Application Form for Country Proposals

Rotavirus Vaccine Introduction

Submitted by

The Government of [NIGERIA]

Date of submission: [April 2021]

Date of re-submission: [June 2021]

Deadline for submission: XXXXXXX

Please submit the proposal using the form provided.

Enquiries to: proposals@gavi.org or representatives of a Gavi partner agency. The documents can be shared with Gavi partners, collaborators, and the general public. The Proposal and attachments must be submitted in English.

Note: Please ensure that the application has been received by the Gavi Secretariat on or before the day of the deadline. The Gavi Secretariat is unable to return submitted documents and attachments to countries. Unless otherwise specified, documents will be shared with the Gavi partners and the general public.

Gavi

GRANT TERMS AND CONDITIONS

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in

advance by the Gavi. All funding decisions for the application are made at the discretion of the Gavi Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THE APPLICATION

The Country will notify the Gavi in its Annual Progress Report if it wishes to propose any change to the programme(s) description in its application. The Gavi will document any change approved by the Gavi, and the Country's application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the Gavi all funding amounts that are not used for the programme(s) described in its application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the Gavi, within sixty (60) days after the Country receives the Gavi's request for a reimbursement and be paid to the account or accounts as directed by the Gavi.

SUSPENSION/ TERMINATION

The Gavi may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in the Country's application, or any Gavi-approved amendment to the application. The Gavi retains the right to terminate its support to the Country for the programmes described in its application if a misuse of Gavi funds is confirmed.

ANTI-CORRUPTION

The Country confirms that funds provided by the Gavi shall not be offered by the Country to any third person, nor will the Country seek in connection with its application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the Gavi, as requested. The Gavi reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how Gavi funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of Gavi funds. If there are any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the Gavi in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, and Annual Progress

Report, are accurate and correct and form legally binding obligations on the Country, under the Country's law, to perform the programmes described in its application, as amended, if applicable, in the APR.

CONFIRMATION OF COMPLIANCE WITH THE Gavi TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the Gavi Transparency and Accountability Policy (TAP) and complies with the requirements therein.

USE OF COMMERCIAL BANK ACCOUNTS

The Country is responsible for undertaking the necessary due diligence on all commercial banks used to manage Gavi cash-based support. The Country confirms that it will take all responsibility for replenishing Gavi cash support lost due to bank insolvency, fraud, or any other unforeseen event.

ARBITRATION

Any dispute between the Country and the Gavi arising out of or relating to its application that is not settled amicably within a reasonable period, will be submitted to arbitration at the request of either the Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by the Gavi. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: The Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The Gavi will not be liable to the country for any claim or loss relating to the programmes described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in its application.

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Executive Summary

Diarrhoeal diseases are the leading cause of childhood morbidity and mortality in developing countries and an important cause of malnutrition. Diarrhoea accounts for 15% of under-5 mortality in Nigeria, with a prevalence rate of 18.8%. On average, over 200,000 children under the age of five die annually from diarrhoea disease. In Nigeria, more than 50% of hospitalizations result from Rotavirus infection and 77% of these rotavirus hospitalizations occurred in infants which is also consistent with the age epidemiology on deaths from diarrhoeal diseases[1]. Rotavirus vaccination is in tune with the Global Action Plan for Pneumonia and Diarrhoea (GAPPD), Global Vaccine Action Plan (GVAP), Sustainable Development Goals (SDGs). Other national strategic plans and initiatives that support Rotavirus introduction include national plans such as – National Strategic Health Development Plan II (NSHDPII), country Multi-Year Plan (cMYP), Saving One Million Lives (SOML) Initiatives, Essential Childhood Scale-up Plans, Harmonized MGD alliance plans and more recently the Nigerian Strategy for Immunisation and PHC System Strengthening (NSIPSS) 2018 – 2028. Furthermore, the National Health Summit has endorsed Universal Health Coverage for all Nigerians as a policy thrust for the health sector. The introduction of rotavirus vaccines will significantly lead to the reduction in the number of rotavirus hospitalizations and diarrhoea deaths and save an additional 94,793 lives assuming 80% coverage by 2029[2].

This introduction plan was endorsed by the Core Group on 26th April 2016 and by the ICC on the 29th of April 2016. Gavi put the Rota application on hold because of unresolved audit issues. This was resolved and Gavi had requested the government of Nigeria to initiate the process of Rotavirus vaccine introduction. In November 2019, the NGI-TAG recommended Rotavac as the choice of vaccine. The NVSTT revised the previous proposal for re-submission to Gavi. Nigeria's goal is to reduce morbidity and mortality due to rotavirus disease amongst infants. Specific objectives are to vaccinate 40% of eligible children with three doses of Rotavirus vaccine (Rotavac) within the 12 months following the vaccine introduction and to achieve a 60% rotavirus vaccine coverage by within 24 months following introduction; and to integrate Rota vaccine introduction with other diarrheal disease prevention strategies.

The Rota vaccine will be administered orally to infants at 6, 10 and 14 weeks of age. Nigeria would need an estimated 20,552,489 doses at a buffer stock of 50% to vaccinate 7,104,564 children within 12 months of introduction in 2021/2022. The target coverage of the 3rd dose for the first year of introduction is 40%, with the drop-out rate of 10% between the 1st dose and 3rd dose. The planned introduction will commence in Q2 2022 (April) and will be conducted in two phases starting with 20 states in Phase 1 and the remaining 17 states in Phase 2. The considerations for phasing are to ensure good quality preparations for the introduction in terms of cold chain readiness and health worker training. The planned cold chain expansion will provide additional cold chain storage capacity of 519,000L, 83,233L and 336,207L at national, state and LGA/ward levels, which will cater for the Rota vaccine volume. There will be Improved vaccine management including logistics, cold chain expansion, reduction of wastages. Rotavirus

[1] Combatting diarrhea in Nigeria: Way forward; Akintoronye et.al., 2018
https://medcraveonline.com/JMEN/combating-diarrhoea-in-nigeria-the-way-forward.html

[2] Lived Saved Analysis on Rotavirus vaccine introduction (refer to Annex 2)

vaccination will be integrated with other PHC services and diarrhoeal prevention strategies (e.g., hand washing, exclusive breastfeeding, and provision of quality water and sanitation facilities).

The development and implementation of a robust national and sub-national ACSM plan will consider different audiences including partners, stakeholders, communities, and caregivers, through a multiphase multichannel communication platform, and will leverage other planned and ongoing activities to optimize use of available resources. Capacity building of health staff to deliver immunisation including strengthened monitoring and supervision systems and improved program management will be undertaken using the opportunity of the introduction. Training process will leverage lessons learned during the Pentavalent vaccine, PCV and IPV introduction trainings. The NPHCDA will work with SPHCDAs and partners to ensure at least 2 HCWs are trained per facility. Data tools to accommodate the Rota vaccine are available across all levels. Monitoring will be conducted as routine with other vaccines. Surveillance for the vaccine will be integrated with the routine AEFI surveillance and post introduction evaluation will be conducted within 6 to 12 months of introduction.

In the context of the ongoing COVID19 pandemic and plans to introduce COVID19 vaccine in the coming months, the planned introduction of Rota vaccines will seek-out opportunities to integrate and optimize activities where applicable and feasible. The Rota vaccine introduction activities will be conducted in full compliance with WHO and NCDC COVID-19 IPC guidelines. Due to the evolving nature of the pandemic and plans for COVID-19 vaccine introduction, the planning for Rota vaccine introduction will take a nuanced approach to ensure alignment and avoid disruption of COVID19 introduction activities. Potential areas for integration with COVID-19 vaccine introduction plans and other planned activities include, but not limited to ACSM, training, M&E, supportive supervision, post-introduction evaluations, etc.

The GoN also requests to receive the Vaccine Introduction Grant (VIG) of USD 4,234,993.62 at a cost of USD 0.60 per child. In addition to these funds, GoN will leverage existing resources and partnerships to support the rotavirus introduction. At vaccine cost of $0.85 per dose, Gavi will pay USD 7,511,934.63 to cover the Rotavirus vaccine cost in the first year, while Nigeria will pay USD 9,957,680.78 in line with NSIPSS co-financing projections, year of introduction, and co-financing freeze communicated by Gavi. GoN currently procures all traditional vaccines and is committed to fully financing vaccine procurement of Rotavirus vaccines post Gavi transition. The developed accountability framework (AF) for NSIPSS ensure that GoN meets up with its vaccine financing commitments as enshrined in the NSIPSS document. The Government has set aside funds in service wide votes to meet co-financing obligations, as well as launched the Basic Health Care Provision Funds (BHCPF) to meet funding for other primary Healthcare services.

1 Background and Country context

1.1 Geo-Political Context

Nigeria operates a three-tier system of government comprising the Federal, 36 States and a Federal Capital Territory (FCT), and 774 Local Government Areas (LGAs). The LGAs are divided into 9565 political wards. According to the population estimates from the Nigerian National Population Commission (NPopC), the 2021 population is estimated to be 211,493,324 million persons. Nigeria has a predominantly young population with approximately 45 percent being under 15 years of age and 20 percent under five years of age. Women of childbearing age (15-49 years) account for 22% of the total population and the birth cohort constitutes 3.4% of the total population. The projected birth cohort for 2021 is approximately 7,104,564 million[3].

1.2 Socio-Economic Context

A country of rich diversity, Nigeria has over 300 ethnics groups, but the major languages are Hausa, Igbo, and Yoruba. Most of the population (60-70%) live in rural areas[4]. However, with rapid urbanization, several cities now have a population of over 1 million. Scattered settlements abound in many rural areas with nomadic populations being found largely in the north. Rural populations engage predominantly in agricultural, livestock and fishing activities.

Nigeria is the largest economy in Africa with a Gross National Income (GNI) per capita of US$1960[5] yet; the national 2014 World Development Report revealed that 70% of the population lives on less than $1.25 a day.

