in strengthening the routine immunization services. Given that the cold chain capacity had been prepared long ago to hold out for PCV and Rota which is 40% more than what is needed for IPV, cold chain issues would not affect the IPV nationwide introduction.

As we embark on our accelerated match to catch up with the rest of the world that have eradicated polio and achieved the MDGs, it is our understanding that other donors would support Nigeria as a friend in critical need of support in the same manner that GAVI and BMGF are doing in supporting our quest for IPV. Rota virus diarrhoea still remains a major cause of mortality in children and the earlier we protect the children by vaccination the better.

On this note, I wish to appeal to all our partners to stand firmly by us so that together we will deliver the country with respect to polio endgame and the health MDGs.

Thank you.



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Executive Summary

Nigeria remains one of the three countries in the world with endemic polio transmission. Tremendous efforts have been put in the programme in Nigeria to halt the transmission of the virus. The Presidential Taskforce on Immunization was formed solely to oversee the polio eradication program in Nigeria, guide it and report to the President of the Federal Republic of Nigeria. Similarly State and LGA level Task Forces were also formed to oversee the programme at State and LGA level respectively. In the area of Supplemental Immunization Activities (SIAs), a number of innovations and activities were conducted to ensure improvement in quality of the campaigns. The program in Nigeria took a right turn after these and other interventions. In 2013, Nigeria reported 53 WPV1 cases compared to 122 in 2012 representing a more than 50% reduction in polio cases. The country has also not recorded a single case WPV3 since November 2012. The number of circulating cVDPVs decreased by 83% in 2013 compared to 2012.[1] OPV coverage data have also improved significantly over the years with cumulative OPV3 of 87% nationally as at Dec. 2013.[2]

As part of the polio end-game strategy, Nigeria decided to include Government decision to use IPV for routine immunization (RI) at the WHO-AFRO Regional Committee meeting of Health Ministers in September 2013. The Nigerian EPI schedule which stipulates that BCG, OPV, Penta-valent, MV, Yellow Fever and Hepatitis B vaccines should be administered to every child in their first year of life in five routine contacts with primary health care services, and will add pneumococcal vaccine in Q4 2014.

This document describes two plans that are occurring in parallel but are distinct activities with different timelines:

NATIONWIDE INTRODUCTION: The *primary intent* of the introduction plan described in this document is the application for GAVI support for the **nationwide introduction** of the 5-dose vial of the stand-alone IPV in December 2014.

ACCELERATED LIMITED INTRODUCTION: This document also provides *a brief overview* of a parallel activity that is led by the Nigeria Polio Emergency Operations Center (EOC) of **an accelerated limited introduction** in the highest risk polio states in Northeast Nigeria and potentially a small state in South Nigeria no later than June 2014. The purpose for this accelerated introduction is to halt transmission of WPV and stop circulation of cVDPV by December 2014 in security compromised areas and underserved populations that may not be reached all the time. Simultaneous accelerated introduction in a Southern state will be an opportunity to document the process and lessons learned used to scale up the use of IPV in the country for RI as part of the polio end-game strategy. **This application is not seeking GAVI support for the accelerated introduction**, but is described herein to capture the comprehensive strategy taken by Nigeria to achieve polio eradication and endgame goals. The funding source for this is to be determined.

Nigeria's RI system has been substantially strengthened in the past year particularly after the Pentavalent vaccine introduction and preparations for the PCV introduction, and has adequate capacity to introduce one dose of IPV. Positive storage capacity requirements for the National and state levels respectively is 113,367 L and given FIC volume of 0.069 L for current schedule + PCV+IPV for four shipments, there is excess capacity at all

[1] More up-to-date numbers can be found at http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx

[2] NPHCDA RI & Logistic monthly feedbacks Dec. 2013

these levels. Meningitis A vaccine was introduced for campaigns in 2011. Pentavalent vaccine was introduced through a phased rollout beginning in 2012. More recently, a National Immunization Strategic Plan 2013-2015 was developed to map out strategies to achieve high national coverage (>87% sustained national coverage) of lifesaving childhood vaccines. GAVI has already approved the introduction of pneumococcal vaccine into the routine immunization program for Nigeria in the end of 2014.

The Government of Nigeria (GoN) is requesting full support from GAVI for one dose of IPV and supplies without any country co-financing. Nigeria would need an estimated 11,560,620 doses during the first year, assuming vaccine costs ($1 per dose), target infants in 2015 (7,433,884), target coverage of 87%, wastage rate of 30%, and accounting for 25% buffer stock for year 1. Thus, GAVI will pay USD 12,138,651 to cover the IPV cost and freight (5%). The GoN also requests to receive the Vaccine Introduction Grant (VIG) at USD 0.80 per child targeted for a total of $ 5,947,107.20. These funds will be important for meeting the accelerated IPV timeline and, in addition to leveraging existing resources and partnerships; they will support the preparation activities described in the introduction plan.

The cMYP feeds into the National Strategic Health Development Plan (NSHDP) 2010 – 2015 which presents interventions to improve health outcomes in line with national and global targets. It articulates key strategies to achieve EPI goals and objectives and includes capacity building as critical to strengthening immunization service delivery. Training for immunization personnel will occur at all levels with due emphasis on improving capacity at LGAs and health facilities.

The cMYP is estimated to cost US$2.4 billion over the 5-year period of which 25% of the cost is contributed by vaccines and injection supplies and one-third of the cost is due to SIAs. The funding gap based on secure funds averages 63% over the 5-year period while that based on secure and probable funds, including potential GAVI support, averages 21% over the same periods. Using secured funds only, there is an almost 10-fold increase with significant variations in the cost components of the funding gap between 2011 and 2015. In 2011, less than 10% of the funding gap is contributed by vaccines and injection supplies while an estimated 70% is due to SIAs. The situation is reversed by 2015 with about 50% of the funding gap being contributed by vaccines and supplies while SIAs contribute less than 25%. Mechanisms for mobilizing resources from government, development partners, extra-budgetary sources, the private sector, etc, to bridge the funding gap are described in the plan.

Key milestones during the process from decision to implementation of IPV nationwide include: establishing and developing TORs for a national introduction planning team; development of the introduction strategy and timeline; approval from the inter-agency coordinating committee (ICC) on immunization; stakeholder engagement. Other activities for the new vaccines introduction, also described in the cMYP and in the introduction plans, include cold chain readiness; advocacy, communications, and social mobilization; pharmaco-vigilance; training; and monitoring and evaluation.

The fact that 40% of causes of death among children under 5 in Nigeria are vaccine preventable, underscores the country is not likely to attain the fourth Millennium Development Goal (MDGs) to reduce mortality among children <5 years of age to 64/1000 by 2015; and hence the urgent need to step up immunization programs to reduce the pool of unimmunized children and reverse regional inequities in the coverage. The GoN has been approved for GAVI support for the introduction of pneumococcal vaccine and substantial efforts have been made to ensure country readiness to introduce pneumococcal vaccine. The GoN wants to ensure that the accelerated efforts to introduce IPV in Nigeria do not derail the plans to introduce pneumococcal vaccine and future plans to introduce rotavirus vaccines, which will help Nigeria reduce childhood mortality and reach the MDGs. Inadequate funds to meet the operational preparedness needs of the IPV introduction could be a barrier

to successful introduction. Mitigation strategies have included engaging donors, partners, and stakeholders to leverage existing partnerships and collaborations to coordinate ongoing and recent efforts and investments toward new vaccine introductions and RI strengthening.

National positive and negative cold storage capacity is adequate to accommodate the planned introduction of new vaccines (Penta, MenAfriVac, Pneumo) and traditional vaccines for routine and supplemental activities until the end of the revised Country Multi-year Plan (cMYP) 2011-2015. The storage capacity needs for IPV are small in volume (@5-7% of total volume for a fully immunized child[3] and with the recent expansion of the cold storage capacity to accommodate penta-valent and the planned pneumococcal introduction, Nigeria has substantially improved the cold chain storage capacity. More importantly, because these improvements have been against a future rotavirus introduction as a benchmark that is much greater in volume than one dose of schedule of multi-dose IPV, **Nigeria has adequate storage capacity to include IPV by the end of this year considering that more cold chain capacity gaps will be bridged with ongoing cold chain equipment procurement nationally and in states**.

The 2010 Effective Vaccine Management Assessment (EVMA) identified good infrastructure and cold chain equipment; satisfactory knowledge of vaccine management and temperature monitoring at most national and state storage facilities as strengths of the cold chain system. It however revealed inadequacies in transport facilities; temperature monitoring systems; and operational and management issues in the cold chain system especially at the LGA and health facility levels. Based on the EVMA findings, an improvement plan was developed and is being implemented to mitigate the challenges. The plan emphasizes supportive supervision of personnel at lower level stores and provision of transport and cold chain equipment where required. The GoN with support of donors (GAVI, EU, and JICA) have substantially increased efforts to ensure adequate storage space and sufficient supplies of quality bundled vaccines and devices at all levels at all times.[4] These efforts have led to remarkable improvements in the vaccine supply and logistics situation and include among others: expansion of the National Strategic Cold Store, procurement of solar direct drive refrigerators, and investments in improvements in knowledge and skills of cold chain personnel at all levels.

The EPI injection safety policy stipulates 100 percent bundling of all vaccines with auto disable syringes and safety boxes. Waste management for EPI is a subset of a country-wide health care waste management policy at early stages of implementation which promotes the use of waste disposal units at LGAs.

Nigeria has an approved HSS phase I grant (2009-2011) and as of December 2013, approximately 74% of the proposed activities were implemented with a target to implement >95% by end of June 2014. In addition, a revision of the HSS phase II grant (2014-2019) proposal has been submitted. The Phase I activities and those proposed in Phase II have markedly improved and will continue to enhance demand creation, service delivery, RI coverage (DTP3 containing antigen coverage >80% at the end of 2013), data quality, and cold chain storage capacity for new vaccine introduction as shown by the recent EVM progress report[5]. The cold chain has been substantially strengthened through the recent pentavalent introduction and the planned pneumococcal introduction and in anticipation of applying for support to introduce rotavirus vaccine in the near future.

[3]Introduction of IPV in Routine Immunizations. Available at http://tinyurl.com/ipv-intro
[4] HSS Cash Support Phase II application,
[5] EVM Progress Report 2013

The Government of Nigeria has IPV included in the National Routine Immunization Strategic Plan 2013-2015 which was aligned with the cMYP and updates its strategies. Therefore IPV will be included in the next cMYP in 2015 when it is revised along with the NSHDP this year in the third quarter. Similarly, the next EVM will be conducted in September 2014. Section 4.3 describes findings from the previous EVM assessment and the recent EVM improvement plan and progress. Section 4.4 provides a description of the vaccine management system in Nigeria.

Beyond the cold chain system, additional impacts on the health system from the introduction of IPV include concerns surrounding increased workload on frontline health workers, perceptions and attitudes surrounding multiple injections, and application of the multi-dose vial policy (MDVP) of discarding IPV vials after 6 hours or at session end, whichever comes first. These issues will be monitored and evaluated through training, follow-up supervisory visits, surveys, strong advocacy, communications, and social mobilization efforts.

1 Justification for introduction of IPV and national decision-making process

In 2013, the World Health Assembly endorsed *The Polio Eradication and Endgame Strategic Plan*[6] which addresses the eradication and containment of polio caused not just by wild viruses but also cases associated with oral polio vaccine (OPV). To address risks associated with OPV use, the Plan calls for a phased withdrawal of OPV globally beginning with removal of the type 2 component of tOPV through a switch globally from trivalent OPV (tOPV) to bivalent OPV (bOPV, containing only types 1 and 3) in 2016. To ensure that a substantial proportion of the population is protected against type 2 polio after OPV2 withdrawal, the WHO's Strategic Advisory Group of Experts (SAGE) has recommended that all countries introduce at least one dose of inactivated polio vaccine (IPV) in their routine immunization programs before end of 2015, prior to the tOPV-bOPV switch. SAGE recommends that all polio endemic and high-risk countries develop a plan for IPV introduction by mid-2014.[7]

Nigeria remains one of the three countries in the world with endemic polio transmission. Tremendous efforts have been put in the programme in Nigeria to halt the transmission of the virus. The Presidential Taskforce on Immunization was formed solely to oversee the polio eradication program in Nigeria, guide it and report to the President of the Federal Republic of Nigeria. Similarly State and LGA level Task Forces were also formed to oversee the programme at State and LGA level respectively. In the area of Supplemental Immunization Activities (SIAs), a number of innovations and activities were conducted to ensure improvement in quality. The program in Nigeria took a right turn after these and other interventions. In 2013, Nigeria reported 53 WPV1 cases compared to 122 in 2012 representing a more than 50% reduction in polio cases. [8] The country has also not recorded a single case WPV3 since November 2012. The number of circulating cVDPVs decreased by 83% in 2013 compared to 2012. The GoN wants to capitalize on these significant gains, interrupt transmission of polio once and for all, and complete the eradication and endgame of polio.

As part of the polio endgame strategy, Nigeria subscribed to the decision to use IPV for routine immunization (RI) at the WHO-AFRO Regional Committee meeting of Health Ministers in September 2013. Pursuant to this commitment, the National Primary Health Care Development Agency (NPHCDA), which has the mandate of integrating inputs from the Interagency Coordinating Committee (ICC) working groups and providing oversight, on behalf of the ICC for the planning and implementation of all immunization activities in Nigeria, reviewed the SAGE recommendations and the WHA mandate in December 2013 in the context of the Nigerian polio and RI situation and agreed to pursue GAVI support for the introduction of IPV according to the Endgame timelines.[9] The Executive Director of NPHCDA directed the immediate constitution of an IPV Introduction Working Team with broad representation from the GoN, Development Partners, and stakeholders (Pediatric Association of Nigeria and Nigeria Academy of Sciences).[10]The Steering Committee of the "Saving of One Million Lives (SOML) Initiative" had a meeting on 13 February 2013 and reemphasized the need to rapidly introduce IPV in Nigeria.

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[6]Available at http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx (Last accessed, 15 January 2014)

[7] SAGE position & WHO position paper [http://www.who.int/wer/2014/wer8901/en/index.html]

[8]More up-to-date numbers can be found at*http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx*

[9] Core Group, Meeting Minutes, December 2013

[10] Core Group, Meeting Minutes, December 2014

There is an inter-agency coordinating committee (ICC) on immunization with the mandate to co-ordinate Development Partners (WHO, UNICEF, Rotary International, USAID, DFID, EU, JICA, CHAI and others) supporting various aspects of the EPI programme in the country. The Core Group as the technical arm of the ICC meets every two weeks will preview the plan ahead of any ICC meeting to endorse the plan. Endorsement is being sought from the ICC that will be convened in March or April (opportunity to tap into the March or May GAVI application window), where members will review and ratify the IPV introduction plan. significantly, the plan was packaged by a multi-agency working team comprising of NPHCDA, WHO, UNICEF, BMGF, IVAC, CDC, PRRINN MNCH, Nigerian Academy of sciences and Paediatric association of Nigeria, Engagement of States, LGAs, civil society, scientific organizations, traditional , religious and other stakeholders was an integral part of the decision making process to introduce IPV in Nigeria.

Health systems strengthening across all levels have likely contributed to the improvement in DTP3 coverage above 80% in 2013.[11] One specific contribution is related to the phased introduction of pentavalent vaccine which had associated improvements in service delivery, cold chain system across all levels, data reporting, stock management, demand for vaccines, and health workers' knowledge through training and supportive supervision. The introduction plan for IPV will capitalize on these gains but also continue the trend in RI strengthening with emphasis on aspects of the system that are still relatively weak. The National Routine Immunization Strategic Plan (NRISP) 2013 – 2015 had envisaged IPV introduction and as a strategy emphasized health system strengthening and accountability, for which quick wins were already being implemented

[11] NPHCDA 2013 Administrative Data

2 Overview of IPV

2.1.1 Vaccine preference and introduction date

Table 2: IPV vaccine preferences and estimated date of introduction

Preferred IPV vaccine	Month and year of first vaccination	Preferred second presentation	Preferred third presentation
5-dose stand-alone IPV	December 2014	10-dose stand-alone IPV	1-dose stand-alone IPV

The planned date of IPV introduction nationwide will be December 1, 2014.

Nigeria prefers to use the WHO prequalified stand-alone IPV in the order of preference of 5-dose, 10-dose and 1-dose vials (Table 1). This preference strikes a balance between reducing cost and wastage, and optimizing storage capacity. The estimated gross capacity required for IPV during 2015 was **82 m^3 (82,000 litres) for the 5-dose presentation** (@7.6% of total cold space) compared to the required estimated gross capacity of **55 m^3 (55,000 litres) for the 10-dose presentation** (@5.3% of the total space).[12]

At an estimated cost of $1 per dose for projected 2015 infant population of 7,433,884, the estimated vaccine cost is $11,560,619 for 5-dose, which assumes 30% wastage rates versus $16,168,698 for the 10-dose vial which assumes 50% wastage[13].

The additional cost for IPV thus would be **an extra $4,608,079 per year for the 10-dose vial** compared to the 5-dose vial. Meanwhile, the incremental cold storage space investments of the 5-dose vial would only be an additional 2% of the total cold space. Given that the recent cold chain improvements in Nigeria have been against a future rotavirus introduction that is much greater in volume than the incremental space requirements of 5-dose vial of IPV, **the benefits of the cost-savings of 5-dose vial outweighs the benefits of the small saving in space from the 10-dose vial.**

2.1.2 Licensing information and procurement obstacles

The National Agency for Food and Drugs Administration and Control (NAFDAC) is a functional national regulatory authority (NRA) responsible for licensure of biological and pharmaceutical products in Nigeria. NAFDAC is not yet WHO certified, although this is not a pre-requisite for IPV licensure in Nigeria. Two processes exist for importation of vaccines that meet WHO prequalification, such as stand-alone IPV, both of which require NAFDAC approval.

1. Expedited Registration: NAFDAC does follow WHO expedited procedures for registration by the manufacturer.
2. Waiver: NPHDCA may apply for a waiver to import the WHO prequalified vaccine, which is the current practice for many prequalified vaccines in the Nigerian EPI. Shipment of each batch to the country requires a request for waiver that is submitted to NAFDAC by NPHDCA.

[12] WHO repository -- Immunization Systems Management Group estimates

[13] Assuming projected infants population in 2015 (7,433,884), target coverage of 87%, and accounting for 25% buffer stock for year 1

The IPV product already licensed in Nigeria is the 1 – dose presentation from Bilthoven Biologicals which is in use in the private sector. Once a product is registered in-country, no specific local customs regulations, requirements for pre-delivery inspection, or special documentations requirements are required whereas vaccines with waivers undergo pre-delivery inspection by NAFDAC.

All vaccines for the country are purchased through UNICEF.

2.1.3 Estimated target population for vaccination through 2018

Table 1: Estimated number of infants to be vaccinated with IPV in the RI programme, 2014-2018

Number	Targets				
	2014	2015	2016	2017	2018
Total infant population	7,201,973	7,433,884	7,673,726	7,921,810	8,178,463
OPV3 coverage (%)	82%	87%	90%	90%	90%
DTP3 coverage (%)	82%	87%	90%	90%	90%
IPV target in <1 (with DTP3/OPV3)	7%	87%	90%	90%	90%
Number of infants to be vaccinated) with IPV	492,135	6,467,479	6,906,353	7,129,629	7,360,617

3 Introduction and implementation considerations

3.1.1 Policy development issues

National Strategic Health Development Plan (NSHDP 2010-2015) is a five year strategic plan from which annual operational plans are derived. National planning and budgeting is done annually (January - December). The content of the cMYP 2010-2015 is aligned with the NSHDP. These plans articulate key strategies to achieve EPI goals and objectives, among which include the introduction of new vaccines. It is expected that the cMYP will be updated in line with the development of the next NSHDP when the current one ends in 2015. Incorporation of new vaccines into these plans would have no impact on existing vaccines.

Nationwide introduction (GAVI support): This application for GAVI support is for the **nationwide introduction** of stand-alone IPV beginning in December 2014, to meet the Endgame objective and support the global withdrawal of OPV use after the eradication of polio.

1. **One dose**: As recommended by SAGE, Nigeria elects to use one dose of IPV for risk mitigation as type 2 component is removed from OPV in 2016
2. **Administered at 14 weeks with Penta-valent and OPV3**: The dose would be administered along with Penta 3 and OPV3 at 14 weeks of age to maximize the immune response of the single dose of IPV. The trade-offs of missing children due to dropout from Penta-valent 1 to Penta-valent 3 is outweighed by the gains in immunogenicity to a single dose of IPV administered at 14 weeks of age when interference from maternally transferred antibodies is lower.
3. **No catch-up:** Children who have received their Penta 3 by the date of IPV introduction will NOT be eligible. The rationale is two-fold. First, infants born before the introduction of IPV and cessation of type 2 component of OPV would have received tOPV and thus be sufficiently immunized against type 2 polio virus. Therefore, only children born after the date of introduction would be eligible for IPV. Second, this policy is practical and in-line with the supply and cost considerations, and will improve stock management and minimize stock-outs.
4. **Injection site:** IPV should be administered by intramuscular (IM) injection along with PCV at the right thigh at least 2 cm apart. For example, if IPV, penta-valent vaccine, and pneumococcal vaccine are to be given during the same visit, IPV may be given with Pneumococcal vaccine in the same thigh at least 2 cm apart; the penta-valent vaccine which is more reactogenic is currently be given in the left thigh.

The fact that 40% of causes of death among children under 5 in Nigeria could be attributable to vaccine preventable conditions such as Pneumococcal pneumonia, Rota diarrhea, measles, tetanus and Hib (Haemophilus influenza type b) bacterial meningitis underscores the country is not likely to attain the fourth Millennium Development Goal (MDGs) to reduce mortality among children <5 years of age to 64/1000 by 2015;[14] and hence the urgent need to step up immunization programs to reduce the pool of unimmunized children and reverse regional inequities in the coverage. The GoN has been approved for GAVI support for the introduction of pneumococcal vaccine and substantial efforts have been made to ensure country readiness to introduce this vaccine. The GoN wants to ensure that the accelerated efforts to introduce IPV in Nigeria do not derail the plans to introduce rotavirus vaccines, which will help Nigeria reduce childhood mortality and reach the MDGs.