The recent passage of the National Health Act creates a Basic Health Care Provision Fund (1% of the consolidated revenue of the Federation) to provide Nigerians with access to basic health care services. Essentially, the BHCPF is set to provide a platform for improved resource mobilization for the Primary Health Care System and the delivery of a Minimum Package of Essential Health Services. It also makes provision for social inclusion, addresses the issue of equity in health, and seeks to protect families from catastrophic health expenditure and impoverishment due to the high cost of healthcare, accelerating Nigeria's progress towards Universal Health Coverage. The Basic Health Care Provision Fund (BHCPF) has been rolled-out with 16 states having received their first tranche of funds through the NPHCDA gateway. All the states have formed contributory health insurance schemes; however, some 21 states still lag in fulfilling the criteria put forward to access the BHCPF funds.

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[3] Projected Target Population for 2021

[4] NDHS 2008

[5] World Bank 2019 assessed from https://macrotrends.net/countries/NGA/Nigeria/GNI-per-capita

1.3 The Nigerian Health Sector

1.3.1 Structure

Nigeria operates a three-tier health care delivery system of tertiary, secondary and primary care. The Federal Government through the Federal Ministry of Health (FMoH) provides tertiary health care services in Teaching Hospitals and Federal Medical Centers and develops policies, strategies, guidelines, plans, and programs for overall direction of the national health care delivery system. State Governments are responsible for secondary health care and Local Governments are responsible for primary health care.

1.3.2 Trend in Neonates, Infant and Child Mortality

Childhood mortality rates (neonatal, post-neonatal, infant, child and Under-5 mortality rates) have shown sustained reduction from the Nigeria Demographic and Health Survey (NDHS) 1990 to 2018 as shown in figure 1 below.

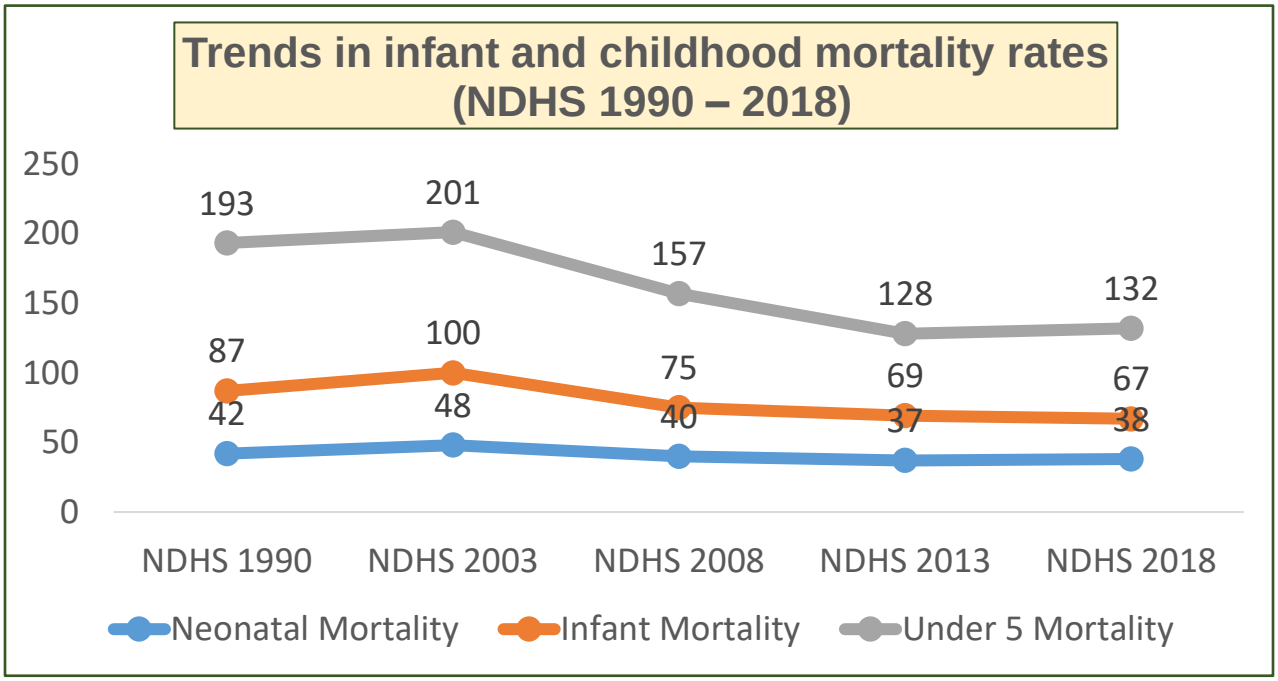

Figure 1: Trends in infant and child mortality, NDHS 1990-2018

Neonatal mortality rates have reduced from 42 per 1000 live births to 38 per 1000 live births. Infant mortality rates dropped from 87 per 1000 live births to 67 per 1000 live births while under-

five mortality rates reduced from 199 per 1000 live births to 132 per 1000 live births[6]. However, between 2013 and 2018, the infant mortality and neonatal mortality rates increased, thus emphasizing the need for introduction of the life-saving Rota vaccine to support a rapid reduction in infant, neonatal and under-5 mortality rates.

1.4 The Expanded Program on Immunisation (EPI) in Nigeria

The Expanded Program on Immunisation (EPI) was initiated in 1979 and has witnessed fluctuations in its level of performance. Between 1988 and 1990, third dose Diphtheria-Pertussis-Tetanus vaccine (DPT3) coverage peaked at 81.5 percent, followed by a drop in coverage to less than 25% in the late nineties[7]. This resulted in the establishment of the National Program on Immunisation (NPI) in 1996 to revitalize and promote a sense of national ownership of the EPI. In 2007, following Health Sector Reforms, the NPI was merged with the National Primary Health Care Development Agency (NPHCDA) and the Department of Disease Control & Immunisation of the NPHCDA is now discharging its functions. The Routine Immunisation system has been substantially strengthened in recent years and has undergone many changes from the implementation of the National Routine Immunisation Strategic Plan (NRISP) 2013-2015, cMYP (2016- 2020) and National Strategy for Routine Immunisation and Primary Health Care System Strengthening (NSIPSS 2018 – 2028). The NSIPSS is expected to contribute significantly to the reduction of mortality by reducing vaccine-preventable deaths. Following on this, the goal of the NSIPSS is the attainment of at least 80% equitable, sustained national coverage with all scheduled routine antigens by 2028.

Nigeria's immunisation coverage has fluctuated significantly over the years, with wide variations across regions. The 2016 MICS-NICS showed a national weighted average Penta-3 coverage of 33% with a wide range from 3% in Sokoto to 80% in Lagos. The 2018 NDHS report showed improvement in Penta 3 coverage from 38% in 2013 to 50% in 2018. The 2018 NDHS report (2017-birth cohort) showed that 29 of 36 states and the FCT have Penta3 coverage less than 80%. Access to immunisation services varied from 17% in Zamfara to 97% in Lagos while utilization of services also ranged from 7.2% in Sokoto to 93% in Ekiti. A comparison of the NDHS results in 2013 with 2018 shows that Penta3 coverage declined in 10 states of which seven were in the South. Routine analysis of the DHIS2 data confirms a similar trend. The results suggest that prior to establishment of NERICC, multiple routine interventions in the northern parts of the country, supported with huge investments in PHC and RI as well as polio resources may have contributed to the increases observed.

[6] NDHS 2018

[7] cMYP 2011-2015 - This target is valid for all antigens already in the immunisation schedule as at March 2018. New vaccines planned for introduction may not reach the 80% target at 2028