[14] NPHCDA bottleneck analysis 2012; NRISP 2013-2015

3.1.1.1 Limited-scale accelerated introduction (non-GAVI support)

This section provides ***a brief overview*** of a parallel activity that is led by the Nigeria Polio Emergency Operations Center (EOC) of **an accelerated limited introduction** in the highest risk polio states in Northeast Nigeria and potentially a small state in South Nigeria no later than June 2014.

Note:

- This planned *limited scale introduction* of IPV is for the purposes of facilitating interruption of polio transmission in endemic areas of Nigeria and **has to occur on an accelerated timeline** compared to the GAVI support for nationwide introduction which is for the purposes of the Endgame.
- The limited scale introduction is **not a component of application for GAVI support** but is described herein to capture the comprehensive strategy taken by Nigeria to achieve polio eradication and endgame goals.

In addition to the nationwide introduction, the Core Group recommended that the introduction of IPV in Nigeria will address two important needs of the country: the polio-free areas and polio-endemic areas. To address the pressing needs of interrupting polio transmission in the Northern Nigeria and preventing spread to polio-free areas, the proposal calls for an incremental accelerated process that will include limited introduction of IPV in the **highest risk areas** of Northeast Nigeria **no later than June 2014** before the peak season for polio begins in August. The Core Group also proposed that consideration should be given to a simultaneous small-scale introduction in a Southern State for socio-political reasons and balancing (as described below).

To achieve this objective, a separate protocol of activities, occurring in parallel and on an accelerated timeline compared with the GAVI application process, will be developed by the EOC to map out the accelerated introduction, with the following possible considerations:

Main Objective

The main objective will be to raise population immunity in children living in areas that are mostly inaccessible due to either insecurity and underserved hard to reach areas to rapidly achieve interruption by end of 2014.

Specific Objectives

- Halt transmission of wild poliovirus in security compromised areas and underserved populations that may not be reached all the time by December 2014
- Stop circulation of cVDPV by December 2014 as part of early implementation of the polio end-game strategy
- To document the process and lessons learned used to scale up the use of IPV in the country for RI as part of the polio end-game strategy

Considerations

1. **Introduction before June 2014:** For this strategy to succeed, the introduction of IPV in these high-risk areas would have to occur **no later than June 2014, before the onset of the peak polio season in August.**

2. **Availability of limited number of doses:** Due to the short-lead time, only a limited number of doses are likely to be available (to be defined, but perhaps around 200,000 doses as 1 dose presentation initially until the 5 dose becomes prequalified) thus **limiting the scope of this introduction to areas with the most convincing epidemiological need**.

3. **Focusing on the highest risk LGAs:** Limited availability of IPV doses due to the short lead time before introduction no later than June 2014 warrants consideration of identifying the highest risk security compromised areas (lowest OPV coverage) to maximize the per contact immunogenicity with IPV and OPV.

4. **Immunizing children <5 years of age**: Special **epidemiological concerns** such as the gap in vaccine coverage or surveillance in recent years in these high risk areas warrants that **consideration be given** to **immunize all children <5 years of age with IPV and OPV** during the immunization contact in areas with pockets of low OPV coverage.

5. **Socio-political considerations:** A *limited number of the available doses* could be applied simultaneously beginning in June 2014 in RI schedule of a small Southern state (**one dose at 14 weeks of age alongside Penta-valent3/OPV3**). This strategy could foster:
    a. Balance the country's socio-political context.
    b. An opportunity to document the process and lessons learned used to scale up the use of IPV in the country for RI as part of the polio end-game strategy.

6. **Advocacy, communication, and stakeholder consultation:** extensive consultations with key stakeholders and buy in before introduction of IPV in the country is crucial because of misconceptions of polio vaccines in the country: linkage to infertility, HIV infection etc., led to halting the polio programme in some northern states in 2003 which resulted in resurgence of polio cases.

7. **Procurement challenges:** If the available product is not registered, **ensuring a waiver of request is filed and granted in a timely manner** to NAFDAC with the IPV presentation and batch number will avoid any vaccine importation delays. Procurement could be directly through the manufacturer or through UNICEF, **whichever meets this important accelerated timescale.**

3.1.2 National coordination mechanism to ensure the successful introduction of the vaccine

Key milestones during the process from decision to implementation are included in Table 3 and include: Pre-implementation planning and decision-making activities such as establishing and developing TORs for a national introduction planning team, under the guidance of Nigeria's Core Group; development of the introduction strategy and timeline; approval from the inter-agency coordinating committee (ICC) on immunization; stakeholder engagement.

Additional activities to ensure a successful introduction include reviewing RI data and improvement plans; identifying weak components of the immunization system and plans to rectify; identifying poor performing and high risk LGAs and targeted activities planned for improving their performance; establishing technical subcommittees for cold chain and vaccine management, training, monitoring and evaluation, advocacy/communications/social mobilization, and adverse events following immunization monitoring and mobilizing human resources and developing a budget and ensuring availability of sufficient funds for the

operational costs of a successful IPV introduction process. Institutional strengthening activities are also required in the areas of operational research, social mobilization; logistics supply chain and pharmaco-vigilance.

Proposed timeline of activities for the NATIONWIDE introduction of IPV

		2014												2015					
1	**Program management and coordination:**	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1.1	Draft implementation plan for nationwide introduction, including **identifying key activities** important for a successful IPV introduction																		
1.2	Ensure licensing of IPV and procurement pathway																		
1.3	Secure funding from GAVI and other partners																		
1.4	Hold Inter agency Coordinating Committee meeting to ratify introduction plan and GAVI application																		
1.5	Hold monthly Core group meetings																		
1.6	One day stakeholders meeting with professional bodies (NMA, Pharmacetical Council, Nursing Council, Medical Laboratory Council, PAN																		
1.7	One day stakeholders meeting with States (HCH/ES- PHCB and DPHC)																		
1.8	One day stakeholders meeting with NGOs, NCWS, CAN, Islamic Supreme Council and Key influencers																		
1.9	Establish procedures for implementation - workplans,																		
1.9.1	Operations room: Communications 6 months pre introduction to 3 months post introduction																		
1.9.2	Fuelling of operations vehicles																		
2	**Planning and preparations:**																		
2.1	Review RI data tools (4 day meeting)																		
2.2	Update the REW and Basic Guide for service providers																		
2.3	Develop facilitators guide and training manual (4 day)																		
2.4	Transfer by GAVI of Vaccine Introduction Grant to GoN (Federal level)																		
2.5	Disburse training and Social mobilization funds to States and LGAs																		
2.6	Update HF catchment area microplans at LGA levels every quarter																		
3	**Training & meetings:**																		
3.1	Develop self directed learning DVDs																		
3.2	Develop training materials																		
3.3	Conduct National Training of Trainers																		
3.4	Conduct State level training																		
3.5	Conduct LGA level training																		
4	**Social mobilization, IEC, advocacy:**																		
4.1	Conduct Community acceptibility studies supported by CDC																		
4.2	Develop Information, Education and Communication (IEC) materials & other media messages																		
4.3	Develop communication plan for educating communities informed by a Knowledge, Attitudes, Practices and Perception (KAPP) study																		
4.4	Train pediatricians on advocacy, communication and media use																		
4.5	Air Radio jingles																		
4.6	Conduct Radio discussion programs																		

5	**Reproduction of materials:**																		
5.1	Print and distribute training manuals, facilitators guides																		
5.2	Reproduce and distribute DVDs																		
5.3	Print and distribute data tools																		
5.4	Print and distibute IEC materials (Posters fliers and FAQ)																		
5.5	Printing of AEFI registers and forms (case reporting and investigation forms)																		
5.6	Printing of report of the introduction process (Introduction plan, Post introduction evaluation)																		
6	**Per diems for staff and volunteers:**																		
6.1	Advocacy and assessment of state of preparedness																		
6.2	Monitor states and LGA level training																		
6.3	Involve vigilante/security for challenged areas and disaster zones to deliver vaccines																		
7	**Cold chain equipment & maintenance:**																		
7.1	Confirm cold storage gaps at HF levels																		
7.2	Procure additional CCE (SDD refrigerators/others) to bridge HF cold chain gap																		
7.3	Maintain additionally procured SDD refrigerators																		
7.4	Procure relevant spare parts																		
7.5	Clear vaccine supply from customs																		
7.6	Transport vaccine to states and LGAs																		
7.7	Transport IPV to HFs and outreach sites																		
7.8	Construction of Zonal and State dry stores																		
8	**Vehicles and transport:**																		
8.1	Procurement of 2 Prado jeeps																		
8.2	Procurement of 2 hilux vehicles																		
9	**Immunisation session supplies:**																		
9.1	Detailed item 1... [Soap and cottonwool, bowls, towels]																		
9.2	Detailed item 2... [AEFI kits - promethazine, dispersible paracetamol, hydrocortisone]																		
10	**Waste management:**																		
10.1	Procurement of incinerators																		
10.2	Training of operators																		
11	**Surveillance and monitoring:**																		
11.1	Strengthen the Emergency Preparedness and Outbreak Response																		
11.2	Quarterly AEFI Expert Committee Meeting for case reviews and caussality assessments (National)																		
11.3	Post marketing surveillance and monitoring																		
11.4	Supportive supervision visits Federal to States & health levels																		
11.5	Institute monitoring of adverse events following immunization (AEFIs) for IPV																		
11.6	Monthly reporting of IPV doses delivered																		
11.7	Analyze reported IPV data																		
11.8	Submit progress report to GAVI																		
11.9	Submit financial report to GAVI																		
12	**Post-introduction evaluation:**																		
12.1	6 months post introduction evaluation(PIE) with supportive supervision (6months after introduction)																		
12.2	Publish PIE report																		
13	**Technical assistance:**																		
13.1	Support of 2 communication expert																		
13.2	Support with 2 data officers																		
13.3	Pharmacovigilance expertise																		
14	**Other: Operations research**																		
14.1	Forward Cold Chain studies by UNICEF																		
14.2	Sero-surveys to generate local data																		
14.3	Wastage rates across routine vaccines and assess wastage-related knowledge, attitudes and practices at the health facility and LGA levels.																		
14.4	Renovation including shelving of existing Zonal and state dry stores																		
14.5	Review of existing cMYP and development of cMYP 2016-2020																		
14.6	EVM assessment																		

3.1.3 *Affordability and sustainability*

The Government of Nigeria (GoN) is requesting full support from GAVI for one dose of IPV and supplies without any country co-financing. Nigeria would need as estimated 11,560,620 doses during the first year, assuming vaccine costs ($1 per dose), infants population in 2015 (7,433,884), target coverage of 87%, wastage rate of 30%, and accounting for 25% buffer stock for year 1. Thus, GAVI will pay USD 12,138,651.00 to cover the IPV cost and freight of 5%.

The GoN also requests to receive the Vaccine Introduction Grant (VIG) at USD 0.80 per child[15] targeted for a total of $5,947,107.06. These funds will be important for meeting the accelerated IPV timeline and, in addition to leveraging existing resources and partnerships; they will support the preparation activities described in the introduction plan. If these funds could be released before October target date for PCV introduction it could facilitate integration of introduction activities for PCV and IPV thus saving paying twice.

The GAVI support for IPV without co-financing and provision of the VIG substantially facilitates the decision to introduce and the introduction process of IPV in Nigeria according to the rapid Endgame timelines. To ensure a successful introduction and a significant uptake of IPV post introduction, the following responsibilities are expected from differing government levels:-

1. **Federal:** Provision of Inactivated Polio Vaccines, injection devices and safety boxes and distribution to state stores. Development of data tools, training materials and support for Health Care Worker (HCW) training
2. **State:** Support for vaccine distribution and cold chain management within states, social mobilization and demand generation activities, support for HCW training.
3. **LGA:** Support for vaccine distribution and cold chain management within LGAs and HFs, social mobilization activities.

In addition, many ongoing efforts supported by government and donor funding are directed towards strengthening of RI to improve coverage of traditional vaccines and prepare for the introduction of pneumococcal vaccine within the next year and rotavirus vaccine in the future. These efforts will be leveraged to help defray any additional non-vaccine costs for introduction of IPV. In Table 4, the overall trend of Nigeria's immunizaton and funding sources for the immunisation program costs are stratified by source of funding and type of costs.

[15] The GAVI Application Form for IPV [http://www.gavialliance.org/support/apply/]

Table 4: Cost and financing

			Government support	Partners support*		GAVI support
	Cost Category	TOTAL COST US$	Amount US$	Name	Amount US$	Amount requested US$
1	Program management and coordination	188,860.19	127,410.19	UNICEF (33,318.75) &WHO(28,131.25)	61,450.00	-
2	Planning and preparations	6,011,913.22	5712500	CHAI	66000	233,413.22
3	Training and meetings	1,859,312.50	1,562.50	WHO	62,500.00	1,795,250.00
4	Social mobilization, IEC and advocacy	1,708,812.50	1,875.00	CDC(31,250.00) UNICEF(3,125.00)	34,375.00	1,672,562.50
5	Reproduction of materials	10,272,812.50	-	GAVI PCV VIG-2.2m, WHO 71m, GAVI HSS2 3.9m, PCV VIG 3.6m, CHAI 12.5k	9,915,781.25	357,031.25
6	Per diems for staff and volunteers	481,000.00	-	-	-	481,000.00
7	Cold chain equipment & maintenance	4,682,312.50	428,437.50	GAVI HSS2	3,640,000.00	613,875.00
8	Vehicles and Transportation	125,000.00	-	-	-	125,000.00
9	Immunisation session supplies	1,656,625.00	1,656,625.00	-	-	-
10	Waste management	4,728,125.00	4,728,125.00	-	-	-
11	Surveillance and monitoring	967,625.00	482,405.00	EU 193k, GAVI HSS2 291k	485,220.00	-
12	Post-introduction evaluation	400,000.00	-	-	-	400,000.00
13	Technical assistance	300,000.00	-	-	-	300,000.00
14	Other (please specify)	2,157,551.75	62,500.00	WHO 413k & UNICEF 600k	2,076,301.75	18,750.00
	Total	35,539,950.15	13,201,440.19	UNICEF,WHO,CDC,CHAI	16,341,628.00	5,996,881.97

Table 4 : Overall trend of Nigeria's immunization funding sources

		Estimated costs per annum in US$ (in thousand US$)				
Cost category	**Funding source**	**Base Year**	**Year 1**	**Year 2**	**Year 3**	**Year 4**
		2008	**2012**	**2013**	**2014**	**2015**
Routine Recurrent Cost						
Vaccines (Routine Traditional)	Government	17,000	11,865	12,641	13,694	16,827
Vaccines (Underused)	Government/GAVI (Co financing)	5,300	26,865	44,566	72,831	83,929
Vaccines (New)	Government/GAVI Co financing	0	0	31,883	65,189	121,032
Injection supplies	Government (GAVI INS till 2010)	7,014	4,425	4,584	4,768	5,136
Personnel	Govt, WHO, UNICEF, EU, GAVI (ISS)	40,821	51,364	57,727	64,631	72,637
Transport	Govt, UNICEF, GAVI (ISS)	5,392	10,645	12,802	16,073	19,844
Maintenance and overhead	Govt, UNICEF, USAID, GAVI(ISS)	5,086	9,631	12,100	12,704	14,124
Short term training	Govt, UNICEF, WHO, GAVI (HSS)	1,675	2,271	2,643	3,017	3,608
IEC/Social mobilization	Govt, UNICEF, Rotary, GAVI (ISS) B&MGF	4,668	5,346	5,284	5,689	6,456
Disease surveillance	WHO	1,477	19,289	23,216	26,722	31,608
Programme management	Govt, WHO, USAID, UNICEF, EU, DFID	614	13,713	16,822	20,480	24,765
Routine Capital Costs						
Vehicle	Govt, WHO, UNICEF	789	1,866	1,209	1,569	1,998
Cold chain equipment	Govt, UNICEF	1,112	4,470	4,258	4,166	4,166
Other capital equipment	Govt UNICEF EU	11	447	447	447	447
Campaigns						
Polio	Govt, World Bank, B&MGF, WHO, Rotary, KFW, UNICEF	102,601	139,229	151,070	100,930	106,494
Measles	Govt, Measles Partners, UN Foundation	29,468	0	0	33,282	0
TT	Govt, UNICEF & WHO	0	3,433	0	0	0
Meningitis	Govt& GAVI, WHO, MVP, & UNICEF	0	28,264	25,675	0	0
GRAND TOTAL		**223,028**	**333,123**	**406,927**	**446,192**	**513,071**

The cMYP is estimated to cost US$2.4 billion over the 5-year period of which 25% of the cost is contributed by vaccines and injection supplies and one-third of the cost is due to SIAs.[16] The funding gap based on secure funds averages 63% over the 5-year period while that based on secure and probable funds, including potential GAVI support, averages 21% over the same periods. Using secured funds only, there is an almost 10-fold increase with significant variations in the cost components of the funding gap between 2011 and 2015. In 2011, less than 10% of the funding gap is contributed by vaccines and injection supplies while an estimated 70% is due to SIAs. The situation is reversed by 2015 with about 50% of the funding gap being contributed by vaccines and supplies while SIAs contribute less than 25%. Mechanisms for mobilizing resources from government, development partners, extra-budgetary sources, the private sector, etc, to bridge the funding gap are described in the plan.

3.1.4 Overview of cold chain capacity

3.1.4.1 The Cold Chain System

The cold chain system consists of the National Strategic Cold Store (NSCS) in Abuja, six zonal cold stores located in each of the six geo-political zones, 36 States vaccine cold stores plus the Federal Capital territory (FCT) and 774 Local Government Area (LGA) vaccine stores serving about 20,630 health facilities providing immunization services. The NSCS and the zonal cold stores constitute the national level cold storage capacity which operates as a single entity.[17]The cumulative total capacity of the cold chain system in all 36 states and FCT and LGAs is 320,827 and 229,960 liters for positive and negative volumes respectively[18].

3.1.4.2 National Strategic Cold Store (NSCS) and Zonal Stores

The National Strategic Cold Store is located in Abuja and receives all nationally procured vaccines coming into the country. In addition there are six zonal cold stores for vaccine and dry materials storage located in the six geopolitical zones (Table 5). Together these stores provide the total nationally available cold storage capacity of 210,420L positive storage and 83,665L negative but flexible[19] storage. Vaccines and dry materials are distributed to the thirty-six States and the Federal Capital Territory from the NSCS and/or zonal stores, coordinated by the NSCS. The routine immunization buffer stock (3months of national supplies), campaign vaccines and strategic vaccines for emergencies and disease outbreaks are held in national and zonal stores. The distribution of routine vaccines and supplies from the NSCS to state stores occurs quarterly based on state requests determined by current stock levels in state stores.

[16]cMYP 2011-2015

[17] Cold chain capacity assessment, 2013

[18]Inventory Repair and Replacement Planning tool, March 2014

[19] Cold rooms can be switched to positive storage conditions and vice versa

Table 5: Cold chain capacity of national level stores[20]

Cold Chain capacity at the National Strategic Cold Store Cold Store	Net storage Litres (+2°C to +8°C)	Net storage Litres (-15°C to -25°C)
NSCS, Abuja	42,858	23,810
SW Zone, Lagos	50,298	19,021
NC Zone, Minna	26,786	12,262
SS Zone, Warri	28,572	9,524
NE Zone, Bauchi	19,048	4,762
SE Zone, Enugu	23,810	14,286
NW Zone, Kano	19,048	0
TOTAL	210,420	83,665

Zonal stores in all locations are now fully functional. The negative storage is flexible in the sense that it can be converted to positive storage anytime the need arises. Additional expansion in national storage capacity is also anticipated with installation of 40m^3 cold rooms; 3 at the NSCS and 2 for each planned vaccine hub. A cold house will be built for the NSCS. This is an additional positive storage capacity of 47,620Litres which could greatly increase if the planned vaccine hubs become fully implemented. Eventually a cold house of 500m^3 if built as proposed in the GAVI HSS phase 2 proposal will take care of all future new vaccines (PCV, Rota, HPV, 2nd dose Measles along with Rubella) and vaccine switches (Td, bOPV, Measles Rubella vaccines) that will occur up to 2020.

3.1.4.3 State Cold Stores

Each State and the FCT in Nigeria has a functional cold store which is run and maintained by the State Ministry of Health. The State government, NPHCDA and Development Partners, provides cold chain equipment in state cold stores. The cumulative total capacity of the cold chain system in all 36 states and FCT is 320,827and 229,960 litres for positive and negative volumes respectively[21].

3.1.4.4 LGA Cold Stores

There is progress in addressing the capacity gaps at LGAs to accommodate new vaccines through GAVI, JICA, EU-SIGN supported cold chain equipment (CCE) procurements and repairs of CCE. The LGAs have adequate cold chain capacity to store one-month's routine and supplemental vaccines requirements for the LGA. The

[20] NLWG assessment update

[21]Inventory Repair and Replacement Planning tool, 2013)

predominant cold chain equipment in the LGAs are refrigerators and deep freezers. Each LGA has at least 2 solar refrigerators providing additional 40 litres to the cold storage capacity and greatly improving vaccine management at the LGA and Health Facility (HF) levels where frequent power outage is major challenge. There is progress in addressing this challenge where state governments, with support from the Federal Government, provide funds to run back-up electric power generators.

Government policy specifies that at least 1 HF in each of the 9,555 political wards nationwide must be fully equipped to provide regular routine immunization services. As of 2013, only 30% of ward health facilities have refrigerators while others have cold boxes but plans are being implemented to equip all HFs with solar refrigerators. Presently, government at all levels with support from development partners provides funding for this expansion: GAVI Health Systems Strengthening Support (HSS 1) grant funded the provision of 485 solar refrigerators; the Federal Government procured 644; and UNICEF additional 400 solar refrigerators. With re-programmed ISS funds, HSS1 is adding additional 1656 SDDs and repairing 1150 broken down SRs.

3.1.4.5 Storage capacities available compared to needs

Nigeria is on course to ensure that national positive and negative cold storage capacity is adequate to accommodate the planned introduction of new vaccines (MenAfriVac, Pneumococcal, and Rotavirus) and traditional vaccines for routine and supplemental activities until the end of the revised Country Multi-year Plan (cMYP) 2011-2015. Because the storage capacity needs for IPV are small in volume (@5-7% of total volume for a fully immunized child) and the recent expansion of the cold storage capacity to accommodate penta-valent, the planned pneumococcal and rota virus vaccine introduction, Nigeria has adequate storage capacity to include IPV as computed in the table below.

Table 6: Cold chain capacity requirements

	National	States	LGAs
Target population under consideration	7,433,884	7,433,884	7,433,884
Frequency of shipments	4.00	4.00	12.00
Positive storage requirements (current schedule+PCV+IPV+25% buffer) per FIC@ 0.069 L	160,293	160,293	53,385
Available positive storage in liters	210,420	320,827	97,347
Gap in capacity in liters	(50,127)	(160,534)	(33,889)

The adequacy in national storage capacity has been achieved through integration of the six zonal stores with the National Strategic Cold Store using a highly responsive, effective mechanism for re-distributing vaccines at this level to optimize capacity utilization. This will also help prepare the country for additional future new vaccines introductions like HPV and Rotavirus.
The process of procurement of the CCE under the GAVI HSS Phase one programme / re-programming support to the tune of USD 18,477,368 is on-going; and the last set of the equipment ordered is expected to be delivered in the country latest by September 2014. Items to be procured include the following: standard direct drive solar refrigerators (1,656), 2-3L capacity vaccine carriers (30,566), walk-in cold rooms (6), incinerators (24), electronic fridge tags (6,000), SMS-capable fridge-tags (200); and computerized temperature monitoring devices (32).

Furthermore, the NPHCDA plans to continue with phased procurement and installation of 1334 Direct Drive solar refrigerators with HSS phase 2 commencing in July 2014 to attain 8,140 wards[22] with solar refrigerators by 2015. NPHCDA's efforts to repair the faulty cold chain equipment have so far resulted in repair of 28% of broken refrigerators at all levels for the procurement of cold chain equipment to support the country. All these efforts will guarantee over 80% EVM standards at the periphery.

Investments in cold chain are quite huge and needs to be guaranteed over a long period of time. The present maintenance culture is poor especially in our setting. The need for a proper maintenance scheme has led to the development of SOPs, total cost of ownership approach in procurement and a planned preventive maintenance manual. Provision of funds for guaranteed maintenance contract has been made in the GAVI HSS proposals.

3.1.4.6 Provision for waste management and injection safety

The EPI injection safety policy stipulates 100 percent bundling of all vaccines with auto disable syringes and safety boxes. Waste management for EPI is a subset of a country-wide health care waste management policy at early stages of implementation which promotes the use of waste disposal units at LGAs. With the GAVI HSS support the frontiers for waste management has been advanced by provision of incinerators 100kg per hour burning rates for every one million vaccination injections in the 2011 – 2015 MenAfriVac campaign, the 2013 integrated measles campaign and 2013 – 2017 yellow fever preventive campaign and the GAVI HSS reprogramming. Of 130 incinerators needed 41 have been delivered, 24 more is on its way leaving a gap of 89[23] incinerators.

3.1.5 Planned health worker training and supervision

Training of health workers (HWs) followed by supportive supervision across all sectors of the immunization program is a top priority in Nigeria.[24] The introduction of IPV offers an opportunity to close some of the barriers with regard to training of health workers and managers, and to reinforce this by supportive supervision and reporting requirements. Previous assessments have identified several barriers and plans are in place through the implementation of National Routine Immunization Strategic Plan 2013-2015 to address these, which will facilitate the introduction of IPV in Nigeria. One overarching objective of NRISP 2013-2015 is to strengthen EPI related capacity of frontline workforce in at least 80% of the service points by 2015. Ongoing work on this objective through a training working group at NPHCDA and the trainings associated with the recent penta-valent introductions will ensure adequately trained human resources across all sectors of the immunization program to introduce IPV.

Top priorities and approaches on training with regard to IPV introduction include:

- **Training materials:** A technical and an operational manual that cover policy, scientific, and operational aspects related to introduction of IPV; a handbook for HWs; FAQs; fact sheets on operational aspects including application of the multi-dose vial policy and multiple injections; case-studies on introduction

[22] Existing functional solar refrigerators 2800, JICA 400, HSS phase 1 1656, repairs 1150, HSS phase 2 1334, EU SIGN 800

[23] Analysis by National Logistics Working Group

[24] NRISP 2013-2018

experience from other settings; training videos; and posters. *Technical assistance from partners will be required*.

- **Training methods:** Of particular interest to NPHCDA is the development of innovative training methods, such as self-directed learning and m-learning ("mobile learning"). In states and LGAs where these methods are inappropriate, cascade training will be used through a series of workshops. The effectiveness of the appropriate training methods will be evaluated through pre- and post-knowledge tests and surveys of its acceptability and usefulness such that it facilitates ongoing and future training/retraining efforts. Specific emphasis will be placed on inter-personal communication as a key vaccinator skill.
- **Integrated training**: Training will be offered as an integrated package to combine material and better utilize training time, to re-train the frontline (old and new) HWs on immunization practices such as injection safety, AEFI communications, cold chain management, data collection, analysis, and use for action).

NPHCDA has already implemented strategies to strengthen current mechanisms for supportive supervision by integrating RI with other components of PHC, regularizing it using standardized checklists and outlining mechanisms for feedback and follow-up. During IPV introduction, supportive supervision is intended to reinforce the messages provided during the training to health workers. Emphasis will be placed on skill improvement for the staff to ensure provision of quality services, assessment of the performance of the EPI and its staff, and provision of feedback and necessary remedies, including on-the-job training. Each supervisory team will be expected to carry out a debriefing to facility staff at the end of each visit. It is recommended that the national level should undertake supervision at least once every two months, states once a month and LGAs three times a month. The supervisory visits will include a review of the monitoring data, injection practices, social mobilization, logistics, stock management, and vaccine handling practices at the healthcare center.

3.1.6 Risks, challenges, and mitigation strategies

Key risks/challenges to the introduction of IPV in Nigeria and mitigation strategies/evaluations that will be employed include:

Financial: The short Endgame timeline will require rapid mobilization of resources to ensure that programmatic concerns are addressed in a timely manner before the introduction of IPV in Nigeria. The VIG will be tremendously useful for ensuring system readiness however there could be short lead time between the receipt of the VIG and planned introduction date.

Mitigation: To address this potential risk, preparatory activities will be initiated before the VIG leveraging existing resources, partnerships, and consultations that could support the preparation activities described in the introduction plan. NPHCDA will welcome partner support to realize this important task of IPV introduction according to the Endgame timelines.

Community acceptability of IPV: The gains toward polio elimination in Nigeria are fragile. Misconception of polio vaccines in the country as a cause of infertility and HIV infection led to halting the polio programme in some northern states in 2003 that resulted in resurgence of polio cases.

Mitigation: NPHCDA in coordination with regional and global partners will develop a strong advocacy and communication strategy. Key strategies will include:

1. Extensive consultations with key stakeholders have already begun to obtain buy in before introduction of IPV in the country is crucial.
2. A crisis communication plan will be developed.
3. Surveys will be conducted to inform messages and tailor the strategies to improve vaccine acceptance. These surveys[25] will:
    i. Document the attitudes and practices of caretakers towards the addition of IPV
    ii. Document the attitudes and practices of healthcare providers towards the addition of IPV

Safety profile of IPV: While having local data can improve vaccine acceptability, it must be recognized that a large global body of evidence already exists on the safety of IPV. IPV has been used globally for decades without any causal reports of serious adverse events. WHO's Global Advisory on Vaccine Safety (GACVS) has reviewed the available safety data and is reassured that IPV and IPV-containing vaccines have a very safe profile.[26]For logistical reasons, an adequately powered safety trial may not be feasible to complete and provide data that would be of use in the context of the Endgame timeline. However several approaches could be considered as described below.

Mitigation: Ensuring a proper review of the safety profile of IPV has been conducted and effective communication of this information to the appropriate partners, stakeholders, and the community is envisaged to be a critical component. In addition development and implementation of a strong advocacy and communication strategy described above, key additional activities to consider include:

1. **Literature review**: Conduct a Desk/literature review on the OPV to IPV switch and IPV safety, drawing lessons from other countries
2. **Workshops:** Scientific workshops for members of scientific professional organizations could increase awareness and knowledge about the safety profile of IPV and provide an opportunity to solicit feedback that would be useful for tailoring communications and advocacy strategies.
3. **Pre and post-licensure sero-surveys& post-introduction safety monitoring:** the accelerated introduction of limited scope in high risk Northeast parts of Nigeria and a polio-free Southern state provides an opportunity to document the process and lessons learned used to scale up the use of IPV in the country for RI as part of the polio end-game strategy. A pre- and post-introduction evaluation could be conducted to assess these issues. In particular, a pre-introduction sero-survey and attitudes/knowledge survey could be conducted in these areas where existing polio resources already exist. Following the introduction of vaccine, intensive active surveillance for potential adverse events could be conducted using the AEFI monitoring plan. In addition, a post-introduction sero-survey could also be considered. This strategy would not only be logistically feasible, but also provide "real-world" data on the safety, tolerability, and acceptance of IPV that could be instrumental for successful introduction of IPV in the RI program nationally.

Programmatic risks:

[25] Community acceptability studies in annex …..

[26] WHO, GACVS meeting on IPV safety, December 12 2013

- **Cold chain--Freezing**: As previously outlined, the cold chain storage is adequately prepared for the introduction of IPV. However, IPV is freeze-sensitive and this is one specific area that warrants attention at the health facility and outreach level.
    - **Mitigation**: Conduct a pre-introduction and post-introduction temperature monitoring study to assess whether vaccines are subjected to below freezing (and/or high temperatures) at the peripheral health centers. These evaluations will specifically incorporate brief intervention strategies (e.g., novel training approach) and the evaluation will be designed to evaluate the effectiveness of the intervention on reducing exposure to extreme temperatures at the peripheral health centers.
- **LGAs with ineffective cold-chain:** Struggles with failing cold chain equipment and non-functional equipment that has highlighted the need for substantial cold chain procurement and a planned preventive maintenance policy. Substantial progress has been made but LGAs with struggles still exist. One particular challenge in some of these LGAs is keeping vaccines cool until administration.
    - **Mitigation**: IPV is heat-sensitive and vials have a VVM7 for monitoring of cumulative heat exposure. IPV is stable for 4 years at 4°C and one month at 25°C. Significant loss of potency occurs at 37°C as early as 1-2 days of exposure. In targeted LGAs with the greatest cold chain struggles to keep vaccines cool until administration, use of fast cold-chains could be considered as a stop-gap measure until functioning cold chain equipment is ensured at all levels.
- **Multiple injections:** IPV will be the second injection (third with the introduction of pneumococcal vaccine). While data from middle and high-income countries support the safety and acceptability of multiple injections, generating local evidence will be crucial to avoid compromising the new introduction as well as the existing RI system.
    - **Mitigation:** Provide emphasis on the safety and acceptability of multiple injections during HW training, advocacy, and communications messaging. Additional surveys will be done to:
        1. Document strategies used to overcome barriers to acceptance of IPV as an additional injection
        2. Document impact of non-simultaneous injections on vaccination rates by 1 year of age in a selected cohort of infants
        3. Provide specific recommendations on strategies for maximizing acceptance of IPV during infant immunization visits
- **Multi-dose Vial Policy:** Multi-dose vials of stand-alone IPV must be discarded after being open for 6 hours or at the end of the session. A previous Nigerian vaccine wastage study in 2010 showed inadequate knowledge of health workers on the national immunization policy at LGA and HF levels on the application of MDVP as only 38% of health workers at HF level knew how to apply it correctly. The inappropriate application of MDVP resulted in turning away many mothers (30%) when they brought infants for vaccination at HFs in the 2 years prior to the study. The primary reported reason for the reluctance to open vials was high wastage rates in the setting of stock-outs.
    - **Mitigation:** Emphasis will be placed on improved stock management and better community mobilization to reduce stock-outs thus avoiding the situation where infants are not vaccinated due to staff efforts to reducing wastage over concerns of stock-out. Nationally-developed stock management forms (e.g. the VM1, VM2, VM3 forms) have since been distributed, along with written instructions on their use.
        1. During IPV introduction, messages will be reinforced through training and supportive supervision of health facility staff on how to accurately calculate wastage rates, be aware of wastage targets and understand the need to avoid missed opportunities to

vaccinate a child. With IPV health worker and LGA staff trainings, immunization policies will be reinforced, particularly on the multi-dose vial policy, when to open a vial and ages of eligibility for routine vaccinations.

2. Close monitoring of the situation, **including consideration of post-introduction assessment** to document wastage rates across routine vaccines and assess wastage-related knowledge, attitudes and practices at the health facility and LGA levels.

- **Emergencies & Security compromised access risks:** Internal and external threats to environment is a real risk that poses a threat to the larger RI program for all VPDs and has particularly jeopardized the gains towards interruption in polio transmission.
    - **Mitigation:** The introduction of IPV could be leveraged to ensure that adequate consideration is directed towards this important risk to the RI program and includes strengthening the **Emergency Preparedness and Response Plan, with functional committees,** to address these issues at all levels, and specifically ensuring vaccines and response commodities are stockpiled to respond in the event of an emergency. In security challenged areas and disaster zones, collaboration with security and rescue agencies, including local vigilante groups, will be needed to deliver vaccines.

4 Situational analysis of the immunization programme

4.1.1 General country context, health system overview and priorities

Nigeria is an emerging economy with a GDP per capita of US$ 1,452 and a total population of about 180million in 2014 projected from the 2006 census. The country is made up of 36 States plus the Federal Capital Territory, divided into 774 LGAs and further sub-divided into 9555 political wards. It operates a three-tier system of government comprising the Federal, States and Local Governments Areas (LGAs). The national healthcare delivery system is also organized as a three-tier system of primary, secondary and tertiary care with the Federal Government providing tertiary health care services through its teaching hospitals and federal medical centers (73); State governments providing secondary health care (969); and Local Governments delivering primary health care through an estimated 21,808 public health care facilities[27]. In 2008, under-5 mortality rate (U5MR) was 128 per 1000 live births indicative of insufficient progress towards achieving the Millennium Development Goal (MDG) 4 to reduce U5MR to 75 per 1000 live births in 2015. [28]

There have been significant variations in Expanded Programme on Immunization (EPI) performance with peaks and drops in DPT3 coverage in the 80s and 90s. Consequently, the National Programme on Immunization (NPI) established in 1996 to foster national ownership of the EPI, merged with the National Primary Health Care Development Agency (NPHCDA) in 2007 where its functions are now being discharged by the Department of Disease Control & Immunization. The DPT3 coverage by survey, administrative reporting and WHO/UNICEF estimates show progressive increase from 24% in 2002 (WHO/UNICEF coverage estimate 2002-2009) to 68% (NICS 2010) in 2010. In 2012, the country recorded low national coverage of DPT3 <60 %, with only 3 states achieving a coverage of ≥ 80 %. Following the various interventions from the GoN and partners, there was significant improvement in the national DPT3 coverage above 80% in 2013.[29]

Table . Trends in national vaccine coverage

Vaccine	Vaccine type Used	2012 Target population[30] (number by age and sex, if available)	Coverage reported	
			2013[31]	2012[32]
BCG	Staten, Japan lab, Serum Institute	5,640,210	94 %	87%
tOPV 3	Sanofi, Glaxo, Haffkine	4,991,910	87 %	77%
DTP1/Penta1	Biopharma	4,343,610	96% (penta)	67% (DPT)
Penta3	Biological E	3,695,310	87%	57 %
Measles 1	Serum Institute	5,056,740	94 %	78%

[27] A directory of health facilities in Nigeria 2011
[28]NDHS Preliminary Report 2013 & 2008, SOCW 2009
[29] NPHCDA Administrative Data 2013
[30] Surviving infants x 2012 coverage
[31] NPHCDA Routine EPI Coverage using administrative data
[32] Official Country Estimates: http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=NGA&commit=OK

4.1.2 *Barriers to immunization*

In past years, substantial strides have been accomplished to address several major barriers to RI through implementation of strategic multiyear plans such as NSHDP, NRISP, cMYP with financial and technical support from the GoN, GAVI, donors, and partners. Nigeria has some serious RI demand challenges particularly in the northern states that have 64% of the total population. In 2012, eight (42%) of the 19 northern states had immunization coverage below 50% for DPT3.[33] Some of the reasons for this low coverage include: poor community involvement in planning and implementation of RI services, Demand-Supply mismatch, poor attitudes, and behaviours and skills of health workers. Other reasons include social and cultural barriers to access (ignorance of potential benefits of vaccinations), minimal strategic allies' involvement in communication-related activities and lack of funding for sustained communication interventions.

Poor engagement of the community members is invariably linked to the poor population demand for immunization services, especially as noticed in the northern states. The Landscape Analysis of RI in Nigeria (LARIN) identified low or non-existent community engagement as one of the numerous barriers for service delivery. NPHCDA cited poor community involvement in planning and implementation of RI services, minimal strategic involvement of allies in communication-related activities and the lack of funding for sustained interventions as additional barriers for community demand for RI. The national government through NPHCDA has been making efforts to address these issues through implementing Volunteer Community Mobilizer (VCM), Maternal, New-born and Child Health Weeks (MNCHW), developing information Education and Communication (IEC) materials and IPC skills training for 4,500 PHC service providers.

Inadequate human resources for health constitute another major challenge for the routine immunization program in Nigeria. The system is suffering from inadequate staffing, rapid turnover and limited training and capacity at the health facility level, especially rural communities. Most of the trained health workers prefer to stay in urban areas than the rural areas, thereby populating the urban health facilities and leaving gap at the rural health facilities. Most times the states / LGAs do not have budget to train their health workers; and so very common to see only one or two trained staff in a health facility, especially at the rural area. And when the one or two officer(s) is/are transferred a gap is left with other officers without the required knowledge and skills for immunization and other primary health care service delivery.

Limited immunization service delivery in the country has resulted in the failure to vaccinate significant proportion of children and missed opportunities. The 2012 routine immunization program report shows that 80% of the nationally planned fixed and 74% of outreach sessions were implemented. This figure widely varies between states and LGAs. The baseline assessment done by CDC in November 2011 across Katsina, Bauchi, Niger, Kaduna, Kano, Jigawa, Sokoto and Zamfara reported that out of 311 health facilities (HFs) in the 7 LGAs included in the assessment, only 246 (79%) of the HFs provided RI services and 186 (52%) conducted outreach immunization sessions.

The majorities of HFs in densely populated and urban areas do not hold daily immunization sessions; and do not open a multi-dose vial until they have an adequate presence of eligible children in the HF. These practices prevent many mothers attending the HFs with their eligible children from getting them vaccinated. The outcome of such immunization practices contributed to the low RI coverage reported in Lagos and FCT for 2012 (where

[33] NRISP 2013-2018

coverage was less than 50%). The Nigerian Vaccine Wastage Study reported that at the LGA level only 59% of health workers knew that a vial should be opened for any eligible infant as stated in the national policy.

There are no substantial gender inequities to immunization in Nigeria. In the 2013 Nigeria Demographic and Health Survey, 39.4% of males 12-23 months received DPT3 compared to 37.0% of females.[34]

4.1.3 Summarize findings from previous programme reviews

A vaccine audit of the RI programme of Nigeria was conducted by the WHO Country Office in 2012. Overall, the audit exercise has corroborated the findings and recommendations made by the EVM assessment of December 2010 in the area of vaccine stock management. Both evaluations have highlighted occurrences of irregular vaccine supply. Although adequate quantities of vaccines are supplied by the NSCS to the state stores, lower quantities are found at the LGA stores, and antigens become scarcely available at Health Facilities.[35]

There were obvious similarities between the findings and recommendations of the audit of December 2012, and those of the EVM of 2010 regarding the indicators of vaccine stock management. And both exercises traced the root causes of stock management issues to the same string of weaknesses of the cold chain and logistics system. The critical factors causing disruptions in the supply of vaccine and devices are:

- Incomplete establishment of SMT at state vaccine stores
- Poor establishment of DVD-MT at LGA stores
- Weak planning of vaccination operations
- Lack of dissemination of norms and standards on stock management
- Lack of financial and logistical support to LGAs and Health Facilities
- Lack of training of managerial and technical staff
- Absence of guides for private HFs providing RI
- Limited private sector use in operational functions

The 2013 cold chain assessment report identified

1. 43 of LGA vaccine stores do not have sufficient capacity to store RI, pneumococcal and rotavirus vaccines.
2. Cold chain capacities at Wards do not reflect national policy of one solar refrigerator per ward.
3. 49% of CC is non-functional, although 75% of units are believed to be economically repairable.
4. Cold chain quality is challenged at LGA and HFs because of generally poor electricity supply.

The following recommendations emerged and are being implemented as described in prior sections:

- Adopt solar direct drive refrigerators as the best suitable type CC equipment for LGA and HFs
- Procure and install SDD cold chain equipment to address storage gaps at LGAs and HFs
- Conduct a technical audit of non-functional equipment to document the scope of repair required

[34] 2013 Nigeria Demographic and Health Survey

[35] Routine Immunization Program of Nigeria; Vaccine Audit Report 2012

- Procure spare parts needed to repair faulty equipment
- Drive a nation-wide rapid repair program, preferably in a phased manner
- Map the deployment of CC at ward level for optimum efficiency of distribution to other HFs

4.1.4 EVM assessment findings and improvement plan

In December 2010, Nigeria concluded an Effective Vaccine Management Assessment (EVMA) which comprehensively reviewed the country's vaccine supply chain from vaccine arrival into the country to service delivery points. Seventy-five facilities at National, State, LGA and facility levels were assessed. The main positive findings were good infrastructure including buildings and cold chain equipment; good knowledge of vaccine management; and satisfactory knowledge of temperature monitoring at most national and state storage facilities. However, the LGAs and HFs did not fare so well and the assessment revealed inadequacies in transport facilities; comprehensive temperature monitoring systems; and operational and management issues. As a result, of the EVMA results, an improvement plan which includes supportive supervision to lower level stores to entrench a preventive maintenance culture was developed and is being implemented to mitigate some of these challenges. Where gaps exist in the availability of cold chain equipment, steps have been taken to hasten the delivery of relevant equipment, temperature monitoring devices and refrigerator trucks as part of the cold chain revamping plan.