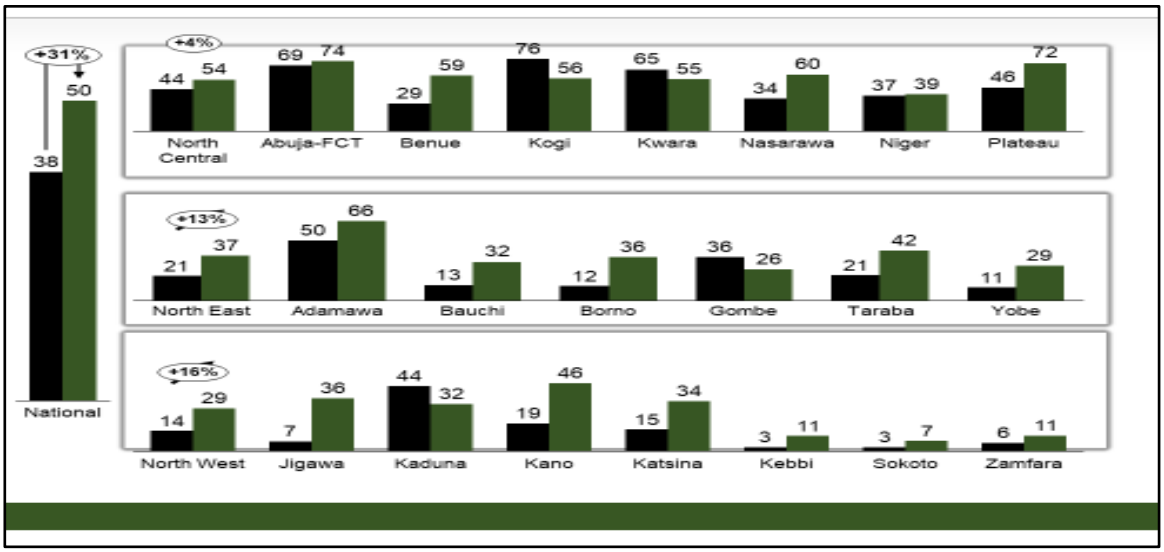

Figure 2: Details trends of Penta3 coverage NDHS 2013 and 2018

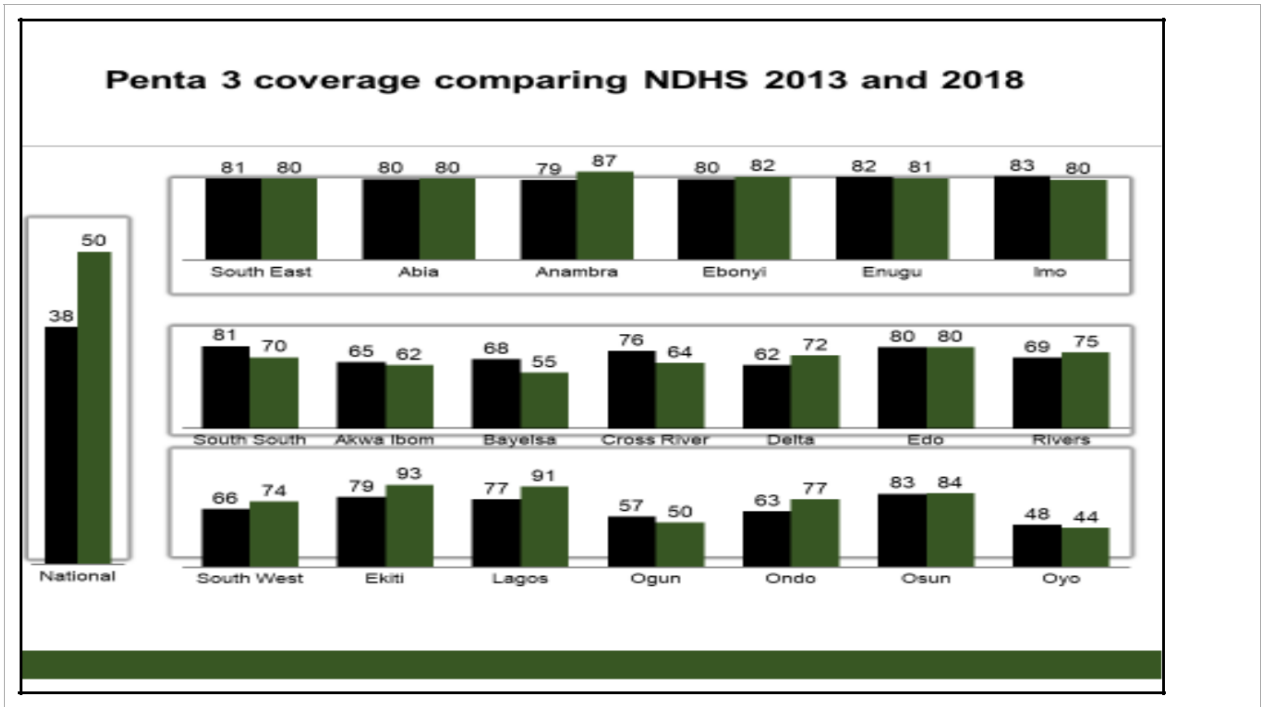

Figure 3: Trends of Penta3 coverage NDHS 2013 and 2018

Though administrative data for 2018 is indicative of improved access and utilisation for immunisation services, WUENIC and survey estimates suggest the contrary. Based on WUENIC estimates none of the routine antigens achieved at least 85% coverage as shown in the Table 2 below.

Table 1: Routine Immunisation Coverage for selected antigens from DHIS2, WUENIC and official estimates, 2018

Antigen	HMIS/DHIS 2	WUENIC 2018	Official Estimate 2018
BCG	***81%***	**53%**	**75%**
OPV 3	***80%***	**57%**	**58%**
Penta 1	***87%***	**70%**	**72%**
Penta 3	***80%***	**57%**	**58%**
PCV 3	***80%***	**57%**	**58%**
IPV	***79%***	**57%**	**N/A**
Measles	***75%***	**65%**	**63%**
Yellow Fever	***73%***	**65%**	**61%**

Equity analysis of utilization of immunisation services show that over the past five years, there is no disparity between gender, while variations in Penta3 coverage exist based on residence, mother's education, and wealth[8]. The trends as shown in Figure 4 below show progress made in bridging increases in Penta3 coverage for each equity barrier, despite the persisting gaps. The findings of the NDHS 2018 show that the infants of mothers with no formal education are three times less likely to be reached with Penta 3 dose compared to those with secondary education. In addition, the rich are 3.5 times more likely than the poor to be vaccinated with Penta3 dose.

There are also disparities in immunisation coverage across geographical regions. Using the penta3 coverage as an indicator, the North West (29.1%) and North East (37.2%) have lower immunisation coverage compared to the South East (83.1%) and the South West (73.8%) zones10. Low immunisation coverage has also been recorded in identified hard to reach areas, underserved communities with very difficult terrain, security compromised areas and urban slums.

[8] Tracking coverage, dropout and multidimensional equity gaps in immunisation systems in West Africa, 2000–2017; Wariri et.al.,2017

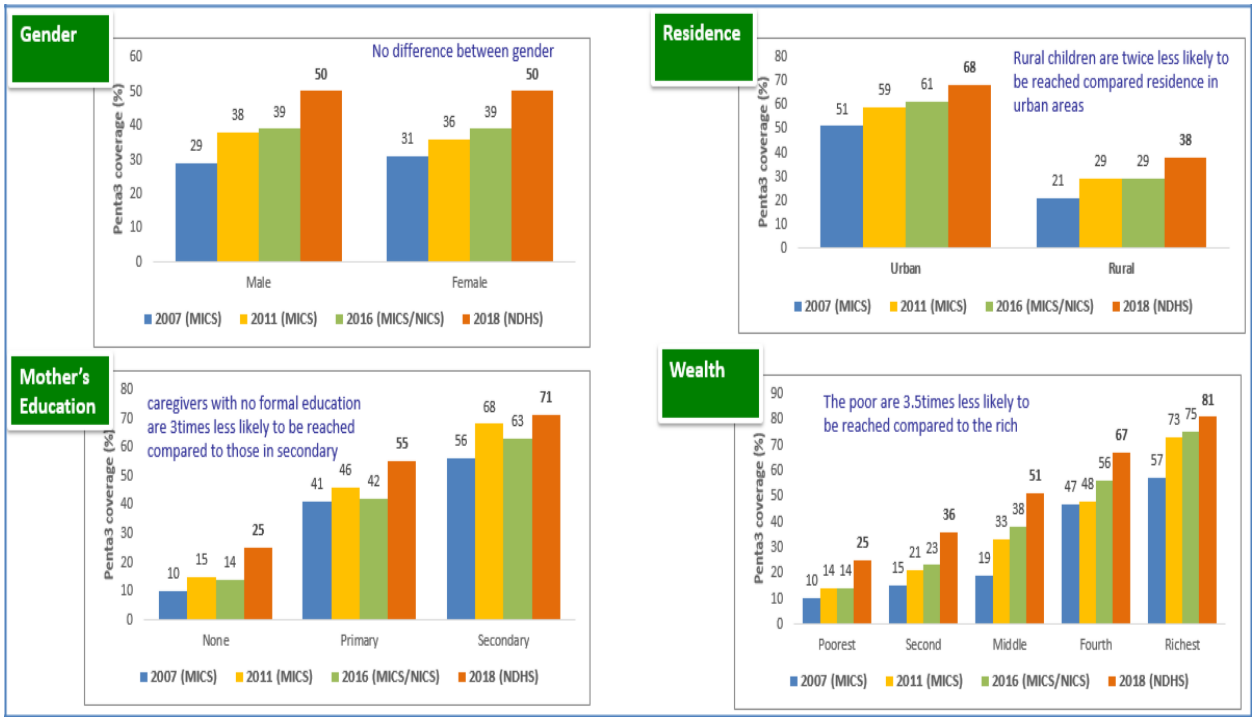

Figure 4 : progress made in bridging increases in Penta3 coverage for each equity barrier, despite the persisting gaps (NDHS, 2018)

The findings of the NDHS 2018 show that the infants of mothers with no formal education are three times less likely to be reached with Penta 3 dose compared to those with secondary education. In addition, the rich are 3.5 times more likely than the poor to be vaccinated with Penta3 dose.

1.4.1 Strategies to address inequity.

To address inequity, the NSIPSS (2018 – 2028) outlined several service delivery strategies which include;

- the optimization of REW strategy,
- scale up of optimized fixed sessions through daily vaccination in all urban, secondary, and tertiary facilities,
- increased number of outreach and mobile sessions to reach the hard to reach, rural communities,
- intensified supportive supervision,
- implementation of community engagement strategy,
- integration of routine immunisation services with PHC services and commodities.

Other interventions to improve immunisation coverage and equity include Maternal and Child Health Week (MNCHW), Local Immunisation Days (LID), State Outreach Days (SOD). On annual basis high risk analysis is conducted and identified LGAs are targeted for optimized integrated routine immunisation sessions (OIRIS), intensification of routine immunisation activities and strategies to reach security compromised areas such as Reaching Every Settlement (RES), Hit and run, Reaching Inaccessible Children (RIC) etc.

1.4.2 Lessons learned from previous vaccine introductions.

Nigeria has had experience introducing new vaccines in the past.

- Hepatitis B and Yellow fever vaccines were introduced in 2003.
- The pentavalent vaccine was introduced to replace DPT in 2012.
- PCV10 and one dose of IPV were also introduced in 2014 and 2015, respectively.
- Meningitis A vaccine was introduced nationwide in 2019 while Measles 2nd dose was introduced in 2019 in 17 southern states (Phase 1) and in 2020 in the remaining 19 states (phase 2).

These introductions were conducted in a phased approach except Meningitis A, which was a nationwide introduction. The introduction of these vaccines has provided learning opportunities for the EPI program some of which include:

- Stronger government-led coordinating mechanisms such as the National Emergency Routine Immunisation Coordination Centre (NERICC), New Vaccine Introduction Task Team (NVSTT), State Emergency Routine Immunisation Coordination Centre (SERICC), national and state-level vaccine introduction operations rooms
- The availability of the vaccine introduction grant (VIG) in a timely manner allows preparatory activities to be conducted well in advance of the introduction, particularly in the production of data management tools, IEC, and other training components of the introduction. Given that this is already a feature of the Gavi New Vaccine Introduction (NVI) grant, timely transfer four months ahead will provide sufficient lead time for implementing preparatory activities.