Progress report on the EVM improvement plan: The EVM process is about entrenching good storage and distribution practices. The package has been designed so that it can also be used both as an assessment tool for the systematic analysis of strengths and weaknesses across the supply chain and also as a supervisory aid to monitor and support the long-term progress of individual facilities.

Subsequent to the EVM Assessment conducted in 2011, an improvement plan was developed based on the EVMA recommendations to systematically address weaknesses in the vaccine supply chain in Nigeria. Activities have been assigned to each tier of the supply chain. Although significant progress has been made, particularly at National level, there are still some high priority activities that need to be carried out at all levels of the supply chain.

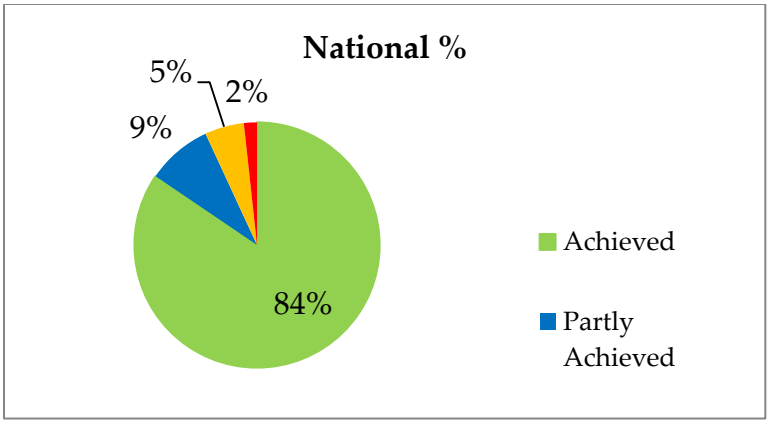


Figure 1: Progress in EVM improvement plan

National Level Progress: At the National level, great progress has been made with several of the improvement activities having been achieved (84%), partly achieved (9%) or in progress (5%). Of concern is that there has been no progress on rehabilitation of the existing dry store with the fitment of organised shelving and the provision of step ladders.

State Level Progress: Improvements at the state level have been less impressive, with only 53% of tasks achieved, 22% partly achieved, 12% in progress and 12% not achieved. Dry storage areas at state level are still a concern, with a number of states still lacking sufficient storage capacity and adequate shelving. Personal Protective Equipment for working in cold rooms has also not been provided. The accurate recording of wastage remains an issue. This needs to be raised with the Data Harmonization Committee for incorporation into data collection tools and ultimately DHIS2. Temperature monitoring has improved, with a number of activities underway, including a temperature monitoring study. A number of state cold rooms have also had continuous temperature loggers with SMS alert capability installed. Majority of states have developed contingency plans which were introduced in the vaccine management training. Storage capacity is currently being addressed under the introduction plan of the new vaccines. Maintenance guidelines are in the process of being developed and basic user maintenance was introduced as a module in the vaccine management training undertaken in quarter 4 of 2013. Majority of the states have developed distribution plans and share these with the LGAs. Job aids and finalisation of the existing SOPs is also in progress.

LGA Level Progress: Improvements at the LGA level have been steady, with 69% of tasks achieved, 21% in progress and only 10% not achieved. Again adequate, well organised dry storage capacity remains an issue. Supportive supervision has improved, with many states now performing supervisory visits on a routine basis. Vaccine storage capacity remains a challenge, but should be addressed with the plans to procure battery and solar directive drives refrigerators for each ward. Planning for the state level vaccine management training (where the LGA level will be trained) is underway, with a few states having confirmed their training dates. This should be finalised by April 2014.

Health Facility Level Progress: At the Health Facility level, 56% of tasks have been achieved, 19% partly achieved, 10% in progress and 6% not achieved. One of the most notable achievements is the revision of the supportive supervision checklist to include monitoring of vaccines and devices. The repair of solar refrigerators and the development of job aids are partly achieved. Training on vaccine management, development of planned preventative maintenance policies and vaccine disposal SOP are in progress and should be achieved shortly. A significant challenge has been the renovation of health facilities and addressing the poor drainage systems and other infrastructure inadequacies.

4.1.5 Brief description of vaccine stock management

As part of the recording and reporting system, various record books and vaccine movement forms are available. Ledgers are available at the national, zonal, state and in some cases LGA levels. In addition, the vaccine management tools (VM tools) are used to record vaccine movement between the LGA and the HFs. Also at the national, zonal and state levels, the stock management tool (SMT) is used to document vaccines movement and utilization. The District Vaccine Data Management Tool (DVD-MT) is also used at the state and national levels to monitor vaccine utilization at the LGA level. Some LGAs also use it to monitor vaccine utilization within the LGA. Stores requisition, issue and receipt vouchers are used for documenting movement of vaccines and other immunization supplies. Reporting is done mainly using the VM tools and the DVD-MT. Other tools used include

the monthly stock balance reporting forms which tracks vaccine balances at the state level including temperature of vaccines within the month. The DVD-MT also reports vaccines received, used and balance from the LGA as well as the temperature of storage within the reporting month. Data from the VM tools are used to report vaccine stock balances and utilization from the HF to the LGA and from the LGAs to the states. From here, the data are inputted into the DVD-MT along with the immunization coverage data for the month and the minimum and maximum storage temperature reached in the LGA within the reporting month.
The states then transmit the DVD-MT to the national level along with the updated stock balance report forms for the state. These are then analyzed at the national level and a feedback is made for each month detailing the core indicators of vaccine management and their status for each state as aggregates for the LGAs. These include vaccine utilization, wastage rates, quality of storage and bundling principle. This provides information for corrective actions to be taken where indicated. The monthly feedback is shared with all relevant authorities including government, partners and IST. The SMT at the national level is also shared with the management and partners and the IST. There are ongoing plans by the NPHCDA and partners to harmonize data reporting platforms through implementing the use of the DHIS for reporting data from health facilities. There are also ongoing projects to implement the automation of stock management systems (Navision) at National, state and LGA level stores.

Transport at the national level consists of cold vans for vaccine distribution. Since the vans cannot accommodate vaccines for each distribution route unless multiple trips are made, third-party transport providers are usually contracted to supplement movement of vaccines and dry materials especially during campaigns when large volumes are involved. A utility truck is also available for day to day operations of the NSCS and also at each zonal store. States have a utility vehicle each, procured by the Federal Government. However, these vehicles are only used for supervision and other EPI activities as the LGAs pull vaccines from the states. The LGAs make monthly trips to the states to collect vaccines and dry materials for immunization. Most LGAs have programme vehicles that are used for vaccine collection. In a few cases, vehicles are hired for the monthly vaccine collection. The HFs collect vaccines on scheduled immunization days using either cold boxes or Giostyle vaccine carriers where storage facilities are not available at the Health Facility levels. In Health Facilities with cold storage capacity, vaccines are collected on a monthly basis and stored for use during sessions. Most Health Facilities use motor cycles for vaccines collection and in some cases bicycles are also used. Cold boxes in form of rush and RCW25 and vaccine carriers are used for vaccine transportation at the various levels. Monitoring of temperatures during transport is not traditionally done as conditioned icepacks are used for vaccine transport. According to the recent EVM Progress report, the transport capacity improvement is expected to meet current programme need and future new vaccine introduction plan if the change is expected to take place in the coming 3 years, as it has been strengthened to accommodate penta-valent and the planned pneumococcal vaccine. Recent supply chain redesign efforts in Lagos and Kano states have resulted in outsourced delivery of vaccines directly to health facilities in pilot LGAs and there are ongoing plans to scale this process up state wide in Lagos and Kano states.

5 Monitoring and evaluation

In Nigeria, EPI monitoring, evaluation, and supervision are basic processes that facilitate the collection and analysis of the data required to verify whether activities planned under the program are being implemented effectively, or to what extent the objectives and targets defined have been achieved.

Information systems will be updated to facilitate collection of core indicators related to IPV introduction as described in following sections. This section provides a broad overview of plans for monitoring and evaluation in the context of IPV introduction, in the context of the Endgame Plan.

As these new vaccines (IPV, pneumococcal and rotavirus vaccines) are introduced, the GoN emphasizes the need to evaluate administrative data to document trends in indicators of routine immunization. Identifying key predictors of RI strengthening will be important through a combination of evaluation designs such as surveys of caretakers, health workers, immunization managers, and key informants; ecologic evaluations of RI indicators; coverage assessments. It will be particularly important for identifying key predictors of RI strengthening, so that future efforts in areas of weaker systems can employ similar interventions for improving immunization coverage.

5.1.1 Plans for updating monitoring tools

To accommodate the addition of IPV, NPHCDA will update immunization forms, vaccination cards, or electronic databases used for recording and reporting vaccine administration, forms for ordering vaccines, and vaccine stock ledgers, and any other forms that list the national immunization program vaccines. These include:

- ✓ Child immunization registers
- ✓ Vaccination cards
- ✓ Tally sheets
- ✓ Summary sheets
- ✓ Stock ledgers
- ✓ Vaccine Management Tools
- ✓ Electronic databases

In addition to the forms, the various information systems that use these data will also be updated to reflect the addition of IPV. This includes systems that aggregate immunization coverage data from LGA level upwards, including reporting at the national level to UNICEF/WHO. Early communication with the national health information system is needed to ensure adequate lead-time to change the system.

The introduction of IPV in Nigeria will be an opportunity to review how information is gathered and used for the immunization program and to improve the quality of routinely reported data in the DVDMT and the DHIS 2.2 as well as using that data to improve program performance at all levels.

Evaluation of IPV introduction will be based on monitoring vaccine coverage and other indicators of successful introduction activities (e.g., vaccine stock outs, wastage) and not on disease burden. Thus, emphasis will be placed during training that record keeping of IPV use must not be aggregated with OPV use.

The main recording tools that are used for immunization-related activities will be adapted to include IPV vaccine.

- ☑ Immunization or child health card: The IPV dose should be recorded on the child's immunization card, which is kept with the child to report their vaccination status, and other information such as monitoring of growth. The updated card will clearly indicate the clinic **where the IPV dose was received** and **date of administration** should be entered. If a child already has an older card without space for recording IPV administration, the information should be transferred to a new updated card.
- ☑ Tally sheet: Tally sheets are important for monitoring vaccine demand by supervisors.
    - Using the new tally sheets, record the monthly tally and the count for children immunized with IPV, alongside all other vaccines.
    - Also record the number of open vials and unopened vials with reason (VVM change, expiry, freezing, breakage, other)
- ☑ Register: New books with a column for IPV will be provided for recording the date when IPV is administered, alongside all other vaccines at the same contact.
- ☑ Stock record: Accurate vaccine forecasting and ordering depends on knowing the quantity of vaccines in stock at all times
- ☑ Integrated monthly report: Stock record forms will vary for the health facility versus the LGA and sub-national levels.

Monitoring the introduction of IPV will be done through:

- Weekly coordination meetings by the EPI focal persons to verify that all introduction activities are occurring on time in a quality manner
- Regular monitoring of core indicators of the implementation of the IPV immunization plan to identify achievements and gaps that need to be addressed. These core indicators will include:

    - IPV doses administered in relation to the target population under 1
    - Vaccine stock & wastage

5.1.2 AEFI monitoring and reporting policy

Adverse events following immunization (AEFI) monitoring in Nigeria will be a critical component of the IPV introduction strategy and the introduction will be leveraged to strengthen the existing national pharmaco-vigilance efforts.

- A national committee on pharmaco-vigilance, AEFI investigation, and response to AEFIs to address relevant rumors and potential allegations was inaugurated with the MenA campaigns in 2011
- The committee was strengthened during the phased penta-valent introduction with the formation of an Expert Committee that is responsible for causality assessments of reported AEFIs.
- IPV presents an opportunity to continue strengthening of this critical component of Nigeria's immunization program.

According to the national AEFI policy, all that should be reported to the relevant manager by mobile phone immediately upon detection by a health worker, include:

1. Serious AEFI (i.e., untoward medical occurrence that at any dose results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is life-threatening);
2. Signals and events associated with a newly introduced vaccine;

3. AEFIs that may have been caused by an immunization error;
4. Significant events of explained cause occurring with 30 days after a vaccination;
5. Events causing significant parental or community concern;
6. Swelling, redness, soreness at the injection site IF it lasts for more than 3 days or swelling extends beyond nearest joint.

Although serious AEFI caused by IPV are extremely rare, coincidental occurrence of a serious AEFI and sensational media coverage may seriously undermine immunization activities. Program managers have been trained to plan in advance a special communication strategy regarding AEFI, so that the program is prepared to respond if there is a problem.

The policy emphasizes that risk communication is important to build trust with the public. Development of materials prior to introduction will include information on possible side effects, education and communications (IEC) materials and when communicating with parents and the community. Efforts will also be placed on increasing awareness among health workers and the public of possible adverse events which will also facilitate early recognition and treatment of side effects, which may reduce their consequences. As part of the national AEFI policy, Nigeria has in place a crisis plan, the basic elements of which include:

- an AEFI committee at different levels that can meet immediately to discuss an action plan; identified, well-respected spokespersons at all levels;
- clear channels of communication with various media;
- engaging with credible opinion and traditional leaders to address misconceptions and rumors;
- training of health workers in how to communicate with the public about AEFIs and safety concerns;
- and having an AEFI action plan with specific roles for immunization program partners.

6 Advocacy, communications, and social mobilization

The gains toward polio elimination in Nigeria are fragile. Misconception of polio vaccines in the country as a cause of infertility and HIV infection led to halting the polio programme in some northern states in 2003 which resulted in resurgence of polio cases. Academicians and clerics preaching against OPV in 2013 led to the killing of polio workers during February IPDs and huge set-back to the programme in Nigeria.

A **critically important component** of the IPV introduction plan includes development of a robust national communication and advocacy strategy geared towards different audiences, partners, stakeholders, communities, and parents.

Emphasis will be placed on ensuring a well-defined and executed communication and advocacy strategy with the following aims:

- To create awareness and demand for IPV
- To foster trust
- To avoid rumors and misinformation
- To improve immunization coverage
- To enhance reporting and detection of potential AEFI
- To build strong community support for the immunization program
- To bring positive attitude change on immunization

NPHCDA in coordination with regional and global partners, particularly with agencies that have a vast amount of global experience with new vaccines (e.g., UNICEF, IVAC) and other agencies with broader communications & advocacy expertise (e.g Save the Children, Christian Aid) will be consulted and engaged early to develop and deploy the advocacy and communication strategy. In addition to this communication experts within the country will be engaged on contractual basis. Key strategies will include:

1. Extensive consultations with key stakeholders which have already begun to obtain buy in before introduction of IPV in the country is crucial.
2. Engagement of traditional leaders
3. Workshops with members of scientific professional organizations
4. Leverage and customize existing tools, including advocacy and global communications materials, to be packaged in a way that is useful for regional and country level advocacy activities
5. Selecting and leveraging potential advocates for training (pediatricians, researchers, civil society)—providing them advocacy, communications, and media relations training.
6. Developing a crisis communications plan
7. Surveys will be conducted to inform messages and tailor the strategies to improve vaccine acceptance. These surveys will:
    a. Document the attitudes and practices of caretakers towards the addition of IPV
    b. Document the attitudes and practices of healthcare providers towards the addition of IPV

IPV introduction also offers a unique opportunity to identify partners (e.g, IVAC, Save the Children) to help NPHCDA build on the foundation established by the MenA and penta-valent introduction by **substantially developing the advocacy and communications expertise at NPHCDA**, including a functional working group

with adequate staff and resources that can develop a longer term vision and policy for the RI program, including the introduction of new vaccines.

7 Annexures

7.1 Activity schedule, Detailed and Summary operational budget as in attached excel workbook

7.2 Concept Note for Assessing Unmet Needs and Community Acceptability of IPV Introduction

Background

Polio cases in Nigeria have decreased from 122 cases in 2012 to 53 in 2013; however, northern Nigeria remains the focal point of transmission in the country. In November 2012 an operational behavioral study was conducted by CDC, along with UNICEF to assess the reasons communities were refusing polio vaccine in five high risk states in Jigawa, Kaduna, Kano, Katsina, Zamfara. According to the study 49% of the respondents indicated that communities were refusing polio vaccine because they believe polio vaccination is unnecessary (i.e. "no felt need"). In the same study 34% of participants cited other important health and basic needs that are not currently provided by the government, but are at a higher priority as a reason for refusal of the polio vaccine.[36] From their point of view polio is not the main health problem affecting their community and they mention other necessities that are neglected while a great deal of resource and attention is given to polio. Improving our understanding of these gaps in services provided to high risk states will help the EPI partners in developing enhanced programmatic recommendations and communication approaches to not only address the existing needs, but improve vaccine acceptability.

The introduction of IPV into the routine vaccination schedule in Nigeria in combination with OPV is expected to have a significant impact on polio transmission by raising the level of immunity populations. However, considering the high level of resistance to vaccination, it is important to assess the acceptability of the new vaccine prior to its introduction in the target four states.

Objectives:

The objectives of the assessment are:

- Identify the potential constraints and the opportunities to facilitate wide acceptance of IPV and its introduction into the routine immunization schedule.
- Educate and engage leaders in addressing health needs and supporting polio eradication activities
- Determine what interventions could be provided to increase acceptance of oral polio vaccine and plan for introduction of inactivated polio vaccine
- Gain better understanding of unmet health needs in communities

Methods:

Study sites: The study will be conducted in 2 LGAs in four states (Kano, Sokoto, Borno, and Cross Rivers). Borno and Cross Rivers were selected, as they will likely be among the first states to introduce IPV in Nigeria through an accelerated introduction plan and pilot. Kano and Sokoto were selected as they are high-risk states, and Kano remains a reservoir for polio virus. In each LGA, two wards will be selected for a total of sixteen wards in 8 LGAs. In each LGA, one ward will be a highly non-compliant community and one ward will be a compliant community. Participants will include caregivers, village leaders, religious leaders, ward focal persons, ward development

[36] CDC, UNICEF, NFELTP, Missed Children and Refusals during Oral Polio Vaccination Campaigns: Community Perspectives in Northern Nigeria. October 2012 report.

committee members, healthcare workers (doctors, nurses, etc), and leaders from NGOs working in the area. The Wards and settlements will be selected based on the highest refusal rates identified using previous campaign data. In the north, half of the wards surveyed will be compliant, and half will be wards with high refusal rates. In the south there is not an issue with non-compliance, so wards will be randomly selected.

Data collection: A combination of focus group discussions (FGDs) among caregivers and male heads of households or fathers as well as semi-structured interviews (SSI) with key informants will be conducted to gain deeper understanding of the factors affecting acceptability of IPV as well as community needs from a diverse perspective. (Table:1).

1. **Assessing IPV acceptability and unmet health needs among caregivers**

Two FGDs will be conducted in each ward including, one focus group discussion among female caregivers and one among male heads of households or fathers. There will be six to eight participants per focus group for a total of 4 FGDs in each LGA and 32 in the four states. The assessment will target both caregivers who generally accept the oral polio vaccine as well as those who do not. This is because it is conceivable that people who generally accept polio vaccine may have both positive as well as negative attitudes towards IPV. Negative attitudes may come from the fact that IPV is an additional injection (too many injections) or because it is less safe than drops. People who have generally negative attitudes towards the polio vaccine (OPV) may have positive attitudes towards IPV because they view injectable vaccine as a more 'effective' or serious medication, or because it is administered by a professional. For each ward, one focus group discussion will be conducted among caregivers and one among male heads of households or fathers.

2. **Assessing IPV acceptability and unmet health needs among key informants**

Semi-structured key informant interviews will be conducted per ward for the purpose of the study of unmet needs to include the ward focal person, one member of the ward development committee, religious leaders, a healthcare worker/clinician and an official from an NGO. In addition to their social status in their communities, criteria for selecting these key informants will include their length of residency in the area, work with or familiarity with polio issues and for the healthcare worker, the extent of refusals in his/her health area. In each ward, 5 key informants will be interviewed to assess their perspectives on the acceptability of IPV.

Method	Number conducted per ward	Total for all states	Participants per FGD and Interviews	Total participants for study	Setting	Tools	Duration per method
FGDs caregivers	1 FGD with mothers 1 FGDs with male head of households or fathers	32 FGDs	Mothers and male head of households	8X 32=256 (128 caregivers; 128 males)	Community centers or other meeting places	FGDs guide for mothers and male head of household	1hr
Key informant interviews	5 per ward	80 key informant interviews	Key stakeholders (ward development committee,	5 X 16= 80	Area convenient to stakeholders	Questionnaire for key informant interviews	1hr

			religious leader, ward focal person, religious leaders, clinicians)				

Operational plan:

Field study teams: This will be a collaborative study between NSTOP and UNICEF. The 2 state teams will be composed of 2 males and 2 females (2 members from UNICEF and 2 FELTP/NSTOP residents). Each team will organize staff to conduct the study over a period as follows:

- **Day 1:** travel to LGA and get to know area and identify participants and locations for discussions
- **Day 2:** complete 1 FGD and 2-3 key informant interviews
- **Day 3:** complete 1 FGD and 2-3 key informant interviews
- **Day 4:** travel to LGA and get to know area and identify participants and locations for discussions
- **Day 5:** complete 1 FGD and 2-3 key informant interviews
- **Day 6:** complete 1FGD and 2-3 key informant interviews

Supervision: A state lead from NSTOP will be in place to facilitate any data collection or operational issues. Every evening each team will have a conference call with Abuja and state team lead to discuss any issues that arose that day and address any barriers.