- Timely update of cold chain inventory records, coupled with physical verification and general vaccine management training (VMT), will greatly facilitate a successful introduction as was learned with pentavalent vaccine introduction. Presently the Inventory Replacement Plan (IRP) tool has been updated and a mechanism for quarterly updates has been institutionalized with support of partners.
- Post introduction evaluations and frequent spot checks, uptake assessment and deep dives are important mechanisms found useful in effecting corrections early during the introduction.

- Adequate lead-time for production and distribution of relevant tools and materials to cold stores and health facilities is critical to pre-introduction. The revised data tools specifically need to be pre-positioned at states four weeks before the date of introduction.
- Need for continuous messaging around vaccination beyond just the introductory event is important. In addition, messaging on new vaccines should be included during all immunisation campaign programs and other opportunities.

These lessons were adapted to pneumococcal conjugate vaccine (PCV), Inactivated Polio Vaccine (IPV) introduction planning, Meningitis A and Measles 2nd dose introduction and the collective lessons from these introductions will shape the implementation of the Rotavirus vaccine introduction plans well as HPV and other future introductions.

1.4.2 Findings from previous program reviews

In 2018, a cold chain inventory assessment was conducted. Findings from the cold chain assessment showed 28 states have the capacity to store RI and new vaccines (Including Rota). While it is anticipated that the deployment of cold chain equipment will bridge the cold chain equipment gap at both the LGA and Health facilities. However, the cold chain inventory is updated quarterly and the current storage capacity is updated in section 3 (cold chain requirements)

The 2018 cold chain assessment report identified that

- Fifty two percent (52%) of available cold chain equipment are functional, 13% are non-functional but repairable, 33% non-functional and non-repairable while 2% of available CCE are not installed.
- Seventy eight percent (78%) of CCE in the country are WHO-prequalified, 21% are non-prequalified while 2% are either walk-in-cold room or walk in freezer room.
- Ninety three percent (93%) of cold storage sites either have no access or less than eight hours supply of electricity.
- Approximately 30% of states and 56% of LGAs do not have adequate cold chain storage capacity to meet 2028 immunisation needs.
- Only 40% of wards have at least one functional PQS/PIS CCE to support immunisation service delivery as per national immunisation policy.

- 49% of cold chain equipment (CCE) was non-functional, although 75% of these were believed to be economically repairable.

The following recommendations emerged and are being implemented across levels;

- Solar direct drive refrigerators have been prioritized as the most suitable type of CCE for LGA and HFs and has been prioritized for cold chain equipment optimization platform (CCEOP) procurements.
- With the approved CCEOP application, procure and install solar direct drive (SDD) cold chain equipment and ice-lined refrigerator (for tertiary health facilities only) to address cold storage capacity gaps at LGA and ward levels.
- In the first tranche of delivery, deployment of 2975 cold chain equipment under the CCEOP is ongoing in 28 states.
- Ongoing nationwide repair of non-functional but repairable cold chain equipment by states
- The maintenance unit has been set up across all states to manage planned preventive maintenance and minor curative maintenance.
- Planned preventive maintenance guidelines have been revised to include curative maintenance and procedure for decommissioning and disposal of obsolete CCE.

1.4.3 2017 EVM assessment findings and improvement plan

In May 2017, an Effective Vaccine Management assessment (EVMA) of Nigeria which comprehensively reviewed the country's immunisation supply chain from vaccines' arrival into the country to the point of making them available at service delivery points was conducted.

There had been three previous EVM Assessments in 2010 and 2014 and 2017. Each Assessment was followed by the development of an improvement plan aimed at addressing identified gaps from the Assessment. The main positive findings from the 2017 EVM were good; infrastructure including buildings, cold chain equipment, and transport; good knowledge of vaccine management; and satisfactory knowledge of temperature monitoring at the national and most of the state storage facilities. However, the assessment revealed inadequacies in equipment maintenance, stock management, vaccine distribution and comprehensive temperature monitoring systems particularly at the LGAs and HF levels. As a result of the identified gaps, which were ascribed to a lack of ownership on the part of stakeholders at the lower levels, the improvement plan for the 2017 EVMA was developed through a consultative process involving stakeholders from national and sub-National levels., The improvement plan which prioritizes supportive supervision to lower-level stores to entrench a preventive maintenance culture was developed and is being implemented to mitigate some of the identified challenges. The country is leveraging the Gavi Cold Chain Equipment Optimization Platform (CCEOP) to fill gaps in the availability of cold chain equipment at the service delivery level. Steps have also been taken to hasten the procurement and delivery of relevant equipment at other levels (including temperature monitoring devices) as part of the cold chain revamping plan.

The status of Supply Chain Fundamentals based on the 2017 EVM Assessment is indicated in figure 5 and 6 below showing the at the various levels of the iSC.

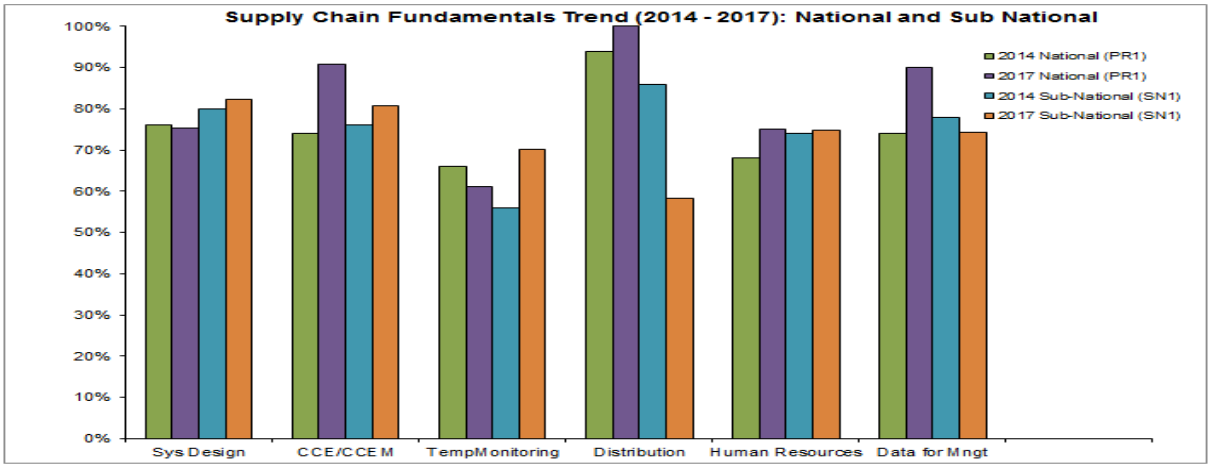

Figure 5: Status of Supply Chain Fundamentals: National and Sub-National

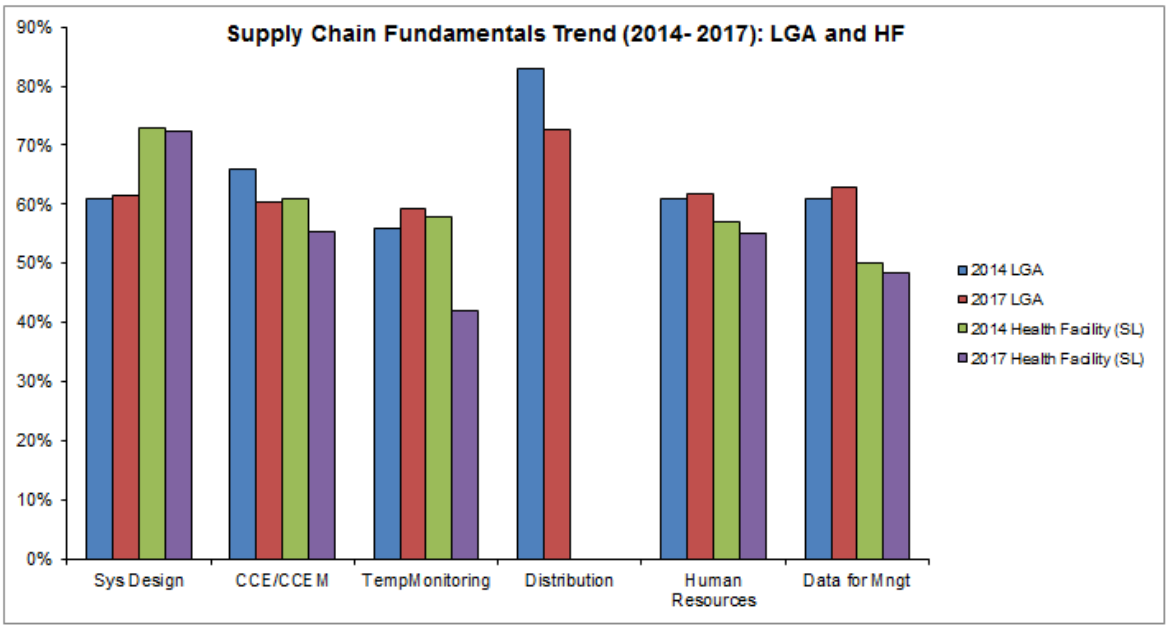

Figure 6: Status of Supply Chain Fundamental: LGA and HF

The progress made in achieving the Supply Chain Objectives from 2014- 2017 across all levels of iSC is also indicated in figure 7 below;