FGD: Two teams (one female and one male) per state will be formed to serve as FGD facilitator and note-taker and they will conduct 8 FGDs in each state. The community focal person can assist with recruitment of participants and serve as a timekeeper/observer during the FGDs. A team will consist of a facilitator, note taker, and community focal point. The female team in the state will do the female focus group, and the male team will do the male focus group.

Key informant interviews: UNICEF and NSTOP team leads will conduct in-depth interviews with key informants.

	Staff needed per state	Total for 4 states	# to be conducted per day	Total FGD/interview per state	Total for 4 states
Facilitators	4 (2 female and 2 male)	16	Team will complete 1 ward (2 FGD & 5 key informant interviews) per 2 days	8 FGDs & 32 key informant interviews	32 FGDs & 128 key informant interviews

Selection of participants:

Participants will be selected using data from previous campaigns. A UNICEF focal point and NSTOP participant in each state will assist with the recruitment of participants and logistics for the FGDs and interviews. Each FGDs participant will be paid 500 Naira as compensation.

Survey tools:

1. FGDs guide for caregivers
2. Semi-structured interview questionnaire for key informants

Proposed Timeline:

Activity	Week of Jan 20th	Week of Jan 27	Week of Feb 3	Week of Feb 10	Week of Feb 17	Week of Feb 24	Mar 11-12	Mar 14-21	Mar 20-Apr 1	Apr 1-Apr 18	Apr 21-30
Finalize concept note											
Identify teams											
Select wards											
Draft questionnaire											
Draft FGDs guide											
Develop training for data collection team											
Finalize data collection tools											
Conduct Training											
Data collection											
Data entry											
Data analysis											
Report											

Budget:

Ethical Clearance:

The Field Epidemiology and Laboratory Training Program in Nigeria submitted to the Nigeria's ethical review board (EMHREC) for ethical clearance. The purpose of this project is to inform the national immunization program and provide input for planning the social mobilization strategy for polio vaccine. During the study

collection of names and other identifiable information is not required. The findings will be program specific and will not be generalized. We will describe the project and any possible risks and benefits and obtain consent from all participants before requesting their participation.

Informed Consent

All study respondents will be required to give informed consent before participating. The consent will include an explanation of the study and study procedures, potential risks and benefits, issues regarding confidentiality, voluntary participation and the rights of the participant. The voluntary nature of this study will be emphasized and respondents will be told that they can refuse to answer questions at any time. The consent will be read to participants in Hausa and English as appropriate.

Data analysis plan:

Qualitative data analysis is an iterative process that begins during data collection. Data collectors will be required to submit raw notes, a report summarizing their fieldwork, and the taped information for each FGDs and semi-structured interview. Transcripts and notes from FGDs and SSIs will be documented and assessed after fieldwork is completed. Data analysis will be performed by CDC in conjunction with FELTP and UNICEF.

Training:

16 UNICEF and NFELTP data collectors with experience interviewing and conducting focus group discussions will receive extensive training in qualitative data collection methods. The training will include techniques on how to ask open-ended questions, facilitating focus group discussions, approaches on interacting with respondents, and note-taking skills. Emphasis will also be placed on obtaining informed consent and ethical issues related to carrying out research. Training methods will be designed to encourage participation and ensure practical experience. Approaches will include role plays and mock interviews. These interviews will be observed by the trainers and followed-up with constructive suggestions regarding ways to improve. The training will also include identifying themes in qualitative data.

Data Collection:

Focus Group Discussions

Data collectors will be responsible for carrying out the focus group discussions according to the interview guide (see attachment 1). The focus group discussions will be held in community centers, schools, or other venues that will be appropriate and neutral. Critical to the focus group discussion process will be the appropriate use of probes to ensure that the data is complete. For every focus group session there will be a facilitator who asks the questions and a note taker. During the focus groups, the note taker will record notes directly into a notebook.

The FGDs will be conducted in comfortable settings where all parties are seated and the interviewer follows the focus group discussion guide to ensure that key topics are covered during the interview. The facilitator should encourage active discussion from all participants.

After completion of the FGDs, the facilitator and note taker will discuss the raw notes and expand upon them, if needed, and then record the notes observations, etc into a Word document. All group discussions will also be recorded on a tape-recorder; the recorded information is to be used to write up the transcript after the fieldwork and as a backup to clarify information collected or provide illustrative quotes.

Key informant interviews

The key informant interviews will be conducted individually and in community centers, markets, clinics, or wherever convenient for key informants with village leaders, religious leaders, ward focal persons, ward development committee members, leaders from NGOs, and healthcare workers. The interviewers will pose open ended questions to gather information regarding unmet basic and health needs in the community as well as acceptability of IPV. The topics to be discussed include basic primary health care needs felt in the community, general knowledge about polio program, suggestions to increase vaccine acceptability, and sentiments about injectable polio vaccine. The interviewer should ask follow-up questions and probes. This method allows for the free flow of information, more like a discussion than an interview, in which the interviewer is able to probe specific lines of questioning and the interviewee may emphasize information that he/she feels is of particular relevance.

Benefits of the study results

Findings from the community acceptance will inform the development of an effective strategy to introduce IPV which takes into account community perceptions. In particular, appropriate messages will be developed accordingly to address concerns about the addition of IPV to OPV in the child routine vaccination schedule on the one hand, and reinforce positive perceptions about the vaccine in order to improve its acceptance. By actively involving the community in the process it is likely the polio program will gain more trust and create a collaborative effort in increasing vaccine acceptability.

Additionally, there will be questions to understand the community basic and health needs from data collected through the interviews and FGDs from the caregivers and community leaders. The results of the study will have the potential to reveal mechanisms to engage the community in designing interventions and approaches to improve vaccine acceptability. In order to increase polio vaccine coverage in the worst performing LGAs with high rate of refusals it is important to create a platform for stakeholders to voice their needs, concerns, and suggestions.

Guide for Discussion with Caregivers

Instructions for Moderators (note that these instructions below and other specific instructions will be covered during trainings)

Note taking

- Take detailed notes to try to capture as much as possible of the discussion. Write down what each participant says, trying to capture exact quotes (do not write just summary statements from the discussion). **Use the recording device provided to ensure you capture the details.** The facilitator and note taker should write expanded notes immediately after the discussion (use the audio recordings). Recordings will be used to complement the notes. The facilitator will also complement the expanded notes with his own observations or recollections
- Keep a note of "key words" mentioned by the respondents throughout the FGDs
- Final notes should be typed in a Word document and sent to Drs. Matsutse, Ndiaye , and Andrea, for analysis.

Using the discussion guide

- A list of questions is provided as a guide to lead the discussion (see below); however, they should not be asked as a questionnaire. The conversation should be allowed to flow naturally, and you should try to encourage everyone to voice their opinion. However, discussions on each question should not exceed 10 minutes. Whenever the conversation stops or needs to be redirected, you can do so by asking one of the questions that has not been discussed. Before the conversation ends, make sure that all the topics in the questions have been covered.

Time management

- Before the session, arrange for someone (not a participant) to act as time-keeper and make a plan for how you will be notified of the time.
- Manage the time so that each topic is covered, according to the time allowed.
- Use verbal cues to help keep time with statements like:
  - "There is only time for one more comment."
  - "This discussion is very important, but in the interest of time we need to end this part of the discussion now. We will have time for a final discussion later."

Agenda

Welcome, instructions and consent	5Mins
Ground rules and introductions	5Mins
Discussion	80 Mins
Close-out	5 Mins
Total time	95Mins (1hr and 35 min)

Managing Group Dynamics

- The moderator's major goal is to collect useful information from all participants.
- Ensure even participation. If one or two people are dominating the discussion, then call on others to participate. Consider using a round- table approach, including going in one direction around the table, giving each person a minute to answer the question.
- Ensure only one person talks at a time and there is only one conversation occurring at a time (no side conversations).
- Promote mutual respect, especially when participants disagree. Remind them that everyone has a right to voice their point of view even if others do not agree.

Discussion Guide

Welcome, Instructions and Consent (5 minutes)

- **Introduction**
  Welcome and thank you for agreeing to participate in this focus group. My name is _____, and I'll be guiding today's discussion. I work with _____. To assist me with this activity are _____ [names of note takers and observers].

- **Purpose of Participation**
  As caregivers, you are all key players in the effort to eradicate polio from Nigeria. You have been asked to participate in this focus group discussion because we want to know your opinions and gain an understanding of the community's sentiments about child health, immunization, and, importantly to understand unmet needs from your perspective. We also want to know your opinion about another vaccine option for fighting polio. We value your experience and want to listen to your views and hear your thoughts. The knowledge and the information we collect will help us to come up with programmes that serve the needs of people living in this part of Nigeria.

- **A comfortable participation for everyone:**
  We welcome all your comments, questions, and suggestions. We are eager to hear from each of you, but also want you to know that there is no obligation to answer any question that you do not feel comfortable answering. There is no right or wrong answer to the questions I'm going to ask, so please relax and feel free to speak openly.

- **Informed Consent and Confidentiality**
  Before we start, I would like everyone to understand that anything you say here will be kept anonymous and that there won't be any negative effects on you based on what you say. Neither your name nor any information about you will be shared with any other person or organizations. No one will ever know who said each comment; we will only share the summary of your combined responses and some anonymous statements. I would also like to make sure everyone choosing to be a part of this focus group discussion willingly.

  [*Read the informed consent in Hausa and answer any questions participants might have regarding their participation]*

  [Ask if anyone wishes not to participate, and they will be excused to leave]

  [Pause to see if anyone does not want to participate. If anyone does decide to leave, allow them to leave the room and then proceed.]

  We would like to record our discussion today just to avoid my missing out on anything that you talk about during our conversation. My colleague will also take notes during the discussion. Does anyone object to that?

  [Pause to see if anyone objects.]

  OK,…..[*name*]…., please start the tape recorder.

Ground Rules and Introductions **(5 minutes)**

- **Ground Rules/Guidelines for Discussion:**

To make our discussion more comfortable and for it to run smoothly, there are a number of ground rules we will need to follow.

[Read the ground rules and post them on large newsprint or white board in a location that will enable all participants to see them and where you can refer to them if needed. The information in brackets is not to be written, it is just for you to explain it. Ask *if any other ground rules are needed for everyone to feel comfortable; seek general consensus].*

- Everyone's input is important.
- Please speak one at a time. Avoid side conversations.
- Please speak so that everyone can hear you.*[Remember, you are being audio taped. I may at times repeat what you say to make sure that your opinion is captured on tape.]*
- Stay focused on the question. *[I may need to cut a discussion short because of the limited time that we have. So please try to be brief.]*
- It is OK to disagree with another person's opinion or perspective. *[If you dislike something or disagree with something that is said, I want to hear about it. However, please avoid debating or trying to sway the opinion of others.*]
- Be respectful.
- If you have your cell phone, please turn it off or put it on silent mode.

Introduction of Participants:

So, let's get started by getting to know one another a little better… I'd like to go around the table and have everyone introduce themselves to the group.

[Start by introduce yourself in a friendly way to help everyone relax and get to know each other better.]
Please tell us:

- Your name (first name only)
- How long have you lived in this community?
- How many children do you have?

Well, let's get started.

Discussion **(50 minutes)**

Health issues affecting the community

1. What is the biggest health challenge facing your community?
    a. Probe: "Why is it important to you?"
    b. Probe: "What health needs are you not receiving in your community?"
    c. Probe: What would your community need to improve all over health in your village?
2. How did you learn about health issues, including childhood vaccinations/immunizations?
    a. Probe: What sources of information do you trust the most?

Immunizations

1. Please tell me what you know about childhood "immunization"/"vaccines" available for children

    a. Probe: "Is immunization beneficial for children? Why or why not?" For what diseases?
2. "Have your children taken injectable vaccines?"
    a. Probe: "Have your children experienced any problems with the injectable vaccines? If so, what problems?"
    b. Probe: "What is your opinion about your child receiving more than one injectable vaccine at a time?"
3. Please tell me what you know about polio.
    a. (look for knowledge about causes of polio, how can prevent, attitudes about polio vaccine)
    b. Probe: Are you worried about polio affecting children in your community? Why or why not?

Transition to IPV community acceptability

Now we are going to ask you some questions related to injectable polio vaccine (IPV).

Introduction to IPV: Currently children in Nigeria are receiving the oral polio vaccine (OPV) to protect them against the polio virus but there is a proposal to give them the injectable polio vaccine (IPV). IPV is an injectable vaccine that your child will take at fourteen weeks of age along with pentavalent. Providing both IPV and OPV improves a child's protection against polio. In several countries around the world, including Saudi Arabia, children regularly get injectable polio vaccine in addition to oral polio vaccine. This "injectable" vaccination is given once to boost your child's health. In the future your child will still continue to receive "polio drops" until your child is fully protected against Polio. Do you have any question before we begin?

Questions:

1. What do you think about injectable polio vaccine?
    a. (Probe here for perceptions of 'usefulness" of IPV as well when discussing this question)
    b. (if there are concerns, ask how should the concern(s) be addressed and probe for reasons of skepticism or hesitation and proposed solutions)
2. Would you accept your child to receive the injectable polio vaccine? Why or why not?
    a. (probe for "attitudes" that could explain the intention to accept the injectable polio vaccine)
    b. What would make you more likely to accept injectable polio vaccine?
3. What would you think about your child getting an injectable polio vaccine AND an oral polio vaccine together?
4. Would you allow your child to continue receiving polio drops after receiving injectable polio vaccine? Why or why not?
5. How can we make it easy for your child to receive injectable polio vaccine?

a. *(look for cues to potential interventions, especially for actionable ideas, that is ideas that we can do something)*
b. Probe: "What information would you need about IPV or vaccines for your children?
c. Probe: Who would you prefer to provide you information on IPV or other vaccine

6. Are there any other concerns or questions that come to your mind about this injectable polio vaccine?

Close-out	**(5 minutes)**

Thank you again for your time today. Please recall that everything said here was confidential. This discussion has provided valuable information that will shape the future of Nigeria's health programs.

Semi-Structured Questionnaire for Key Informants for IPV acceptability & unmet needs

Instructions for interviewers

A. Politely greet and introduce yourself to the respondent and tell him/her for whom and where you work. Explain that you are working to help improve the health of Nigerians.
B. Explain the purpose of the interview. We are working to protect the health of children in Nigeria. We are talking to mothers and male caregivers in particular but we are also asking community key informants like you to help us understand what those basic needs are and how we could best address them. We have a polio vaccine that is an injection and can better improve the immunity of children to the polio virus when combined with the oral polio vaccine that is currently being used. This injectable vaccine is being given in other countries, including Saudi Arabia. We need to know how people feel about this vaccine in order to find ways to best make it acceptable and easy for their children.
C. Explain why they are selected to participate: "You have been asked to participate in this interview because we believe that you know your community and are among its most well-known, influential and respected members and your opinion matters. We want to know your opinions and gain an understanding of the community's sentiments about polio vaccination and other felt needs from your perspective. We also want to know your opinion about injectable polio vaccine. We value your experience and knowledge, and the information we collect will help us design interventions that will serve the needs of people living in Nigeria and eradicating polio from your community so your children can live a healthy long life."
D. Explain that their responses will not have any negative effects on them, that participation is fully voluntary. Also mention that we are not asking for anyone's name and all responses will be kept completely anonymous. No information about them will be shared with any people or organizations.
E. If applicable, explain that this discussion will be recorded to ensure you accurately capture everything they are saying.
F. Interview respondents in a friendly and non-threatening way.

Date and location

Date of interview	
Name of interviewer	
State of interview	
LGA of interview	
Ward of interview	

Demographic

1. Age of key informant	
2. Gender	
3. Position in community	
4. Ethnicity	
5. Religion	
6. Highest educational level	

Health issues affecting the community

3. Please tell me about your community. What is the biggest health issue in your community?
    a. Is it being addressed by the nearest health facility?
    b. What are the other services you would like to see provided?
4. What are the priority health concerns for young children under the age of five in your community?
    a. Are these diseases being addressed by the nearest health center?

Immunizations

5. How is routine immunization regarded in your community (i.e. BCG, OPV, pentavalent, yellow fever, measles vaccine)? (probe for overall concerns and attitudes)
    a. What are parents' concerns about children receiving immunizations/vaccines?
6. Are there people in this community who do not take their child to get routine immunization? If so, who? (Probe for educational status, occupation, health workers, religion, others)

    a. Why do you think they do not?
    b. How can we convince them to take the child (less than 1 year old) to complete their immunization schedule at the routine immunization site? Who will be the best person to convince the caretakers?
    c. Are there caregivers who do not taking their child for routine immunization but accept polio drops during campaigns? Why do you think they are doing that?
    d. Have you heard someone in this community talking against taking immunizations?
7. In your opinion, what key messages must caretakers know in order to be convinced to take their children regularly for routine immunization?
8. Are you concerned about Polio affecting children in your community? Why or why not?
    a. What is being done in your community to protect against polio?

IPV

Introduction to IPV: 'Children in your community have been receiving the oral polio vaccine (OPV) to protect them against the polio virus, but there is a proposal to give them the injectable polio vaccine (IPV). This is a shot that children will take once after fourteen weeks of age. It is not a substitute but a complementary vaccine to increase the immunity of your child. In many countries of the world, including Saudi Arabia, children regularly get injectable polio vaccine in addition to oral polio vaccine. This "injectable" vaccination is given only once to boost a child's health. In the future children will still continue to receive "polio drops" until children are fully protected against Polio. Do you have any questions?

7. What do you think about the injectable polio vaccine?
    a. *(Probe here for perceptions of 'usefulness" of IPV as well when discussing this question)*
    b. *(if there are concerns, ask how should the concern(s) be addressed and probe for reasons of skepticism or hesitation and proposed solutions)*

2. How do you think the community will perceive injectable polio vaccine?

    a. Which members of the community do you expect will be most resistant? Why?

    b. Which members of the community do you expect to be most supportive? Why?

3. What specific concerns or problems do you think there are with giving children the injectable polio vaccine and oral polio vaccine together at the same time (during the same visit)?

    a. What would make caretakers more likely to accept taking IPV with OPV?
    b. Who would best convince the caretakers in this community?

4. What do you think caregivers will think about continuing to use oral polio vaccine during vaccination campaigns after the child receives injectable polio vaccine?

    a. What would make caregivers more likely to accept that their children continue to receive the oral polio vaccine during vaccination campaigns?

5. What would make you more likely to accept that this vaccine be given to your children or promote it in your community?
    a. What information would you need about IPV?
6. Would you allow your children to receive IPV? Why or why not?

7.3 The forward cold chain project (FCC)

Rationale

Nigeria's introduction of new vaccines requires an evaluation of the country's supply chain readiness and an ongoing cold chain vigilance program. The government plans to introduce inactivated polio (IPV), pneumococcal conjugate (PCV), human papilloma virus (HPV), and rotavirus vaccines into the routine vaccination schedule. These vaccines lose their potency and risk deactivation by prolonged exposure to either heat or freezing temperatures, heightening the importance of an effective national cold chain.

The most recent Effective Vaccine Management (EVM) Assessment, conducted by FMOH, NPHCDA, UNICEF and WHO in 2011, documents the need to strengthen the vaccine cold chain at each level. For the requirement that "All vaccines and diluents are stored within WHO-recommended temperature ranges," the evaluation gave Nigeria an average score of 45 of 100, 35 points below the minimum standard. The report strongly recommends an exhaustive temperature monitoring evaluation at each storage level and transit link of the vaccine supply chain in order to target cold chain strengthening efforts. Further recommendations include the routinization of such monitoring throughout the system and standardization of how its results are managed.

These new vaccines will dramatically reduce child mortality in Nigeria but only if they are stored and transported effectively from the national store through to the point of administration to the vaccinee. NPHCDA together with implementing partners has developed an evaluation program to assess the cold chain's readiness and enable ongoing measurement and targeted improvement throughout the vaccine cold chain.

Evaluation

NPHCDA will implement the WHO protocol "WHO/IVB/05.01: *Study protocol for temperature monitoring in the vaccine cold chain*," as called for in the EVM recommendations. In this protocol, "temperatures are monitored continuously as vaccine shipments travel through the cold chain, from primary stores, to intermediate stores, to health centres and, finally, to the outreach delivery site/s." Working with technical partner, eHealth Africa (eHA) in Kano, Nigeria, and building on past work NPHCDA has completed in the evaluation of the AFP surveillance cold chain, this program is designed to provide ongoing rapid, targeted evaluations that can be done at a point in time.

Research Questions

1. At which levels of the system and in which equipment are freeze-sensitive vaccines exposed to temperatures below 0degC?
2. At which levels of the system and in which equipment are heat-sensitive vaccines exposed to temperatures above 10degC?
3. What are the characteristics of cold chain temperatures at each level of the system and in each type of equipment? i.e., frequency of excursions, excursion min/max/mean temperatures, excursion durations, cumulative durations above, within, and below 0-10degC, rates (degrees/minutes) of excursions, frequency of freeze-thaw cycles, and dispersion and variance of temperature results by category.

4. What drives these temperature results? i.e., which inputs correlate to which outputs? e.g. products (equipment type/age, etc.), process (vaccine handling/management procedures, level of staff, etc).
5. In addition, the project aims to conduct an interventional study to determine the effectiveness of the recent vaccine management training

Objectives

1. To evaluate the CC system with temperature monitoring and data collection tools that will determine whether vaccines are at risk.
2. Build capacity for periodic, rapid evaluations.

Methodology

Electronic Data Collection

The program will use electronic data collection forms and smart phones. Electronic data collection avails the evaluation to a number of functional advantages including integrated geotagging, photo documentation, and barcode scanning as well as form logic that can dramatically simplify and standardize data entry, reduce entry error, and accommodate contingencies in the data collection process. The forms are saved locally on the device for each storage and transit link. When complete, are pushed to a dedicated server via the cellular network, allowing for rapid, centralized review. The process can be further bolstered by redundant paper-based data entry.