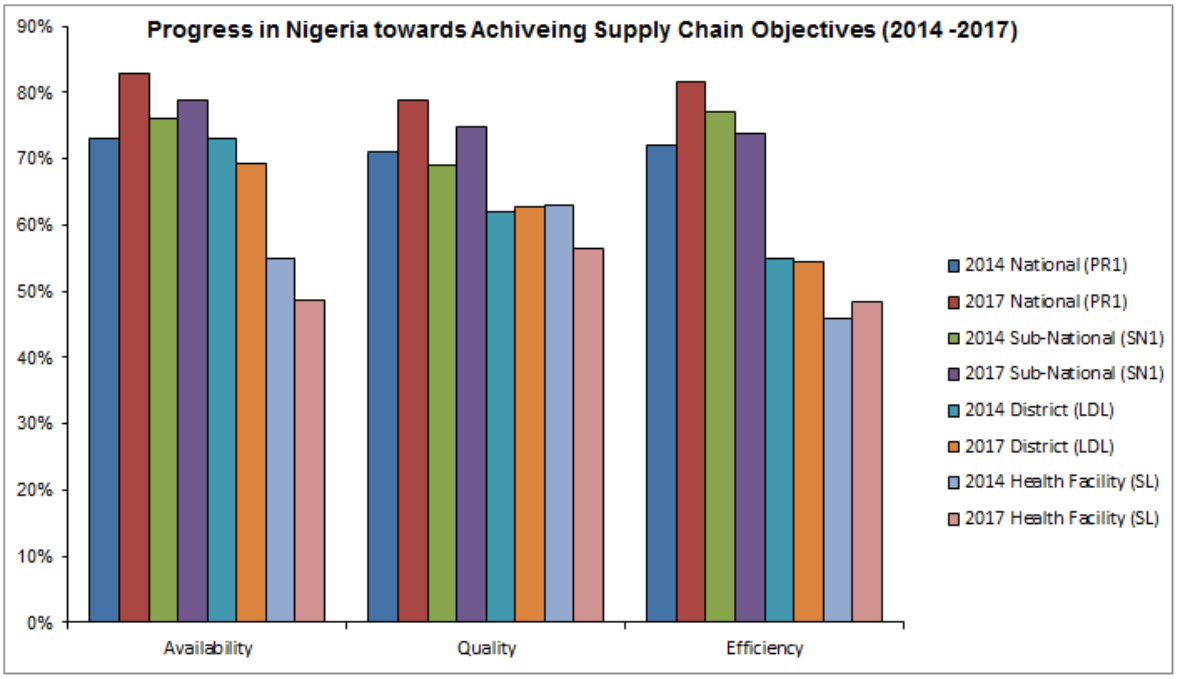

Figure 7: Progress towards achieving supply chain objectives.

1.4.4 Progress report on the 2017 EVM improvement plan

Following the EVM Assessment conducted in 2017, 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 with expected timeline of completion as contained in the 2017 improvement plan. Although significant progress has been made, particularly at the National level, there are still some high priority activities that need to be carried out at all levels of the supply chain.

National Level Progress: Progress has been made at the National level. As of October 2019, 32.14% of activities are fully completed; 51.79% are in progress, 7.14% are not due; 3.57% have not started and 5.36% have been deferred. The cold chain capacity expansion (3-hub and WICRs) is however in progress.

State Level Progress: Following the 2017 EVMA, a comprehensive state-specific continuous improvement plan was developed to be implemented between 2018-2020, with involvement of all stakeholders. Each state conducted a series of advocacy for funding and integration of the costed activities into the state's budget for various sources of funding to ensure gaps identified in the 2017 EVMA are addressed. State level implementation has progressed at a moderate pace since commencement of EVM cIP in January 2018 with up to 40% of states showing steady progress towards achievement of their targets with funding challenges. 43% of tasks have been achieved at this level, while 16% is partly achieved, 16% is in progress and 24% not yet 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 all walk-in-cold-rooms is to be provided. The accurate recording of vaccine wastage rate remains an issue which will be addressed in collaboration with the Data Harmonization Committee by the incorporation of wastage data into data collection tools and ultimately, into DHIS2. Temperature monitoring has improved, with a number of activities underway, including a temperature monitoring study. All the state cold rooms have been equipped with Remote Temperature Monitoring devices (RTMDs). Storage capacity is currently being addressed under the New Vaccines Introduction plan. Maintenance guidelines have been developed and basic user maintenance was introduced as a module in the vaccine management training undertaken in the fourth quarter of 2013. The majority of the states have developed distribution plans and shared them with the LGAs. In addition, the development of job aids and finalization of the existing SOPs are also in progress.

LGA Level Progress: At this level, forty-seven percent of tasks have been achieved, 3% partly achieved, 33% in progress and only 17% are not yet achieved. Adequate, well organized 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. States have equally trained LGA staff on vaccine management.

Health Facility Level Progress: Thirty-three percent of tasks have been achieved, 24% partly achieved, 24% in progress and 18% not yet 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 have commenced. Training on vaccine management, development of planned preventative maintenance policies and vaccine disposal SOP are in progress. A significant challenge has been the renovation of health facilities and addressing the poor drainage systems and other infrastructure inadequacies.

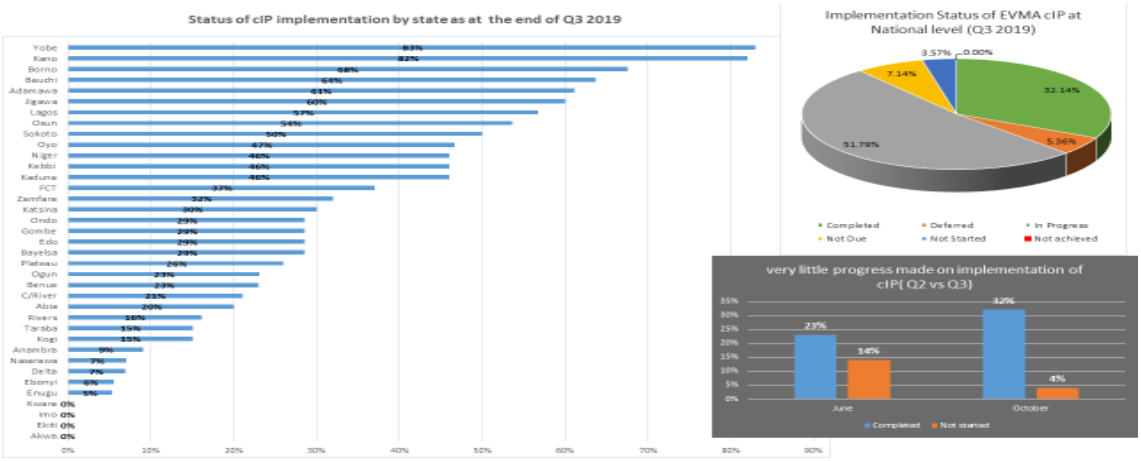

Figure 8: Implementation Status of EVMA cIP at National level and state levels

At the state level, the level of implementation varied with the level of commitment to funding specific activities for the immunisation supply chain. On average only 25% of planned activities as of 2019 have been completed; 37% are in progress, 28% have not started and 10% of activities have not been achieved. There is clear improvement in the implementation of activities (above 50% completion rate) in the MoU states (apart from Sokoto and Kaduna). However, states like

Adamawa and Jigawa (Non-MoU) recorded significant improvement due to the high level of commitment by the state.

It is important to note that the EVMA 2.0 is currently being conducted externally and necessary action points have been taken to improve the system alongside the 2017 updated cIP pending the next official EVMA.

1.5 Rotavirus disease burden

Rotavirus infection is a highly communicable disease that is the single most common cause of severe diarrhea in children, which can lead to severe dehydration and in some cases, death[9]. Transmission of the rotavirus is via fecal-oral route. The virus, which is typically shed in high concentration from the stool of an infected person, is very stable, and may remain in the environment for a long period. Recovery from rotavirus infection does not always cause natural immunity to future infections. An estimated 38% will be protected against future infection, while 77% are protected against rotavirus diarrhea[10]. All children are considered at risk, regardless of location or access to clean water. Those at highest risk include children below two years, as well as those with weakened immune systems. Cases can occur in older children and adults; however, these cases are typically milder.

Diarrhoeal disease generally is one of the leading causes of childhood morbidity and mortality in developing countries, including Nigeria. Exposure to diarrhoea-causing pathogens is frequently related to consumption of contaminated water and to unhygienic practices in food preparation and disposal of excreta (NDHS 2018). The combination of high cause-specific mortality and the existence of an effective remedy makes diarrhoea and its treatment a priority concern for health services and according to the NDHS survey findings of 2018, 13% of children under age 5 were reported to have had diarrhoea in the 2-week period before the survey. This represents an increase from 2008 and 2013 (10% in both years). Children aged 6-11 months and 12-23 months (20% each) were more likely than children aged 48-59 months (7%) to have had diarrhoea in the 2 weeks preceding the survey (NDHS 2018).

The prevalence of diarrhoea is also slightly higher among children in households with an unimproved source of drinking water (16%) than among those in households with an improved source of drinking water (12%). The prevalence of diarrhoea is slightly higher among children in households with unimproved sanitation (16%) than among those in households with improved sanitation (11%). The prevalence of diarrhoea is highest in Gombe (35%) and lowest in Ogun and Bayelsa (1% each).

9

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1.5.1 Global Burden of Rotavirus

Globally, nearly every child experience rotavirus diarrhoea disease by age 5. Nigeria contributes the greatest number of Rotavirus deaths (30%) as a proportion of all global rotavirus deaths amongst under 5 children, The disease accounts for: 1 in 5 visits to clinics; 1 in 65 hospitalized; and 1 in 293 dies from the disease.[11] In 2016, rotavirus infections resulted in 128,500 deaths in children under-5; this represents 29% of deaths attributable to diarrhea and makes Rotavirus the third leading pathogen associated with child mortality, behind malaria (517,000 deaths) and Streptococcus pneumoniae (359,000 deaths).[12] Over 95% of rotavirus deaths are in low-income countries in Africa and Asia. In these countries, access to diarrhoea treatment is often limited or unavailable.[13] This is potentially due to a number of factors, including greater rates of malnutrition and poor access to rehydration therapy.

Figure 9: The Countries with the Greatest Number of Rotavirus Deaths as a Proportion of All Global Rotavirus Deaths in Children under 5 (2017)

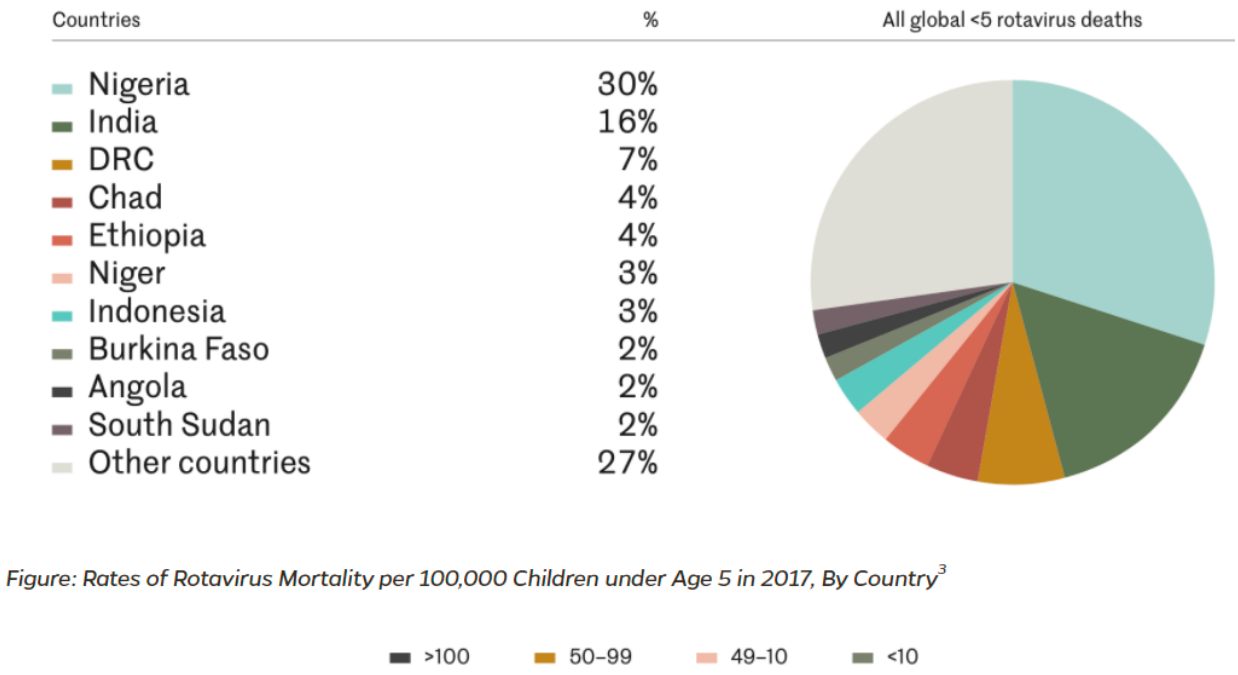

Figure: Rates of Rotavirus Mortality per 100,000 Children under Age 5 in 2017, By Country[3]

[11] Robert F. Ramig et al. Pathogenesis of Intestinal and Systemic Rotavirus Infection, Journal of Virology Oct 2004; 78(19): 10213–10220.

[12] Troeger C, Khalil IA, Rao PC, et al. Rotavirus Vaccination and the Global Burden of Rotavirus Diarrhea Among Children Younger Than 5 Years. JAMA Pediatr. 2018;172(10):958–965. doi:10.1001/jamapediatrics.2018.1960

[13] http://www.gavi.org/support/nvs/rotavirus/

1.5.2 Rotavirus burden in Nigeria

Childhood diarrhoea is the third leading cause of childhood mortality in Nigeria, accounting for 15% of all under-five deaths,[14] an indication of over 200,000 deaths every year. In South-east Nigeria, about 56% of children hospitalized tested positive for rotavirus and 77% of these rotavirus hospitalizations occurred in children under one year[15]. This is consistent with the age epidemiology for diarrhoea deaths. Rotavirus infections occur throughout the year in Nigeria and [16] Studies show diversity in the rotavirus strains circulating in the country. In northwestern Nigeria, 18% of samples from children with diarrhea were detected to carry rotavirus antigens, the majority of which revealed long electropherotypes and VP6 subgroup I+II specificity.[17] Meanwhile, a smaller study in northwestern Nigeria showed rotavirus antigens in 9% of stool samples. In this study, VP6 subgroup II specificity (58.3%, long RNA electropherotypes (41.6%), VP7 genotype G1 (33.3%) and VP4 genotype P [6] (33.3%) were the most common strains in the community.[18] A study in northwestern Nigeria indicated that more than a third of specimens displayed a mix of G and P genotypes[19]. In a study in Lagos, subgroup II was predominant (51%), with only a few confirmed subgroup I strain (4%). Of the VP7 genotypes in this study, G1 was the most prevalent (45%), with G3 strains occurring less frequently (5%); of the VP4 genotype the most frequent was P [6] (30%) and P[8] (25%), and only one P[4] strain.[20] In Eastern Nigeria the most prevalent genotype combinations were G12P [8] (27.1%), G3P [6] (16.5%) and G10P [6] (7.3%).[21]

1.5.3 Most recent Rotavirus disease burden from surveillance data

Cumulatively from January to December 2020, a total of 1,103 children were enrolled across the WHO rotavirus sentinel surveillance sites in Nigeria. 99% (1,087 of 1,103) developed diarrhea,

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[14] End preventable deaths: Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea, WHO/UNICEF 2013 http://apps.who.int/iris/bitstream/10665/79200/1/9789241505239_eng.pdf

[15] Tagbo et al, Epidemiology of Rotavirus Diarrhoea among Children Younger than 5 Years in Enugu, South East, Nigeria. The Pediatric Infectious Disease Journal • Volume 33, Number 1, Supplement 1, January 2014

[16] http://www.ncbi.nlm.nih.gov/pubmed/18788254

[17] Aminu M et al, (2008) Rotavirus infection in four states in north-western Nigeria. Nigerian Journal of Medicine; Assessed online http://www.ncbi.nlm.nih.gov/pubmed/18788254

[18] Aminu M et al, (2008) Epidemiology of rotavirus and astrovirus infections in children in northwestern Nigeria, Annals of African Medicine; Assessed online http://www.ncbi.nlm.nih.gov/pubmed/19623918

[19] Aminu M et al, (2010) Diversity of Rotavirus VP7 &VP4 in North Western Nigeria; Assessed online http://jid.oxfordjournals.org/content/202/Supplement_1/S198.long

[20] Audu R et al, (2002) Diversity of human rotavirus VP6, VP7, and VP4 in Lagos State, Nigeria Assessed online http://www.ncbi.nlm.nih.gov/pubmed/12022161

[21] Molecular Characterization of the Circulating Rotavirus Strains in Under Five Children with Diarrhoea in Enugu Nigeria, Tagbo et al, Yet to be published

and 38% (414 of 1,087) of samples from the children with diarrhea were detected to carry rotavirus antigens. This data serves as a baseline for testing the impact of the rotavirus vaccine introduction.

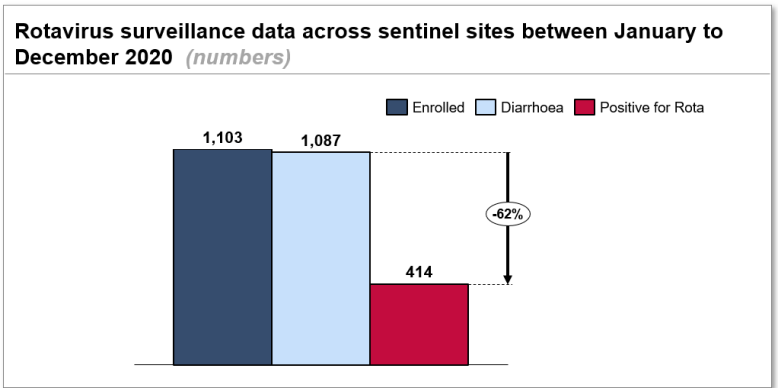


Figure 9: Most recent rotavirus disease burden[2218]

[2218] WHO rotavirus surveillance data January to December 2020

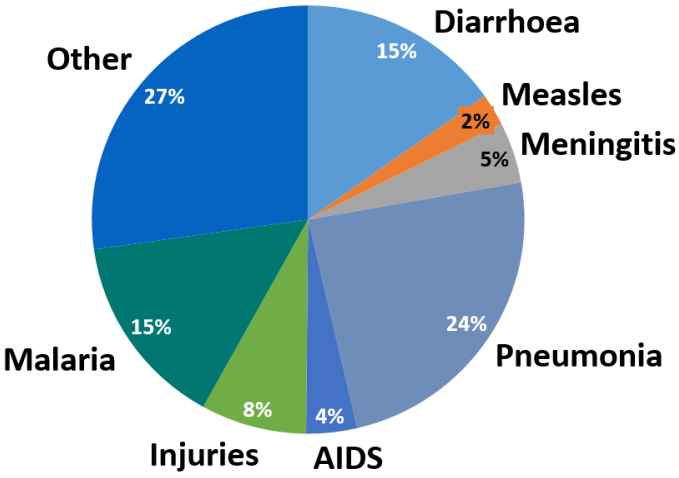


Figure 10: Child mortality by diseases highlighting Rota [23]

1.5.4 Efforts to reduce the burden of rotavirus diarrhea in Nigeria

Nigeria has a large share of Rotavirus diarrhea disease burden in Africa. Concerted efforts are ongoing in Nigeria to reduce the incidence of diarrhea. Given that rotavirus diarrhoea continues to be pervasive in both developed and developing countries and remains the primary cause of diarrhoea and hospitalizations among children <5years, vaccination with Rotavirus vaccines is an essential complementary intervention to prevent childhood deaths due to diarrhoea.