Continuous Temperature Recording

The evaluation will collect temperature data with WHO-prequalified LogTags TRIX-8 temperature recording devices. With the barcodes scanned, or serial numbers entered manually into the form, the LogTags used during the evaluation are related to the other data entered on the form, including cold chain equipment make and model, facility location, transit link, vehicle type, date/times of start, and other use-case information necessary to analyze the results. Staff will retrieve LogTags and return them to regional locations for downloading and resetting.

Data Management

Completed survey forms are downloaded from the server and entered into a database programmed to relate them to the corresponding LogTag date. After the raw LogTag data have been programmatically censored to match the appropriate start and stop times of the outreach and manually reviewed, custom scripts (algorithms) written in the database perform several complex data management tasks, which can be tailored to fit research questions specific to the evaluation. The scripts can segment the record according to milestones (certain actions or occurrences observed in the process) and visually annotate the temperature curve accordingly.

Data Analysis

Scripts facilitate the review and categorization of deployments. Temperature excursion scripts assess and organize the performance of the deployment in significant detail, including cumulative performance of the

deployment or segment of deployment (time above, within, and below the temperature range; percent of deployment above, within, and below temperature range; maximum, minimum, and average temperature; number of heat and freeze excursions) and detailed information about each excursion (minimum, maximum, average temperature; rate of excursion). The system then executes scripts to perform descriptive processing on the global dataset, helping to identify broad trends across the measures. The data are organized in tables that are displayed in an easy-to-read reporting interface and available for further analysis in a statistical package.

Program Team

NPHCDA will lead the project, provide the data collection equipment, and provide and/or coordinate the staff to implement the program. eHA will provide ongoing technical support in the form of electronic data collection instrument design, development, and hosting, staff training, data management, and analysis.

Interventional Study

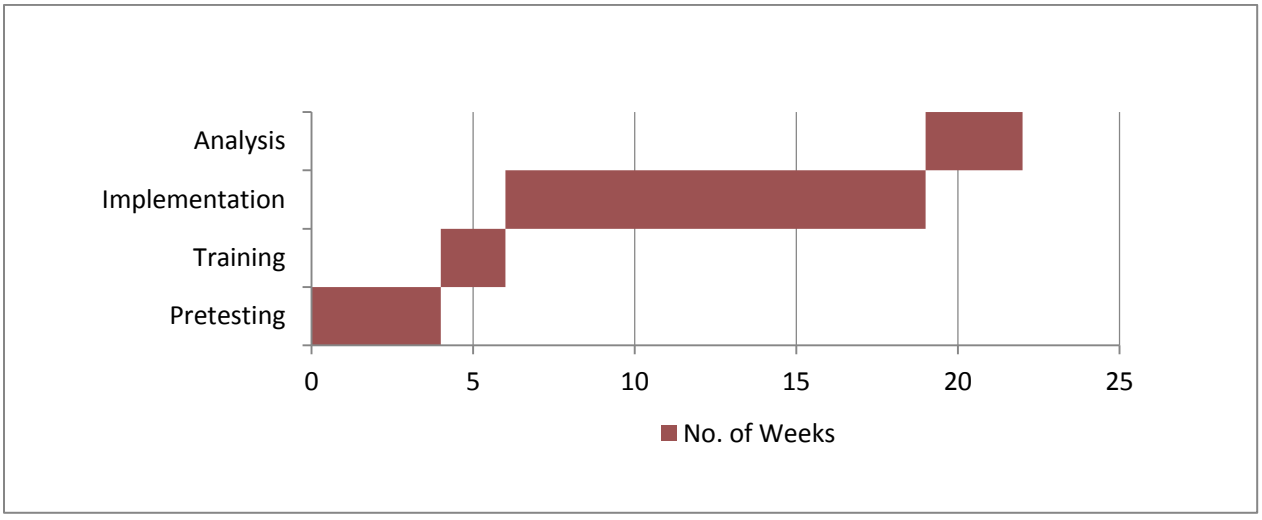
In determining the sample LGAs to conduct the temperature monitoring studies, states which have already conducted the vaccine management training will be compared to a control group where no recent vaccine management training has taken place in order to draw conclusions on the effectiveness of the training.

Implementation

Schedule

The team will begin with a pretest from the central store and select a single facility at random at each subsequent level of the cold chain. With the results of the pretest, the team will conduct a broader evaluation across all the zones. Following the initial evaluation, a series of post-IPV introduction evaluations and targeted follow-up evaluations should be scheduled as the process becomes more routine.

Timeline



National Training

A national training for Zonal Cold Chain Officers, UNICEF VSLs, eHA Support Staff and other partners willing to support will be planned for 1 week and conducted for 2 days. Extra 2 days will be given for arrival and departure. Training analysis and report will take additional 2 days. The National Training will be for a maximum of 2 weeks.

RI Study

In real time, vaccines are usually stored in the NSCS for 4 weeks, 2 weeks in the ZCCS, 1 week in the SCCS and 2 weeks in the LGA CCS. It takes a day to ship these vaccines from one storage point to another. This gives a total storage duration of 9 weeks that depends on demand and availability of funds. It will take 5 days for the total shipping of vaccines from national to HF or outreach.

For planning purposes, it will be safe to assume a maximum of 10 weeks of storage and shipment of vaccines for RI.

SIAs Campaign Study

Vaccines targeted for campaigns go through one of two possible routes:

1. National-State Route: In this scenario, vaccines are shipped directly to States from National 1 week before implementation. The vaccines are stored in the SCCSs for few days. The LGA Technical Facilitators collect vaccines for their respective LGAs.
2. National-Zonal-State Route: The vaccines are shipped from the National to the ZCCSs and stored there for a maximum of 2 weeks before implementation. The vaccines are then shipped to the States where they are stored for few days before collection by the LGA Technical Facilitators. In the LGAs, the vaccines are stored for few days or distributed immediately for use during implementation.

For planning purpose, vaccines for campaigns are stored and shipped within a maximum of 3 weeks from NSCS.

Pre-Test (FCT)
The pre-test will determine the efficacy of monitoring real time storage and transit through the cold chain system. The FCT Pre-testing will take a maximum of 4 weeks. This will include pre-test training, using sample vaccine to monitor temperature, and pre-test analysis.

Timeline Summary

1.	Pretest	-	4 weeks
2.	Training	-	2 weeks
3.	Implementation	-	13weeks
4.	Analysis and report	-	3 weeks
5.	**Total**	**-**	**22 weeks**

Site Selection

Following the pretest, the team will implement in sample of facilities based on the EVM Site Selection Tool, which is determined by the number of units in the lowest distribution level and then to calculate the sample size using the EPI Standard. This called for 40 LGAs across 6 zones for a confidence level of 80% and a precision interval of ±10%, and then the random selection of a ward or health facility within each LGA and the State, Zone

and Central store supplying the LGA. LGAs are selected on the probability of population each serves, but the team will add the selector criteria that the sample of LGAs also draw from a ranking of LGAs with the highest number of hard-to-reach settlements to reflect those stores serving predominately rural areas. This will provide approximately 127 distinct storage measurements.

Deployments

Data collectors will include 40 NPHCDA Zonal Technical Officers (ZTOs) assigned to 1 LGA and they may be supported by partners at the States/LGAs. Each will travel to the facility to initiate the storage monitoring, completing an electronic form and initializing a LogTag. The data collectors will have a maximum of 2 days to carry out the activities at each storage point. The data collectors will follow the chain of the respective vaccines assigned to their LGAs from the ZCCS. When the vaccines arrive at the State Stores, the data collectors will be there to initiate Log Tags and retrieve transit Log Tags from Zonal Stores. This will add up to an estimate of 10 days data collection from Zonal to HF/Outreach.

There will be 6 Senior Technical Supervisors (STS) for each geo-political zone from NPHCDA Headquarters to assist in resolving any technical difficulty, retrieval of LogTags and carryout periodic supervision by administering a checklist for each storage point and if possible, vaccine shipment. The STS will be required to visit 10 storage points and spend a maximum of 3 days (1 day arrival, 1 day supervision and 1 day departure) for effective supportive supervision to the data collectors.

Reactivity

Data collectors will be trained on non-interference and best practices for minimizing the visibility of the evaluation to limit health-worker desire to alter their standard behavior due to the awareness they are being observed. Options for discretely placing LogTags within vaccine boxes and other hidden-evaluation methods will be evaluated in the pre-test. Nevertheless, reactivity in this case, to the extent it persists, is expected to have a positive programmatic effect nonetheless, particularly as monitoring is routinized.

Analysis

Data cleaning and analysis will include relating forms and LogTag data, annotating the temperature-over-time curves, and processing the data to characterize the process inputs (user behavior, equipment) and temperature outputs. eHA and NPHCDA will collaborate on a final report and policy recommendations to meet the objectives of the program.

Budget Summary

Costs Analysis

1. Pretest (FCT)
   Responsible: 1 NPHCDA Focal Person and 6 NPHCDA data collectors.

   Responsible officers will be based in the FCT and will only be allocated 1 day DSA, and 1 day communication allowance within or outside the FCT for each of the 14 storage points of the Pretest (1 Zonal, 1 FCT CS, 6 Area Council CSs and 6 HF/Outreach). This gives a total of 14 days allowances to be allocated for the Pretest.

2. Training will be carried out in 2 clusters, north and south clusters. Data collectors from Zonal and State Offices will be invited to attend the training for their respective clusters for 3 days. There will be 4 National facilitators, 6 secretariat staff at each of the clusters making a total of 60 attendees (30 at each cluster).
3. Deployment:
   RI Study: A maximum of 10 days DSA, transportation and communication allowances will be allocated to each data collector.
   SIAs Campaign Study: A maximum of 10 days DSA, transportation and communication allowances will be allocated to each data collector.
4. Supervision: For effective supportive supervision, the 6 Senior Technical Supervisors (STS) for each geo-political zone will visit a total of 10 storage points and spend 3 days each. Therefore, 30 days DSA, transport and communication allowances will be allocated to supervision.
5. Devices: The Project will require 50 Android phones, 50 Log Tags, 50 Log Tags bags, 1 Lap Top and 50 sets of stationeries.
6. Contingency cost of 5% to cover unforeseen expenses that may arise.

Costs Summary

1.	PRETEST	-	N1,428,000.00
2.	TRAINING (NORTHERN)	-	N4,460,000
3.	TRAINING (SOUTHERN)	-	N4,460,000
4.	DEPLOYMENT (RI)	-	N8,720,000.00
5.	DEPLOYMENT (SIAS)	-	N8,720,000.00
6.	SUPERVISION	-	N3,804,000.00
7.	DEVICES	-	N3,050,000
8.	CONTINGENCY	-	N1732100
9.	**TOTAL**	**-**	**N36,374,100.00**

Addendum to the Forward Cold Chain Project (Temperature Monitoring Study)

- The Forward Cold Chain Project serves to monitor & analyse temperatures vaccines are exposed to end-to-end along the vaccine supply chain in Nigeria. The study coincides with a national cascade training recently conducted in vaccine management and cold chain logistics. By the time that this study commences, a proportion of states would have conducted vaccine management training down to LGA level, while other states are yet to be trained. This timing has provided a unique window of opportunity to assess the effectiveness of this training by measuring one of the key objectives of the training, which is to ensure that vaccines are stored and distributed under the appropriate conditions.
- This addendum serves to add an additional research question to the study, which is to determine the effectiveness of the vaccine management training by comparing temperature data in the vaccine supply chain of a control group (the untrained states) and with a test group (states which have cascaded the training).
- In order to make inferences from the data, the sample size would need to be doubled to yield the same confidence interval. The financial implications are that the original study costing approximately N36m, will increase to N72m.
- As large amounts of money are spent on vaccine management training every year, it would be worth the investment to test its efficacy.

7.4 Randomized controlled clinical trial of oral poliovirus vaccine and inactivated poliovirus vaccine in Nigerian children

Introduction/Background

The effect of Poliomyelitis on the world population had been devastating until the 1950s when polio vaccines were developed. The first to be licensed in 1955 was the low potency Salk inactivated poliovirus vaccine (IPV), then the Sabin live attenuated oral poliovirus vaccine (OPV) was licensed in 1961 and subsequently the enhanced potency IPV (eIPV).

In 1988, the World Health Organization (WHO) set a world target to eradicate polio by the year 2000[1]. Wide spread use of the trivalent OPV has resulted in drastic reduction and interruption of the wild poliovirus (WPV) in many countries and continents of the world [1,2]. Currently, WHO recommends routine and supplemental administration of OPV as part of the eradication strategy. Oral poliovirus vaccine does not only protect against paralytic polio disease but also induces intestinal immunity. This results in control of wild virus circulation[3]. Vaccine virus could also be transmitted to contacts of vaccines resulting in their immunization [3,4]. Additionally, OPV is cheap and easy to administer especially during mass campaigns.

However the disadvantages of reversion of vaccine virus to virulence[5], vaccine associated paralytic polio (VAPP) and presence of circulating vaccine derived polioviruses (cVDPVs) are becoming more pronounced as the polio disease prevalence diminishes[6].

Eventually global polio eradication requires that OPV must be discontinued to eliminate the cVDPVs[7]. Oral poliovirus vaccine has been reported to have lower immunogenicity in developing countries compared to developed countries[1,8]. Some authors have also reported some evidence to show that OPV may fail to interrupt WPV transmission inspite of excellent vaccine coverage[2].

Polio outbreaks have been reported in countries with high OPV coverage for 3/> dose, such as Brazil, Bulgaria, Gambia, Jordan, and Israel. Others are Malaysia, Namibia, Oman, and Saudi Arabia[2]. Extremely very low OPV efficacy has been reported in northern India[9]. The reasons for the low efficacy are not well understood[6].

The lower immunogenicity of OPV in developing countries has been partly attributed to genetic factors,[10] poor immune response in malnourished children and interference by other entroviruses[11,12]. Some developed countries have successfully interrupted WPV transmission by the use of IPV only[4].

Inactivated Polio Vaccine induces lower intestinal mucosal immunity compared to OPV[4]. Consequently, children protected by IPV administration may still excrete and transmit the virus to others. Since IPV is a killed vaccine, secondary immunization by transmission of vaccine virus does not occur unlike in OPV vaccination.

Other studies have shown that the use of a combination of IPV and OPV results in higher immunogenicity than use of either vaccine alone[4,13]. This could therefore enhance interruption of WPV transmission especially in recalcitrant endemic areas. Some disadvantages of IPV include higher cost of vaccine, requirement for skilled health workers and extra injections. Local vaccine production, increased demand, capacity building, combination vaccines and public awareness could help address these issues. Use of live virus for IPV manufacture remains an issue to be addressed in future although development of a new IPV has been prposed[6].

In Nigeria, following the initial significant progress in reduction of transmission of WPV, the last phase appears sluggish as evidenced by fluctuating number of WPVs and cVDPVs. Additionally, up to two-thirds of WPV cases have received three or more doses of OPV. These observations raise some questions. Apart from vaccine potency and low coverage, could there be other factors such as low immunogenicity? Data on IPV immunogenicity are limited[14] and there is no such study in Nigeria known to the authors.

Nigeria also has a good proportion of immunocompromised children who do not only need protection from wild and vaccine polioviruses, but also are at risk of shedding the virus for long periods[15,16]. Studies on efficacy of birth dose of OPV and IPV show variable results with superiority of IPV over OPV[17].

Objective

The primary objective of this study therefore is to evaluate the seroconversion rates in subjects in the 3 study arms. Secondary objectives include comparison of seroconversion rates after 1 dose versus 2 doses of IPV as well as adverse reactions.

This study will not affect the date of IPV introduction in Nigeria but will rather run concurrently with it. The results are expected to enhance policy decisions in future.

Methods

Study setting: The study will be conducted in two major Federal Teaching Hospitals which serve as large vaccination centers in Nigeria, namely the Institute of Child Health, University of Nigeria Teaching Hospital, (UNTH) Enugu and Institute of Child Health, University College Hospital (UCH), Ibadan. These centers cover large proportion of the Nigerian population and are relatively free from repeated sub-national immunization plus days. The centers run 2-3 vaccination clinics per week and are located in areas with relatively stable security situation to avoid interference with the study progress. The study duration will be one year; although subject enrolment will last 3 months, follow up will last 8 months (5 months per child). Data analysis, lab testing, etc will extend 2 months further making it one year (see time chart).

Study design: This study will be a prospective randomized comparative open-labeled study due to differences in the route of administration of the vaccines. It will therefore only be blinded to the lab staff. The study population will consist of infants not older than 7days visiting the clinic for birth doses of immunization.

Inclusion Criteria:

- Not older than 7 days
- Has not received any polio vaccine since birth
- Birth weight not less than 2.5kg
- Term delivery $\geq$ 37 wks
- Informed written consent

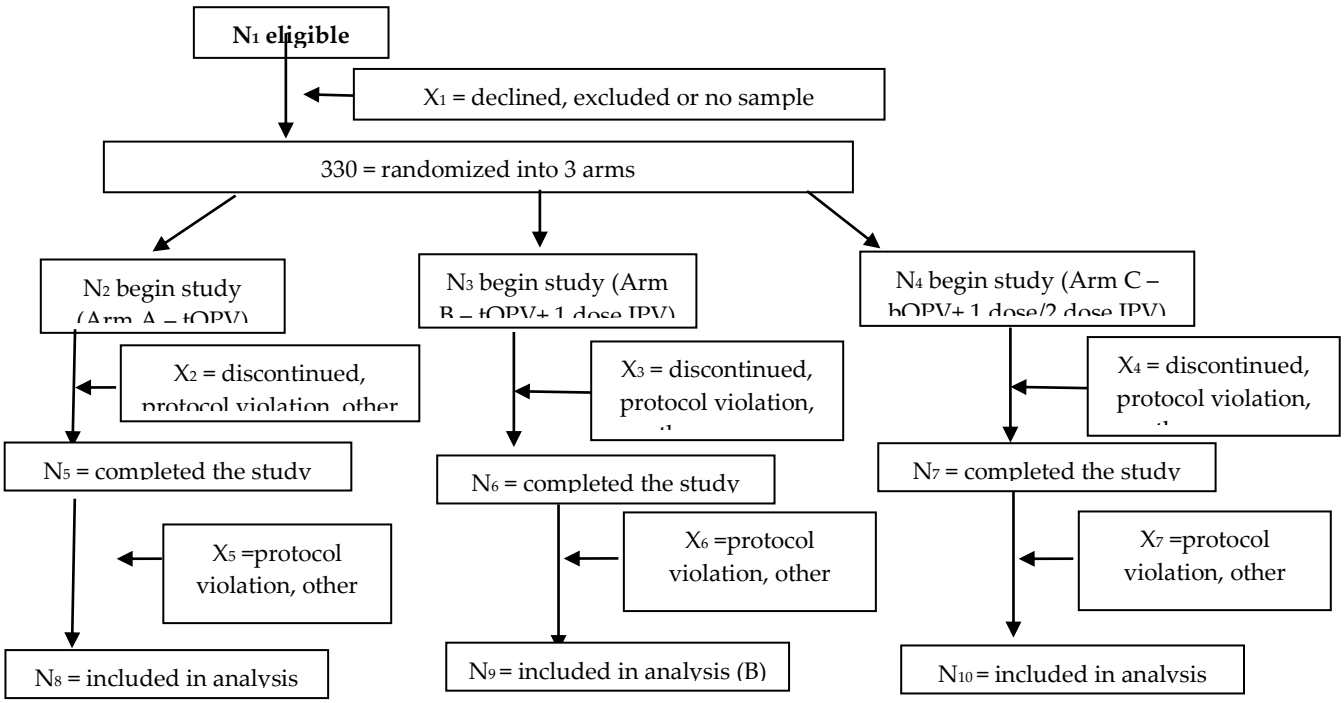
Exclusive criteria:

Infants born at < 37wks gestation, weighing less than 2.5kg or have any major congenital abnormality or serious medical condition; or declined consent will be excluded from the study.

Ethical consideration: Ethical approval will be obtained from the Ethics committee of the 2 participating hospitals, National Ethics Committee, WHO Ethics Committee and National Regulatory Agency. Informed consent will be obtained from each care giver who will either sign or thumb-print the consent form.

Sample size: Based on seroconversion rate of 60% from a previous study[2], a sample size of 100 in each arm has an 80% power to detect an increase of 0.18 with a significance level (alpha) of 0.05 (two-tailed). To allow for anticipated 10% attrition, a sample size of 110 in each group will be used giving a total of 330 for the 3 arms. Each of the 2 sites will therefore enroll a total of 165 subjects (55 in each arm).

Figure 1. Description of eligible, enrolled and participating subjects



Study groups: The study subjects will be randomly assigned to 3 arms using a computer-generated list of numbers. Arm A (tOPV) will be given tOPV at birth, 6, 10 and 14weeks. Arm B (tOPV + 1 dose IPV) will receive tOPV at birth, 6, 10 and 14 weeks, then one dose of IPV at 14weeks. Arm C (bOPV + 1 dose/2 dose IPV) will receive bOPV at birth, 6, 10 and 14 weeks, then IPV at 14 and 18 weeks (Table 1).

All subjects will receive all other routine vaccines but will not receive campaign OPV doses.

Table 1. Study groups

Age	Arm A (tOPV)	Arm B (tOPV + 1 dose IPV)	Arm C (bOPV + 1 dose/2 dose IPV)	Sample
Birth	tOPV	tOPV	bOPV	Blood (Arm A,B,C)
6wks	tOPV	tOPV	bOPV	
10wks	tOPV	tOPV	bOPV	
14wks	tOPV	tOPV + IPV	bOPV + IPV	
18wks			IPV 2nd dose	Blood (Arm A,B,C)
22wks				Blood (Arm C)

The trial will not be masked for subjects and clinical investigators due to the differences in route of administration. However, lab staff will be blinded to the specimens. Subjects would be evaluated for adverse events following immunization by phone calls, home or hospital visits (where necessary) on days 1, 3 and 7 of vaccination at birth, 6, 10 and 14 weeks (arms A, B and C); and 18 weeks for arm C only. Each subject will be provided with a small phone for ease of contact and transportation cost will be offset for enrolled study subjects. Also participants will receive baby wares/toiletries at each visit to encourage compliance. The National Adverse events following immunization (AEFI) form will be used to document all cases of AEFI (see attached).