Nigeria has committed to the Integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD) and Global Vaccine Action Plan (GVAP). This is reflected in the National Health Strategic Development Plan 2018 – 2023 and well defined in the delivery of essential health services packages for which access is enhanced through the rollout of the National Health Insurance Scheme. Significant emphasis is being made to achieve targets of universal health coverage including reducing the burden of diarrhea diseases. In line with this, the NPHCDA and partners have developed and are implementing the Essential Childhood Medicines Scale-up Plan geared towards scaling up prevention and treatment of these leading causes of childhood morbidity and mortality. These interventions include the distribution of Long-Lasting Insecticide Treated Nets to prevent malaria, the scale-up of essential childhood medicines and the use of zinc ORS to treat diarrhoea in addition to breastfeeding, improving hygiene and ensuring proper sanitation and maintaining good nutrition.

Nigeria is implementing streams of funding to improve access to life-saving interventions focusing on reducing mortality among children and women. Since 2015, the Saving One Million Lives

[23] UNICEF. (2018.) Child Mortality Estimates: Global and regional deaths by cause

Initiative Project is contributing to the reduction of maternal and child morbidity and mortality through interventions to; control malaria; increase access to essential childhood medicines; improve immunisation coverage; increase access to nutritional services; maternal services including antenatal and family planning. In 2019, the country rolled out the Basic Health Care Provision Funds to provide support for operational funding for PHC services. The funds contribute to ensure adequate funding for essential commodities and services at the health facilities. The implementation of the Nigeria Strategy for Immunization and PHC Systems Strengthening (NSIPSS) 2018 – 2028 is increasing the access to other vaccines through the introduction of Men A, Measles 2nd dose and switch from PCV10-2 dose to PCV10-4 dose vial. The planned introduction of the rotavirus vaccine would contribute significantly in further reduction of deaths under-five in the country.

1.5.5 The application process for Rotavirus Vaccine Introduction

The NPHCDA through the core group tasked the Routine Immunisation Working Group (RIWG) to accomplish this task in April 2014. The Core Group endorsed this introduction plan on 26 April 2016 and the ICC on 29 April 2016. Gavi put the Rota application on hold because of unresolved audit issues. This has been resolved and Gavi had requested the government of Nigeria to initiate the process of Rotavirus vaccine introduction. In November 2019, the NGI-TAG recommended Rotavac as the choice of vaccine. The NVSTT revised the previous proposal for re-submission to Gavi.

2. Goals, objectives and expected impact and challenges

2.1 Goal

Nigeria's goal is to reduce morbidity and mortality from diarrhoea due to rotavirus infection, which occurs amongst infants in line with the universal health coverage policy as part of the government effort to achieve the Sustainable Development Goals (SDG3).

2.2 Objectives

The main objective is to introduce the Rotavirus vaccine in a phased manner into the EPI schedule commencing from quarter 2 (April), 2022.Specific objectives include;

- To vaccinate 40% of infants with 3 doses of Rotavirus vaccine (Rotavac) within 12 months of introducing the vaccine (by April 2022)
- To achieve a 60% rotavirus vaccine coverage within 24 months of the vaccine introduction (April 2024)
- To integrate Rota vaccine introduction with other diarrheal disease prevention strategies

2.3 Expected impact

Nigeria aims to achieve a reduction in rotavirus hospitalizations and diarrhoea deaths and save an estimated 94,793 lives assuming 80% coverage by 2029. The combined effect of a sustained high coverage for Rotavirus, Pentavalent, Pneumococcal Conjugate (PCV) vaccines will avert 794,006 deaths by 2029[24]. The benefits of the rotavirus vaccine introduction cannot be over-emphasized, as the cost of treating a Nigerian child for Rotavirus Diarrhoea diseases is 250% of the cost of vaccinating with Rotavirus vaccines [25].

The introduction of the Rotavirus vaccine is consistent with Nigeria's plan to implement the integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD). More importantly, the introduction will ensure that the government reach children in states with the greatest mortality due to diarrhoea diseases, which will significantly contribute, to SDGs.

[24] LiST tables annexed to the document

[25] CHAI analysis- Cost benefit of PCV and Rotavirus vaccine introductions

2.4 Challenges to Immunization

Nigeria has one of the highest number of unimmunized children in the world, estimated at 4.3 million children in 2016[26]. The challenges to routine immunisation cut across supply and demand issues:

- Poor engagement of the community members is linked to the poor population demand for immunisation services, especially in the northern states. The MICSNICS 2016/2017 identified poor awareness as one of the numerous barriers for service delivery.
- Inadequate staffing, rapid turnover and limited training and capacity at the health facility level, especially rural communities are other barriers to immunization based on supervisory reports.
- Data quality – limitations on the use of the numerator and denominator that affects improvement of operational plan. There are persistent discrepancies between administrative and survey data.
- Inadequate and inconsistent funding for immunization programme at sub-national level.
- The last mile distribution of vaccines and weak logistics management information systems especially at the health facility level
- The main challenges in logistics are storage capacity, weaknesses relating to human resource for health, data for management, temperature monitoring and control, supply chain optimisation, last mile distribution and sustainability. These challenges affect the achievement of the key objectives of the 6 supply chain fundamentals which are, Availability, Quality and Efficiency.

2.5 Anticipated risks and mitigation strategies

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

2.5.1 Financial sustainability:

Risk: Delay in the release of funds from Gavi or GoN could pose a risk of delay in implementation of preparatory activities for the planned Rotavirus vaccine introduction. In addition, poor funding of routine immunisation activities will also pose a risk to improve and sustain immunisation coverage.

Mitigation: To address this potential risk, preparatory activities will be initiated before the VIG is received, leveraging existing resources, partnerships, and consultations that could support the

[26] 2016 MICS/NICS

preparation activities described in the introduction plan. An RI investment case was established to ensure timely availability of funds for vaccines and sustainable systems are in place to ensure sufficiency of funding by the Government of Nigeria (GoN). This includes a provision in the National Health Act (signed in December 2014) for additional funds for vaccines per annum. There are also ongoing plans to harness contributions from the State and Local government in addition to the current funding by the Federal government for vaccine procurement. Moreover, the NSIPSS financial commitment has incorporated the introduction of Rotavirus vaccine, which addresses the long-term financial sustainability planning process undertaken by the GoN.

2.5.2 Safety profile of Rotavirus vaccine:

Risk: In the past, the rotavirus vaccine has been associated with intussusception. However, recent evidence has shown that there is no increased risk of intussusception among vaccinated children with Rotavac vaccine. Nonetheless, adequate monitoring through effective AEFI surveillance is critical.

Mitigation**:** Strengthening AEFI surveillance is vital (training, detection, reporting, investigation). Additional activities recommended include:

1. **Literature review**: A desk/literature review on the post-introduction AEFI data from other countries
2. **Workshops:** Scientific workshops for members of scientific professional organizations particularly Surgeons and Pediatricians. This would increase awareness and knowledge about the safety profile of the Rotavirus vaccine and provide an opportunity to encourage spontaneous reporting of AEFI and solicit feedback that would be useful for tailoring communications and advocacy strategies.
3. **Pre and post-licensure disease burden evaluations & post-introduction safety monitoring:** Where Rotavirus surveillance sentinel sites exist; conduct a pre-introduction disease burden evaluation and attitudes/knowledge survey. Following the introduction of the Rotavirus vaccine, the NPHCDA and partners will conduct active surveillance for potential adverse events using the AEFI monitoring plan. In addition, NPHCDA and partners will conduct a Post-Introduction Evaluation (PIE). This strategy would not only be logistically feasible, but will also provide “real-world” data on the safety, tolerability, and acceptance of Rotavirus vaccine. In particular, having data on both the impact and the safety of the vaccines will allow decision-makers, academicians, health care providers, and parents to arrive at informed, evidence-based decisions on sustaining use of rotavirus vaccines and achieving the highest possible coverage. The introduction of Rotavirus vaccine will strengthen the existing

Sentinel surveillance sites in the country (ABUTH Zaria, UNTH Enugu, ATBUTH Bauchi, Ilorin teaching Hospital).

2.5.3 Programmatic risks:

***Risk**:* Insecurity poses a threat to RI particularly in security challenged areas of Northern Nigeria.

Mitigation: In security-challenged areas and disaster zones, collaboration with security and rescue agencies, including local vigilante groups, are needed to deliver vaccines at health facilities and health camps

Potential equity barriers:

Risk: RI coverage varies by region in Nigeria and even in seemingly high performing states, low coverage areas exist. Deaths from diarrhoea are more likely to occur amongst hard to reach populations, urban slums underserved communities and rural areas where primary health care services are limited.

***Mitigation**:* Although some progress has been made on improving the routine immunization performance in the country, the NPHCDA and partners have identified equity gaps. These are more significant in low performing LGAs, flagged by the RI LQAS. To address these equity gaps, targeted strategies such as the implementation of OIRIS and other RI intensification strategies have prioritized these LGAs.

In addition, experience from new vaccine introduction in the country is an opportunity to strengthen the RI system especially with the mobilization of resources that come with the introduction activities (training, conduct of sessions, cold chain expansion, supportive supervision, community mobilization and awareness). With this introduction, outreach and mobile services will be integrated with other PHC services and diarrhoea prevention strategies e.g. hand washing, exclusive breast-feeding, and provision of quality water and sanitation facilities. During these outreaches, health care workers will educate mothers on basic diarrhoea prevention strategies and management using zinc and ORS.

Potential high wastage:

Rotavac vaccine (live attenuated) is a liquid frozen vaccine with VVM on the cap. The vaccine must be discarded after six hours or at the end of the session whichever comes first. The introduction of new vaccines highlights concerns about high wastage, knowledge if wastage policies and the quality of stock management if not properly managed.