Specimen collection: Blood samples (2mls) will be collected from study subjects at birth and 18wks for all subjects; and at 22 weeks for arm C only. On arrival at the lab all the blood samples will be centrifuged and serum harvested from them and stored in a well labeled 2ml cryovials in a -60^0C freezer until shipment in ice to CDC laboratory (and UCH Ibadan lab) for micronutralization assay of antibody titers to polioviruses 1, 2 and 3.

Neutralizing antibody determination/Seroconversion: Serum samples will be tested for antibodies (IgG) to polioviruses type 1, 2 and 3 using the micro neutralization method. Seroconversion will be defined as detectable antibody titer (titer ≥ 8) without measurable titer in previous serum or a ≥4fold rise in antibody titer. This will be carried out at the CDC laboratory Atlanta.

Vaccines: Trivalent Oral Polio Vaccine is a live attenuated vaccine consisting of poliovirus types 1, 2 and 3. Bivalent OPV consists of poliovirus 1 and 3. Both are administered per oral at a dose of 0.5 ml (2 drops) by use of a fixed dropper or a dropper vial.

Inactivated Polio Vaccine is the inactivated or killed vaccine also consisting of poliovirus antigens types 1, 2 and 3. It is administered at a dose of 0.5ml intramuscularly or subcutaneously. In this study it will be given intramuscularly on the anterolateral thigh. The IPV manufactured by Bilthoven Biologicals (B.V.), Netherlands will be used for the study since it is the only non-combination IPV available in Nigeria that is prequalified by WHO. Side effects include redness, soreness and swelling at the injection site. Other side effects like fever and excessive crying are usually associated with simultaneous administration of DPT containing vaccines.

The vaccines will be administered separately but along with other EPI vaccines-pentavalent (DPT-Hep B-Hib). Those receiving IPV will receive it at a different site.

Adverse events: Each subject will be observed for 15mins after vaccination and then followed up on the phone on days 1, 3 and 7 after each of the 4 doses of IPV or OPV for any adverse events. Arm C will be monitored for for second dose of IPV at 18weeks too. Those that require visit would be visited if subjects are not able to visit the study centre for further evaluation. Emergency tray containing adrenaline and hydrocortisone will be available at the immunization clinic throughout the duration of the study.

Personnel

This will consist of Paediatricians, research fellow, lab scientists, data managers, public health nurses, lab technicians, research assistants, program managers, etc. The research team members will be trained and certified by WHO on clinical trial. They will also be trained on the study methods and SOPs prior to commencement of the study.

Statistical analysis

Data will be entered into the Microsoft Excel and analyzed using the Graph Pad Prism software.

Statistical tests that will be used to determine significant difference in seroprevalence rate, seroconversion rates, virus identification rates, association between variables, adverse events and basic characteristics between the study groups include x^2 test, student t-test, Fisher's exact test, etc.

Dissemination of research findings

The study findings will be published in a scientific journal and a feedback meeting will be organized to interact with Government policy makers and other stakeholders. A press release will also be published.

Roles and Responsibilities

The primary ownership of this study rest with the National Primary Healthcare Development agency (NPHCDA) and other major partners include: the Paediatric Association of Nigeria (PAN), WHO,GAVI, BMGF, ZOLON / Emzor Group Ltd, CDC, UNICEF and USAID.

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Randomized Controlled Clinical Trial of Inactivated Poliovirus Vaccine and Oral Poliovirus Vaccine in Nigeria Children

Research Consent Form

1. Why are we giving you this form? (Background information)

Polio is a very crippling disease that has resulted in many deaths and disabilities. There are 2 vaccines available for prevention of polio called OPV and IPV. Both are effective and safe for use as recommended by WHO. However, protective effects vary from one population to another. In Nigeria, we have been using the OPV which has helped to reduce polio disease significantly. But total elimination seems to be a problem. Many developed countries are either using IPV alone or in combination with OPV. You are being asked to take part in this study because we are currently investigating the protective effects of these 2 vaccines either alone or in combination in Nigeria children to determine which one is most effective.

2. **Who is carrying out the study?**

The National Primary Health Care Development Agency (NPHCDA) in collaboration with Paediatric Association of Nigeria (PAN), World Health Organization (WHO), United Nations Children Emergency Fund (UNICEF), Zolon Healthcare and other partners is carrying out this investigation. The Principal Investigator is the President of PAN/ Chairman of the PAN Advisory Committee on Immunization (Prof A Olowu) and the Co-Principal Investigator is the Secretary of PAN Advisory Committee on Immunization (Dr Beckie Tagbo).

3. What happens in this research

Research assistants will explain the study and answer your questions. Then they will ask for your consent to participate in the study. If you give consent and sign the consent form (or thumb print), then they will ask you some questions about your child and family such as age, sex, educational qualification and employment. We shall also seek to know your child's immunization status. The information will be kept confidential. Then the assistants will collect blood samples at birth, 18 and 22 weeks of age from your baby. Your baby will receive either of the 2 oral polio vaccines at usual ages; may also receive one or 2 doses of the injectable polio vaccine along with other routine vaccines. **Your baby will not need to receive any polio campaign vaccines during the study period to avoid interference with the study results and confusion in the interpretation of laboratory results.**

4. Possible Problems

This study, to the best of our knowledge will not expose your child unnecessarily to any danger apart from the usual side effects of polio vaccines which are mild in most cases.

5. **Possible Benefits**

Your child will receive the expected protection against polio from the polio vaccines. Your transportation cost will be offset by the study sponsors. Additionally, your participation in the study and the information you will give us will enable us and the government to provide better prevention for polio through a more effective vaccination schedule and thus enhance elimination of the disease in our country..

6. **Payment**

Neither you nor your child will receive any payment for participating in this study.

7. Your rights to participate, not to participate or to withdraw from the study.

Taking part in this study is voluntary. If you choose not to take part in this study, you will not suffer any penalty. You will not loose any benefits to which you or your child is otherwise entitled to except that you did not contribute to the information that will be obtained from this study to help prevent polio. Your child's present or future medical care at the participating hospital will be the same whether or not your child takes part in the study. Even if you allow your child to take part in the study and later change your mind and withdraw your child from the study, your child will still receive standard care at the hospital for any illness.

8. Confidentiality

Your name or your child's name will not be made public and the medical records of your child will be treated as confidential as other medical records are done in the hospital. The research information gathered during the study from your child will be given an identification code number to make it difficult for anyone to identify your child. All information will be stored securely. Information from this study may be used for research purposes and may be published; however, neither you nor your child's name will be made public by the investigators.

Research Subject's Assent Form

I,_____, mother/father/caregiver of the child,

_____, (Name of Child) have been fully informed about the study on Poliovirus vaccine in children. I agree willingly to provide the information required of me and the child's blood and stool samples in the full knowledge that such information will be confidential. A copy of this form signed by me and one of the study investigators is being given to me.

Signature_____

Date_____

I have explained this study to the subject. I am available to answer any question now or in the future regarding the study and the subject's rights. If you have any additional question about you or your child's rights as a study subject, you may also contact the NPHCDA Abuja Dr Abanida phone _____; Paediatric Association of Nigeria at e-mail, pan.nigeria@gmail.com / jelusiyan@yahoo.co.uk, phone +2348033861424; UNTH Enugu Ethical Review Committee, Prof. RE. Umeh at the following telephone number: +234 42 252-022 or UCH, Ibadan Ethical Review Committee at the following telephone number, _____

Name of Investigator Signature of Investigator Date of Signature

Study protocol

Recruitment date _____ Child ID _____

1. Name _____
2. Sex: M ( ) F ( )
3. Age _____ weeks _____ days
4. Date of birth DD/MM/YYY _____/_____/_____
5. Birth weight (kg) _____(to one decimal point)
6. Residential street address _____
7. Contact phone no (test dialed) _____ email (if any) _____
8. Mother's name _____ phone no _____
9. Mother's age _____
10. Mother's highest educational level: Primary ( ) Secondary ( ) Tertiary ( )
11. Mother's occupation: Civil servant ( ) Self-employed ( ) Trader ( ) Student ( ) Unemployed ( ) Others _____
12. Mother's HIV status Positive ( ) Negative ( ) Unknown ( ) Declined ( )

13. Father's name _____ phone no _____

14. Father's age _____

15. Father's educational level: Primary ( ) Secondary ( ) Tertiary ( )

16. Father's occupation: Civil servant ( ) Self-employed ( ) Trader ( ) Student ( )
Unemployed ( ) Others _____

17. Father's HIV status Positive ( ) Negative ( ) Unknown ( ) Declined ( )

18. Any prenatal problems? Difficult delivery ( ) Twin delivery ( ) Prolonged labour ( )
Others _____

19. Did baby cry immediately after delivery? Yes ( ) No ( ) Don't know ( )

20. Breastfeeding? Yes ( ) No ( )

21. If 'Yes'; Exclusive ( ) With water ( ) With artificial milk ( )

22. Any congenital abnormalities or serious medical conditions? Yes ( ) No ( )

23. If yes, mention/describe them _____

First visit (0-7days)

24. Did you receive any campaign OPV dose? Yes ( ) No ( )

25. Age _____ weeks _____ days

26. Weight (kg) _____

27. Study arm Arm A ( ) Arm B ( ) Arm C ( )

28. Blood sample-1 collected ? Yes ( ) No ( )

NOTE BLOOD SAMPLE MUST BE COLLECTED BEFORE ANY VACCINATION

29. Polio vaccine given? Yes ( ) No ( )

30. If yes, was it injection or oral? Injection ( ) Oral ( )

31. If oral was it tOPV or bOPV? tOPV ( ) bOPV ( )

32. Other vaccines given: BCG ( ) Hepatitis B ( ) Others _____

33. Any adverse events after birth dose immunization? Yes ( ) No ( )

34. If Yes, describe below:

S/N	Event	No of days after vaccination	Treatment (if any)
1			
2			
3			
4			
5			

Second Visit (6wks)

35. Did you receive any campaign OPV dose? Yes ( ) No ( )

36. Age _____ weeks _____ days

37. Weight (kg) _____

38. Study arm Arm A ( ) Arm B ( ) Arm C ( )

39. Polio vaccine given? Yes ( ) No ( )

40. If yes, was it injection or oral? Injection ( ) Oral ( )

41. If oral was it tOPV or bOPV? tOPV ( ) bOPV ( )

42. Other vaccines given: Penta ( ) Others _____

43. Any adverse events after second dose polio immunization? Yes ( ) No ( )

44. If Yes, describe below:

S/N	Event	No of days after vaccination	Treatment (if any)
1			
2			
3			
4			
5			

Third Visit (10wks)

45. Did you receive any campaign OPV dose? Yes ( ) No ( )

46. Age _____ weeks _____ days

47. Weight (kg) _____

48. Study arm Arm A ( ) Arm B ( ) Arm C ( )

49. Polio vaccine given? Yes ( ) No ( )

50. If yes, was it injection or oral? Injection ( ) Oral ( )

51. If oral was it tOPV or bOPV? tOPV ( ) bOPV ( )

52. Other vaccines given: Penta ( ) Others _____

53. Any adverse events after third dose polio immunization? Yes ( ) No ( )

54. If Yes, describe below:

S/N	Event	No of days after vaccination	Treatment (if any)
1			
2			
3			
4			
5			

Fourth Visit (14wks)

55. Did you receive any campaign OPV dose? Yes ( ) No ( )

56. Age _____ weeks _____ days

57. Weight (kg) _____

58. Study arm Arm A ( ) Arm B ( ) Arm C ( )

59. Polio vaccine given? Yes ( ) No ( )

60. If oral was it tOPV or bOPV? tOPV ( ) bOPV ( )

61. If yes, was it injection or oral? Injection ( ) Oral ( )

62. Other vaccines given: Penta ( ) Others _____

63. Any adverse events after fourth dose polio immunization? Yes ( ) No ( )

64. If Yes, describe below:

S/N	Event	No of days after vaccination	Treatment (if any)
1			
2			
3			
4			
5			

Fifth Visit (18wks)

65. Did you receive any campaign OPV dose? Yes ( ) No ( )

66. Age _____ weeks _____ days

67. Weight (kg) _____

68. Study arm Arm A ( ) Arm B ( ) Arm C ( )

69. Blood sample-2 collected? Yes ( ) No ( )

NOTE BLOOD SAMPLE MUST BE COLLECTED BEFORE ANY VACCINATION

70. Polio vaccine given? Yes ( ) No ( )

71. If yes, was it injection or oral? Injection ( ) Oral ( )

Sixth Visit (22wks)

72. Did you receive any campaign OPV dose? Yes ( ) No ( )

73. Age _____ weeks _____ days

74. Weight (kg) _____

75. Study arm Arm A ( ) Arm B ( ) Arm C ( )

76. Blood sample-3 collected? Yes ( ) No ( )

Time Line for the study

YEAR 1

MONTH	1	2	3	4	5	6	7	8	9	10	11	12
ITEM												
Institutional preparation relationship with the Research team	X											
Ethics committees reviews & approval		X										
Recruitment of Patients		X	X	X								
Patient follow up		X	X	X	X	X	X	X	X			
Sample shipment & testing			X			X			X			
Data entry		X	X	X	X	X	X	X	X	X		
Data Analysis			X	X	X	X	X	X	X	X	X	
Report writing												X
Publication of Research findings & feedback meeting with Govt, etc												X

Budget estimate

Preamble

The will be a multicenter study involving 2 sites (hospitals) namely:

1. Institute of Child Health, University of Nigeria Teaching Hospital, (UNTH) Enugu
2. Institute of Child Health, University College Hospital, Ibadan

As a result, it will involve personnel at the 2 sites, from clinical, laboratory and data areas of each hospital. This fact is reflected in the budget.

TOTAL BUDGET FOR THE STUDY

ITEM	AMOUNT IN NAIRA	JUSTIFICATION
TRAVEL		
Local runs (taxi) at 2,000/day x 3days per wk x 4wks per month x 12mths x 3 sites	2,000 x 3days x 4wks x 12mths x 2 sites = **576,000**	Daily transport of blood and stool samples from clinic site to laboratory (at permanent site)
Supervision of sites and periodic visits by the PI (Dr BN Tagbo)	**2,600,000**	Supervision of sites and periodic visits
Lab & Data manager periodic visits to each of the 2 sites	**1,002,000**	Lab & Data managers periodic visits to sites to ensure data harmony and that lab storage procedures conform to study protocol
Transport cost for study subjects at 500 x 6 visits x 210 subjects =	**630,000**	Offsetting subjects transport cost to & fro will enhance compliance and reduce attrition rate since some may not be able to afford the cost
Home/hospital visits for adverse events at 2,000 x 3 days x 4 doses x 72 (~10%) = 4,500	**480,000**	Estimated 10% of study subjects may require home or extra hospital visits for treatment/observation for adverse events following immunization
Shipment of samples by courier 3times/yr to WHO lab, UCH Ibadan from the 2 sites	75,000 x 2 = **150,000**	For antibody titre assay and virus identification in stool at MRC UK at the Gambia
Transport of samples from sites to CDC Reference lab	**600,000**	(to be confirmed by WHO)

Sample packaging materials for transport/shipment (Parafilm, Absorbent tissue, Plastic sealable leakproof, water-tight bags, Packing tape, Sticky labels, Secondary container, Cold box with ice, Outer shipping package)	7,500 x 2 sites x 3 trips = **45,000**	For local and international sample transport **(Cold box will not be returned to us by courier agent and so must be bought for each trip)**
NPHCDA / (WHO) Twice a year superintending visits/Logistics by NPHDCA/WHO	**2,000,000**	
SUBTOTAL	**8,083,000**	
MEETINGS		
Local monthly meetings ▪ Entertainment at 500 x 10 participants x 12mths ▪ Minutes & reports at 100 x 10 participants x 12mths **National meetings** - 2 monthly meeting of 2 site coordinators, PI, 4 Co-investigators, 4 Technical Advisers, + Lab manager & Data manager = 13 ▪ Return flight tickets at flat rate of 100,000 x 13 = 1,300,000 ▪ Taxi at 20,000 x 13 = 260,000 ▪ Accommodation x 2 nights @ 20,000 x 13 = 260,000 ▪ Feeding at 1,500 x 5 meals x 13 = 97,500 ▪ Meeting venue at 200,000 x 1 day	5,000 x 12mths = 60,000 x 2 sites = **120,000** ~~₦~~1,000 x 12mths = 12,000 x 2 sites = **24,000** 2,117,500 x 2 meetings = 4**,235,000**	Monthly reports/data need to be reviewed by the team before it is sent to PIs reduce errors. There is also need for monthly meetings to review progress, address constraints, discuss other issues that may arise
SUBTOTAL	**4,379,000**	
LOGISTICS		

PI Logistics allowance	**2,400,000**	To cover day to day running and coordination of the sites and study
SUBTOTAL	**2,400,000**	
EQUIPMENT		
• Laptop computer + UPS + Stabilizer (Dell, 180 Gig with double processor) x 2 sites • Laptop /accessories x 3 (PI, Data manager & Lab manager) • Laser printer x 2 sites + PI= 70,000 x 3	200,000 x 2 = **400,000** 200,000 x 3 = **600,000** **210,000**	For data entry, analysis and reporting (from the 6 sites)
Power generating set x 2 sites	350,000 x 2 = **700,000**	There is need for a smaller stand-by generator to ensure steady power supply to maintain samples at required temperature in the event of breakdown of site genset since power supply is often epileptic
-20^{0}C freezer x 2 sites at 100,000 x 2 = 200,000	**200,000**	For sample storage separate from routine hospital lab samples storage
Refrigerator for vaccine storage at 60,000 x 2 sites	**120,000**	For separate vaccine storage to avoid mix up with routine vaccines
External storage devices for double data back-up 25,000 x 2 x 2sites	**100,000**	For data security at all levels
Phone for subjects at 6,000 x 350 subjects (+ buffer)	**2,100,000**	To ensure proper patient follow up and reduce attrition rate in view of prevailing economic status of study population
Photocopiers, laminators, others for 2 sites + PI (3x400,000)	**1,200,000**	
SUBTOTAL	**5,630,000**	
COMMUNICATION CHARGES		
Internet access (e-mails, USB stick (5,000 x 8= 40,000)+	**808,000**	Internet subscription for e-mail communication and sharing of data

monthly renewal of internet USB subscriptions at 8,000 x 12mth x 8(2 sites + PI + 2 site coordinators + Data manager + Lab manager) = 808,000 Phone calls • at 15,000/mth x PI & 2 site coordinators x 12mths) • at 10,000/mth x 10 (4 Tech Adv + 4 Co-investigators + lab manager + Data manger) x 12mths • Study follow up of subjects for AEFI, etc at 400 x 210 • SMS reminders for appointments at ₦10 x 4 visits x 210 • Others	 15 x 4 x 12 = **720,000** 10,000 x 12 x 10 = **1,200,000** **84,000** **8,400** **50,000**	and reporting Phone calls for administration and coordination of the study,, meeting, etc.
SUBTOTAL	**2,870,400**	
STATIONERIES		
• One ream per mth at 650/ream/mth x 12mths x2 sites • Printer ink 2 per year x2 sites at 10,000 each • Study questionnaires, consent form, SOPs, etc (12 reams) at 650 x 12 • Log books (clinical & lab) • Others	650 x 12mths = 7,800 x 2 = **15,600** **40,000** **7,800** **30,000** **60,000**	 For administrative and finance documentations
Commercial printing of carbonated duplicate copies of lab forms x 10 booklets	**10,000**	For lab request and lab result feedback to the ward
Printer ink 10,000 x 6	**60,000**	
SUBTOTAL	**223,400**	
VACCINES		
• tOPV at 0, 6, 10wks &14wks	tOPV 1,200 doses x 160	Vaccines are required for the study.

x 2 arms (150 x 2) = 300 x 4 doses = 1,200 • bOPV at 0, 6, 10 & 14wks x 1 arm =150 x 4 = 600 doses • IPV at 14wks (2 arms) and 18wks (1 arm) =150 x 3 = 450 doses	= **192,000** Bopv 600 doses x 160 = **96,000** IPV 450 doses x 500 = **225,000?**	IPV is not a routine vaccine and OPV supply cannot be guaranteed.
SUB-TOTAL	**513,000**	
TRAINING		
National training - PI+4 Co-investigators + 4 Tech Adv + lab manager + Data manger + 2 participants per site (6) + 2 admin/ support staff + 1 WHO = 22 • Transport 22 x 100,000 • Accommodation @ 10,000 x 22 • Feeding at 1,000 x 4 meals x 22 • Training materials 300 x 22 • Preparation of SOPs – clinical, lab & data 50,000 • Stationaries 10,000 • Honorarium for facilitators 150,000 • Projector & screen hire 20,000 • Others 20,000	**2,200,000** **220,000** **88,000** **6,600** **50,000** **10,000** **150,000** **20,000** **20,000**	There is need for a training of trainers (TOT) session at national level
Site training –1 Site coordinator + 2 clinicians + 2 lab scientists + 2 data officers + 3 field assistants + 2 admin/support staff + PI = 13 • Transport 12 x 1,000 =12,000		A step-down training to ensure uniformity and compliance to study protocol

• Transport 120,000 (PI) • Accommodation @ 20,000 x 2nights = 40,000 • Dinner at 2,000 x 2 meals = 4,000 • Lunch at 2,000 x 12 = 24,000 • Tea break at 500 x 12 x 2times = 12,000 • Training materials 300 x 13 = 3,900 • Stationaries 5,000 • Honorarium for facilitators = 100,000 • Projector & screen hire 20,000 • Others 20,000 Total for site training = 360,900 x 2 sites	**721,800**	
SUBTOTAL	**3,486,400**	
PERSONNEL		
Total personnel allowances for the study (see the attached for details)	**18,720,000**	The personnel are already employed staff and therefore only require a stipend as motivation. However, since it is not part of routine work schedule inadequate stipend may make the work unattractive.
SUBTOTAL	**18,720,000**	
OTHER ITEMS		
• Diesel for genset at 20,000/mth x 12mths (10litres/day x 20days/mth) x 2 sites • Scalp vein needles 23G 450 x 2 samples & 150 x 1 sample = 1,050	20,000 x 12mth = 240,000 x 2 = **480,000** **105,000**	Frequent power outages requires adequate supply of diesel to run genset to maintain power.

• Other sample collection consumables (dressing, cap tube, gauze, alcohol swab) x 250 subjects (220+30 buffer stock) x 3 blood samples x 10 • Vaccine administration consumables at 50 x 250 subjects x 3visits • Emergency tray at 1,000 x 2 sites • Proposal writing	**100,000** **53,000** **10,000** **100,000**	
SUBTOTAL	**848,000**	
LAB ITEMS		
See attached estimates from WHO Polio lab, UCH Ibadan	**9,208,895**	As submitted by Polio lab, UCH, Ibadan
Others		
2ml screw cryotubes at 50 x 250 x 4	12,500 x 4 = **50,000**	For storage of blood samples
Plain bottles at 50 x 250 x 3 times	12,500 x 4 = **50,000**	For collection of blood samples at 4 visits per subject
Absorbent lab tissue at 500 x 5 rolls x 3	**7,500**	For lab procedures
Disinfectant (70% alcohol) at 8,000 x 6 packets	10 x 8,000 = **48,000**	For lab procedures
Face mask at 550 x 5 pkts	550 x 10 = **2,750**	For lab procedures
Permanent marker with fine tip at 100 x 40	**4,000**	For writing patient's ID no, etc on all sample bottles
Latex gloves	**50,000**	For lab & clinic procedures
Autoclavable polybag at 150 x 100 pkts	**15,000**	For storage/transport of samples
Vaccine transport/ logistics	**500,000**	

Solar freezers for vaccine storage, vaccine carriers, ice packs for 2 sites	**UNICEF TO PROVIDE**	For vaccine storage, vaccine transport and sample transport
Baby wares/toiletries for 6 visits (350x8x1,000)	**2,100,000**	To encourage compliance
Publication of research findings/ meeting with Government	**1,000,000**	Dissemination of research findings
SUBTOTAL	**13,,036,145**	
TOTAL	**60,189,345**	
PAN Administrative charge & Contingency (10%)	**6,018,934**	
GRAND TOTAL	**66,208,280**	

GRAND TOTAL FOR THE STUDY = ₦66,208,280

COMPREHENSIVE LIST OF PERSONNEL FOR THE STUDY AND THEIR STIPENDS

PERSONNEL	MONTHLY DETAILS	ANNUAL
Principal Investigator – Dr Beckie Tagbo	100,000 x 12	1,200,000
Four Co-investigators	80,000 x 4 x 12	3,840,000
Four Technical Advisers	80,000 x 4 x 12	3,840,000
National Lab Manager & National Data manager	50,000 x 2 x 12	1,200,000
Two site coordinators	50,000 x 2 x 12 =	1,200,000
Two clinicians/2 lab physician/scientist x 2sites	40,000 x 4 staff x 2 sites x 12=	3,840,000
Two data officers /3 field staff (nurses) x 2 sites	30,000 x 5 staff x 2 sites x 12=	3,600,000
TOTAL		18,720,000

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Dr Beckie Tagbo (MBBS, PhD, FWACP(Paed)

Principal Investigator

COMPREHENSIVE LIST OF NAMES OF PERSONNEL FOR THE STUDY

S/N	NAME	POST
A	**NATIONAL OFFICERS**	
1.	Dr. Beckie Tagbo	P1 (Planning, Coordination & overall implementation)
2.	Prof. A Olowu	Co-investigator
3.	Dr. D. Esangbedo	Co-investigator
4.	Dr E A Abanida	Co-investigator
5.	Dr Z Mahmud	Co-investigator
6.	Prof O. Tomori	Technical Adviser
7.	Prof G Onyemelukwe	Technical Adviser
8.	Dr.N. Ibeziakor	Technical Adviser
9.	HRH Haliru Yahaya	Technical Adviser
10.	Dr. Jerome Elusiyan	National Data Manager /Secretary
11.	Dr Adeniji	National Lab Manager
B	**INSTITUTE OF CHILD HEALTH, UNIVERSITY OF NIGERIA TEACHING HOSPITAL, ENUGU**	
12.	Dr. O. Nnani	Site Coordinator
13.	ICH Head	Clinician
14.		Clinician (to be recruited at the site)
15.		Lab physician/scientist (to be recruited at the site)
16.		Lab physician/scientist (to be recruited at the site)
17.		Nurse (to be recruited at the site)
18.		Nurse (to be recruited at the site)

19.		Nurse/Field assistant (to be recruited)
20.		Data officer (to be recruited at the site)
21.		Data officer (to be recruited at the site)
C	**INSTITUTE OF CHILD HEALTH, UNIVERSITY COLLEGE HOSPITAL, IBADAN**	
22.	Dr B. Ogunbosi	Site Coordinator
23.	ICH Head	Clinician
24.		Clinician (to be recruited by the site Coord)
25.		Lab physician/scientist (to be recruited by the site Coord)
26.		Lab physician/scientist (to be recruited by the site Coord)
27.		Nurse (to be recruited by the site Coord)
28.		Nurse/Field assistant (to be recruited by the site Coord)
29.		Nurse/Field assistant (to be recruited by the site Coord)
30.		Data officer (to be recruited by the site Coord)
31.		Data officer (to be recruited by the site Coord)
D	**WHO TECHNICAL ADVISERS**	
32.	Dr Harish Verma	WHO (Superintendency/Oversight function)
33.	Dr Pascal	WHO (Superintendency/Oversight function)
34.	Dr Yinka	WHO (Superintendency/Oversight function)
E	**SPONSORS/PARTNERS**	
	WHO	Funding / technical support/materials

	GAVI	Personnel stipends/ trainings/others
	UNICEF	Cold chain equipment (solar fridges & freezers, vaccine carriers, ice packs, etc) and OPV
	BMGF	IPV/ funding
	CDC	Antibody assay in blood
	Others	Funding / materials

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Dr Beckie Tagbo

(MBBS, PhD, FWACP(Paed)

Principal Investigator

STANDARD OPERATING PROCEDURE (SOP) 1

Task: Identification, enrollment and vaccination of subjects

Summary

This section describes

1. Identification and enrollment of subjects based on inclusion and exclusion criteria
2. Obtaining informed consent from care-givers
3. Random assignment of subjects to the 3 study arm
4. Collection of demographic and clinical data.
5. Collection of blood specimen for polio antibody titres
6. Administration of relevant vaccine(s) to subjects.
7. Observation for and management of AEFI
8. Follow-up for AEFI monitoring and sending of reminders to subjects for next appointment.
9. Subsequent visits.
10. Vaccine storage.

- Lab form
- Emergency tray (Syringes and needles, Adrenalin, hydro cortisone, Promethazine, water for injection, sterile swabs, Paracetamol syrup or drops, etc.)

2. DEFINITIONS

Term infants

Babies born at 37weeks gestation or more

Age 0-7days

Term infants aged 0-7days, but not older than 7days (1week)

Inclusion criteria

- Not older than 7 days
- Has not received any polio vaccine since birth
- Birth weight not less than 2.5kg
- Term delivery ≥ 37 wks
- Informed consent

Exclusion criteria

Infants born at < 37wks gestation, weighing less than 2.5kg or have any major congenital abnormality or serious medical condition; or declined consent.

3. OBTAINING INFORMED CONSENT FROM CARE-GIVER

- If the baby is eligible for recruitment, then administer the consent form/ information sheet
- Allow literate mothers to read through the consent form/information sheet.
- Explain further and allow them to ask questions
- Explain consent form content in vernacular or pigeon English to non-literate care-givers
- Allow time for questions and clarifications.
- If they need to contact or discuss with spouse or other family members, facilitate the move e.g. via phone call.
- Then allow care-giver to voluntarily sign or thumb-print the consent form.
- No care-giver should be coaxed or constrained to give consent
- Where a care-giver is not decided or is unwilling, allow the care-giver to go for routine immunization and re-assure her that she will still receive adequate care like any other client.
- It is unethical to compel care-givers to give consent or to with hold necessary information in order to obtain consent.
- Once the care-giver has signed the form, then the investigator should also sign.

4. SUBJECT ENROLLMENT AND RANDOM ASSIGNMENT OF SUBJECTS TO 3 STUDY ARMS

- Following consent signing each subject is assigned ID code from a generated list
- Then assign subject to a study arm based on subjects ID code number and a computer-generated table of random numbers.
- Using the case report form, demographic and clinical data are obtained as outlined in the form
- A clinician then carries out a physical examination to exclude any gross abnormalities.

Age	Arm A (tOPV)	Arm B (tOPV + 1 dose IPV)	Arm C (bOPV + 1 dose/2 dose IPV)	Sample
Birth	tOPV	tOPV	bOPV	Blood (Arm A,B,C)
6wks	tOPV	tOPV	bOPV	
10wks	tOPV	tOPV	bOPV	
14wks	tOPV	tOPV + IPV	bOPV + IPV	
18wks			IPV 2nd dose	Blood (Arm A,B,C)
22wks				Blood (Arm C)

5. COLLECTION OF BLOOD SPECIMEN

- Blood must be collected before vaccine administration.
- If vaccine is inadvertently given before blood sample collection, then such child should be withdrawn from the study.
- However, such records must be kept for data analysis
- Sample collection is to be carried out by a clinician, lab scientist, lab technician, nurse or whoever has been so trained and designated to do so.
- Fill the Lab investigation/feedback form
- A good vein is searched for, preferably at the back of the hand.

- Loosely tie a tourniquet close to the vein.
- Under asepsis (sterile gloves), swab the area with alcohol.
- Using a scalp vein 23G needle, obtain 2mls of blood into a plain bottle.
- Cock properly and label the bottle with subjects basic information (name, sex, age, ID, date and time)
- keep the sample in the provided container for transfer to the lab not later than 6hrs
- Write the time and date of blood collection on the lab form and CRF.
- Ensure proper labeling of the bottle (name, sex, age, ID, date and time)
- Properly dispose materials in a safety box
- **Do not RE-CAP NEEDLES**
- Fill the specimen log book

See SOP2 for sample transport, initial processing, storage and shipment to reference

6. VACCINE ADMINISTRATION

Blood must be collected before vaccine administration

- Take note of the study arm the subject belongs to, the age and which visit.
- Then look at the chart on the wall /table.
- Administer the appropriate vaccine and other routine vaccines.
- Two drops of the OPV are given orally using either an attached dropper or a vial dropper
- IPV is an injectable single dose vaccine. It is freeze sensitive and is given IM on the upper outer thigh.
- Fill relevant section of CRF and vaccine logbook
- Also complete child's immunization card

7. OBSERVATION FOR/AND MANAGEMENT OF AEFI

- Direct care giver to wait in waiting room for 15-30mins for observation
- If any adverse reactions develop, report to the clinician for appropriate management
- Fever is treated with Paracetamol.
- Redness, pain or swelling will resolve within a few hours to a few days. Reassure the mother.
- Allergic reactions are treated with antihistamine, urticaria with hydrocortisone antihistamine.
- Anaphylaxis with s/c adrenaline 0.1mg/kg of 1:1,000 dilution (or 0.01mg/kg of 1:10,000 dilution).
- Monitor vital signs; if symptoms persist, move child to children emergency room for further treatment
- When indicated, also administer oxygen and intravenous fluids
- Fill the National AEFI form and report immediately to the LGA or state focal person
- Communicate the event maturely via a site designated spoke person
- Note however, that polio vaccines have been shown to be relatively very safe, as adverse reactions are very rare.

- If there are no reactions, the child can go home with all relevant information on any occurrence of AEFI, next appointment, not to receive any other vaccine outside the centre including campaign polio vaccine.
- Ensure a viable phone number and proper residential address

8. FOLLOW-UP FOR AEFI MONITORING AND SENDING REMINDERS TO SUBJECTS FOR NEXT APPOINTMENT

- Each patient is then scheduled on the AEFI monitoring/reminder log book for calls/visits (where indicated) 0n day 1,3 & 7 of each polio vaccine dose
- Each time a contact is made, it is logged in and appropriate section of CRF filled.
- 3 days to next appointment, SMS reminders are sent to each care-giver

9. SUBSEQUENT VISITS

- Follow similar procedures as outlined above for subsequent visits (2^{nd} – 6^{th} visits)
- For 2^{nd}-4^{th}, skip sample collection steps as no samples are needed
- For the 5^{th} visit, a second blood sample **MUST** be collected before vaccine administration
- Only subjects in study arm C will come for the 6^{th} visit during which another sample will be collected
- When a child is scheduled to receive IPV it should be given on a different thigh i.e. on the left thigh if Penta/DPT is on the right thigh or vice versa
- This is to avoid interference

- **Do not leave any question or section of the CRF empty or unfilled.**
- **All research team members must undergo training before commencement of the trial.**

10. VACCINE STORAGE

- tOPV and bOPV are live vaccines that are heat-sensitive.
- They must be therefore be stored at 2-8^{0}C in refrigerator or vaccine carrier (geostyle) with adequate number of ice packs
- IPV is freeze sensitive and should be stored at 2-8^{O}C.
- For long term storage, store both vaccines at the State or Zonal Cold store and periodically collect required quantities

Subjects' files/ CRF copies should be properly filed serially according to ID code to enhance easy retrieval

ANNEXES (outstanding)

1. ID codes
2. CRF (copy from proposal)
3. Lab form
4. Specimen bottle label
5. Logbooks-records, specimen, vaccination, AEFI/reminder monitor, clinical logbook (CRF)
6. AEFI form

PART A: Sample collection:

Method of collection

1. Wash your hands

2. Put on gloves

3. Select the site:

• Young infants – heel or big toe

4. Clean the selected area of skin (heel, toe) with the skin disinfectant swab and allow to dry for 30 seconds.

5. Position the foot or hand with the puncture site downwards. Read the instructions on the protective tab and check whether to twist or pull off the tab. Press the loaded lancing device firmly against the skin and push

6. While holding the foot correctly, apply and release pressure to allow a drop of blood to form. Do not squeeze or "milk" the puncture site as this may dilute the blood with tissue fluid.

1. **Heel-, toe- method**

• Allow drops of blood to collect and fall into the red-top microtainer

• Do not squeeze at the puncture site as this will dilute the blood with tissue

fluid.

• Ideally there should be 500µl of blood (minimum volume

of 250µl).

2. Formal venipuncture

Blood can also be sampled into 4ml red-top tubes. Collect at least 2ml of whole blood

Label the container properly with the patient's identifiers

PART B: Sample reception and Storage.

I. Hours of Operation and Specimen Types

The Diagnostics Laboratory will receive and process specimens Monday through Friday from 9am to 4pm unless special arrangements have been made in advance. Specimens can consist of, but are not limited to, serum and whole blood.

II. Specimen Acceptance/Rejection (See sample Acceptance/Rejection SOP) for more details**:**

Upon receipt of a specimen at the diagnostic Laboratory, the container holding the specimen will be inspected for any leakages or damages, and to assess the integrity of the sample (hemolyzed, lipemic, icteric, etc…), as well as to determine that there is sufficient volume/amount (2ml) of the sample for the test(s) that is (are) requested. Laboratory personnel will then proceed to verify the identifier on the label on the outside of the container by comparing it to the accompanying paperwork that must come with each specimen. Each specimen must be properly labeled with a subject identifier, or name appropriately. The paperwork must include an identifier, date of sample collection, name of the person submitting the sample, and the tests (s) to be performed; or this information must be obtained from the person bringing the specimen; otherwise the specimen will not be accepted.

If the integrity of the sample or the container appears to be compromised, or if the sample identifier on the sample container does not match the identifier on the accompanying paperwork, a note will be made on the paperwork with respect to the observed deviation, and the source/sender of the sample will be notified immediately and asked to provide guidance as to how the laboratory should proceed. The general policy of the Laboratory is to recommend that the sample be discarded if the identifier or sample/container integrity is questionable, or returned to the submitter. The final decision will be the responsibility of the Director of the Laboratory after consultation with the submitter.

If all paperwork is in order, and the specimen is suitable for testing, the sample will be accepted. Once it's determined that a sample is acceptable, it will be logged in on the register.

III. Specimen Processing:

Specific (Testing) SOPs contain specific sample processing and storage information. If a specific procedure is unavailable for, proceed as follows:

Red (Tiger) Top or Gold Top tube (Processing for Serum):

Samples must be processed within 3 hours of collection if stored at room temperature (15-27^{o}C), or within15 hours, if stored at 4^{o}C. The red or gold top tube will be centrifuged at 3,000rpm for 10 minutes. After centrifugation, the serum (top layer in the tube) will be transferred into 2.0 ml cryovials labeled as directed by the submitter (or study protocol), or with exactly the same identifier as on the original blood collection tube if no other instructions are available from the submitter.

IV. Specimen Storage:

Unless a specific processing/storage protocol is available for a specimen, it must be stored at -60^{o}C, or -80^{o}C freezer.

PART B: SAMPLE TRANSPORTATION

Sample Packig

The following is a summary of steps required for packing and sealing samples for shipment.

a. Obtain samples in the laboratory-specified containers and verify the completeness of the sample identification information on the label and the Chain-of-Custody (COC) record. Verify

custody seals on sample containers and/or bags are intact and have been initialed and dated.

b. If packaging aqueous samples or using wet ice for temperature preservation, place a garbage bag or liner in the cooler.

c. Place samples in resealable plastic bags and then into the cooler. If appropriate, place a temperature blank in the center of the cooler.

d. Place ample amounts of wet ice contained in doubled resealable bags inside the garbage bag/liner in cooler. As needed, place bubble wrap or other inert packing material around the garbage bag/liner in the cooler.

Note: Blue Ice is used for temperature maintenance for particulate matter sample media.

e. Seal the garbage bag/liner with duct tape. This is to ensure that if the contents were to spill that the garbage bag/liner would contain the spill.

Note: If samples are to be maintained frozen during shipment, refer to Section 3.4.1 which defines the procedures for the use of dry ice.

f. Place a self-adhesive label on each cooler indicting cooler number based on total number of coolers sent out each day (such as 4 of 8). Use a permanent marker to write number on the label.

g. Sample custodian or designee relinquishes the samples on the COC record by signing their name and providing the date and time that the samples were packed.

Write the shipper's tracking number (such as courier and courier air bill number) on the COC form when a commercial courier is used. If a courier other than UPS or

i. Place the completed COC form in a large resealable plastic bag and tape to the inside lid of the cooler. If multiple coolers are needed, a copy of the original COC form accompanies each cooler that contains the samples identified on the COC form.

j. The sample custodian or designee who relinquished the samples in Step *d* above signs and places date and time on the custody seals. The custody seal signature, dates and times must match the relinquished signature, dates and times as they appear on the COC form from Step *d* above. Place tamper-evident custody seals/tape on two sides such that opening the cooler breaks the custody seal/tape. Tamper-evident custody seals/tape must be able to indicate that the seal has been disturbed (such as leave remnants of the seal or some type of ink residue on the surface when the seal is lifted).

Shipping Samples Using Dry Ice

In addition to the steps identified in Section 3.4, the following steps are required for packing and sealing frozen samples for shipment on dry ice.

a. Place inert material (such as bubble wrap and/or cardboard) in the bottom of the cooler.

b. Place samples requiring frozen preservation in the cooler on top of the inert material.

c. Place an additional piece of inert material on top of the samples to prevent the samples from contacting the dry ice.

d. Put on leather gloves and place one layer of dry ice (approximately 2 inches thick) on top of the second layer of inert material, covering as much surface area as possible.

Note: Do not place more than one layer of dry ice in the cooler. The weight of the dry ice may cause container breakage.

Samples Shipped as Dangerous Goods or Hazardous Material

DOT, IATA, and IMDG regulations governing the shipment of hazardous materials and dangerous goods are followed. These regulations (49 CFR Parts 171 - 180 and the Dangerous Goods Regulations [DGR] for IATA and IMDG) describe proper marking, labeling, placarding, packaging, and shipping of hazardous materials. IATA regulations apply strictly to both domestic and international commercial air transportation. The IMDG regulations apply to the international transport of dangerous goods by waterway. DOT regulations apply to domestic and international shipments originating in or imported to the United States.

The definitions of dangerous goods and hazardous materials, as defined by IATA, IMDG

and DOT, respectively, are presented below.

Dangerous Goods – "Articles or substances which are capable of posing a significant risk to health, safety, or to property when transported by air and which are classified according to the UN hazard classes".

Hazardous Material – "A substance or material which has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated. The term includes hazardous substances, hazardous wastes, marine pollutants, and elevated temperature materials."

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- Office of the Federal Register, National Archives and Records Administration, 49 CFR Parts 171-179, U.S. Government Printing Office, Washington, DC, 2006.

- Tennessee Valley Authority (TVA). *Field Documentation* SOP (TVA-KIF-SOP-06),2009.
- TVA. *Site-Wide Safety and Health Plan for the TVA Kingston Fossil Plant Ash Release Response* (SWSHP), 2010.
- TVA. *Quality Assurance Project Plan for the Tennessee Valley Authority Kingston Ash Recovery Project* (TVA-KIF-QAPP), December 18, 2009.
- United States Environmental Protection Agency (EPA). Region 4, *Packing, Marking, Labeling and Shipping of Environmental and Waste Samples Operating Procedure*. Document Number SESDPROC-209-R1, November 2007.
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Review Sheet

All personnel directly involved with testing of samples for UNTH Virology Laboratory are required to review this SOP prior to initially testing samples for UNTH virology Laboratory and indicate their compliance by signing and dating below. Laboratory Manager must review annually.

Date Adopted:_____

Supersedes: _____

Date	Print Name	Signature	Comments

Date Discontinued: _____

Replaced with: _____