Mitigation: The NPHCDA and partners have put in place strategies to help reduce high wastages, which include vaccine accountability initiatives, follow the vaccine initiative, NLMIS for immunization Supply Chain (iSC) and physical stock count. With this introduction, the NPHCDA will ensure training emphasizes on effective vaccine management practices and MDVP adherence. Adequate supportive supervision and monitoring will also contribute to sensitization of health workers on better control of wastage. In addition, social mobilization activities would be intensified during the introduction to ensure the communities are adequately mobilized to bring

their children for vaccination. Increase in conduct of session and the integration of RI and other PHC services are avenues to reduce missed opportunities and ensure vaccines reach every child

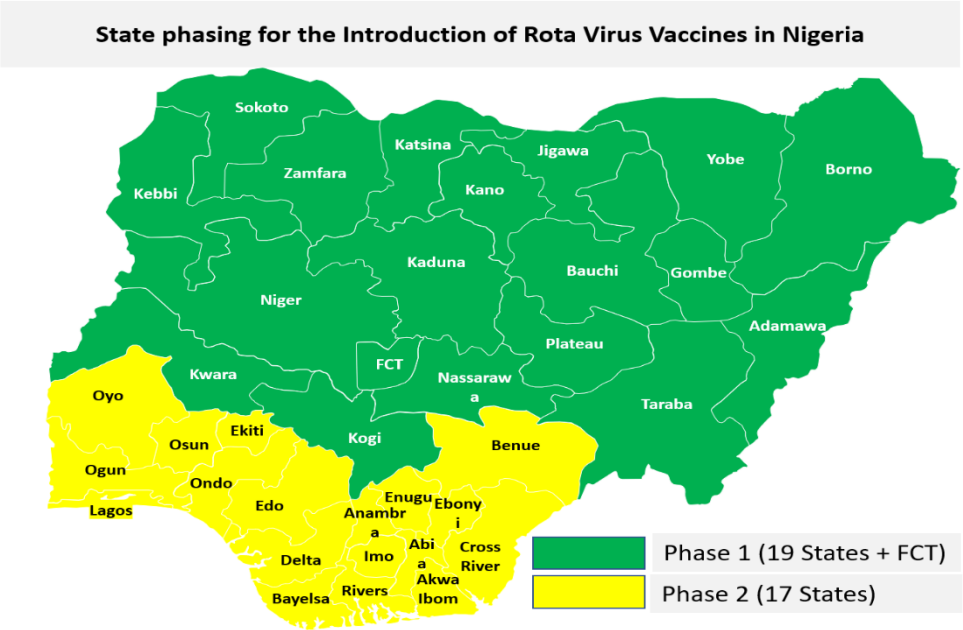
3. Strategies and policies for introducing the vaccine into the national immunisation program

3.1 Target age group and phasing plan

Phasing of new vaccine introductions supports optimal planning and effective monitoring of new vaccine introduction activities. It further complements the vaccine supply constraints given Nigeria's large population. HPV Phasing is determined by criteria that assess vaccine storage capacity, the strength of the RI Program (coverage), the burden of disease, and zonal representativeness. The immunization program made an evidence-based decisions on the phasing of new vaccine introduction based on the criteria mentioned above and Lessons learned on the phasing of Pentavalent, PCV, and IPV vaccine introductions.

Nigeria plans to introduce the rotavirus vaccine nationwide using a phased approach. This is to sustain our focus on reducing morbidity and mortality from rotavirus associated diarrhoea. Based on the documented best practices and lessons learned with the phased introduction of Penta, PCV, IPV, measles 2nd dose, the country has decided to introduce the rotavirus vaccine using a phased approach. The introduction is planned to be completed in 2 phases: Phase 1 will cover the 19 states of the NC, NE, and NW geopolitical zones and FCT in Quarter 2 2022. (Apr) while phase 2 will cover 17 states in Quarter 4, 2022 (June). The selection of states for phasing is to ensure that states are prioritized for introduction based on prevalence of diarrhoeal disease as reported by the Nigeria Demographic and Health Survey (NDHS, 2018), and cold chain capacity. Contiguous states in zones with high burden states were also selected based on programmatic and logistic consideration. etc. (see annex 2 details).

Figure 11: Rotavirus Phasing Map



S/N	Phase 1 States	Target Population (under 1)
1	Adamawa	182,163
2	Bauchi	346,131
3	Benue	180,936
4	Borno	179,182
5	FCT	100,170
6	Gombe	152,229
7	Jigawa	330,616
8	Kaduna	336,549
9	Kano	545,578
10	Katsina	463,713
11	Kebbi	242,899
12	Kogi	164,879
13	Kwara	134,514
14	Nasarawa	113,993

S/N	Phase 2 States	Target Population (Under 1)
1	Abia	140,775
2	Akwa Ibom	126,990
3	Anambra	180,036
4	Bayelsa	65,674
5	Cross River	102,454
6	Delta	172,013
7	Ebonyi	117,272
8	Edo	145,202
9	Ekiti	108,177
10	Enugu	135,247
11	Imo	161,085
12	Lagos	302,445
13	Ogun	150,078
14	Ondo	148,074

15	Niger	229,447
16	Sokoto	234,625
17	Taraba	128,790
18	Plateau	156,663
19	Yobe	124,985
20	Zamfara	225,628
Total		**4,573,690**

15	Osun	119,990
16	Oyo	233,290
17	Rivers	201,725
Total		**2,610,527**

3.2 Vaccine Choice

The vaccine choice for Rotavirus introduction is three-dose schedule Rotavac vaccine.

Table 4: Rotavirus vaccine preferences and estimated date of introduction

Preferred first ROTAVIRUS VACCINE	**Doses in a Vial**	**VVM type**
Three dose schedule Rotavac vaccine. Monovalent Human – Bovine (116 E) rotavirus vaccine	5 doses	Type 2
Preferred second choice Three dose schedules, Rotavac -5D (liquid)	5 doses	Type 2

Given the new information on product availability and characteristics, the NGI-TAG reviewed all available evidence for all prequalified product types for rotavirus vaccines and recommended Rotavac (frozen), 5 dose vial.

However, following Gavi's feedback on the possibility of the prequalification of the Rotavac, liquid, 5 dose vials in Q2,2021, the country would strongly consider a product switch to Rotavac- liquid vaccine once the product has obtained the WHO prequalification. This vaccine could be well suited for the country's EPI given the storage temperature and the country's cold chain capacity.

Table 5: Available PQS Rotavirus vaccine product profile

Key vaccine features and characteristics	Rotavac vaccine. Monovalent Human – Bovine
Serotype	116 E (G9P11), Monovalent
Manufacturer	Bharat Biotech International
Formulation	Liquid frozen
Presentation	5 dose vial
Administration	Oral 0.5 mL (5 drops)
Schedule	Three dose (at 6, 10 and 14 weeks with Penta)
Cold chain volume Per dose Cold chain volume Per course	4.2 cm^3 12.6 cm^3
Vaccine Vial Monitor	VVM 2
Storage temperature	-20 degrees Celsius up to zonal level +2 to +8 degrees Celsius at LGA level and health facilities
Price	$0.85 per dose $2.55 per course

Nigeria prefers to use the WHO prequalified three-dose schedule human monovalent liquid Rotavirus vaccine (Rotavac). This preference is to take advantage of its reduced cost and overall smaller cold chain volume requirement.

The estimated cost of vaccines to vaccinate infant population of 7,184,217 for the first year of introduction is $18,319,753.35 at $0.85 per dose for the three-dose human monovalent Rotavirus vaccine for a total of 20,552,489 doses at 40% target coverage of the 3rd dose (See Annex 3 for evidence informing 40% coverage).

The presence of a Vaccine Vial Monitor (VVM) on the cap of the 5 – dose –Rotavac vial infers that once the vaccine is opened, must be discarded after six hours or at the end of the session

whichever comes first. The estimated cold chain capacity required to introduce the various Rota vaccine schedule is shown in the table below.

Table 6: Cold chain capacity requirement across all levels

iSC Level	Available Capacity (+ve)	Required capacity including Human Monovalent 3 dose schedule (+ve)	Gap	Plans to bridge gaps
National & Zones	290,269 L	379,179L	88,910L	The National and Zonal stores are being redesigned into a 3-hub system. Currently 3 x 175 m3 WICRs are being procured under the COVAX CCE support from GAVI. This will increase the capacity at national level by 525 m3; thereby bridging the gap. Subsequently the implementation of the Abuja hub will come with additional 6 x 175 m3 WICRs making the total capacity 1,575 m3. Work has commenced in parallel for the Lagos hub with the expected

				capacity of 1,500 m3 increasing the national capacity to 3,075 m3.
State	535,348L	27,501L	No gap cumulatively however there are gaps in 4 four states (Taraba, Jigawa, Benue, Zamfara and Ogun)	Taraba and Jigawa gaps will be closed through UNICEF procurement and a purchase order has been placed, while Zamfara, Benue and Ogun states gap is going to be addressed through the COVAX CCE support platform.
LGA	116,714L	67,048L	No gap	

Positive storage capacity

iSC Level	Available Capacity (-ve)	Required capacity including Human Monovalent 3 dose schedule (-ve)	Gap
National & Zones	104,851L	128,174L	23,323L
State	111,165L	26,041L	No gap
LGA	161,614L	27,752L	No gap

3.4 Updated Immunisation Policy

The national immunisation policy currently updated in 2019 serves as a guide on the provision of free immunisation services to targeted population. Routine immunisation (RI) services are provided at both public and private health facilities. The tables below shows the current routine infant immunisation schedule last revised in 2019 that takes account of future introduction of new vaccines and the current Tetanus diphtheria (Td) immunisation schedule for women of childbearing age

Table 8: Immunisation schedule for children less than 1 year

Minimum Target Age of Child	Type of Vaccine	Dosage	Route of administration	Site
	BCG	0.05ml	Intra dermal	Left Upper Arm
	OPV0	2 drops	Oral	Mouth
At birth	Hep B0 birth	0.5ml	Intra muscular	Antero- lateral aspect of Right thigh
	Pentavalent (DPT, Hep B and Hib) 1	0.5ml	Intramuscular	Antero- lateral aspect of left thigh
	Pnemococcal Conjugate Vaccine 1	0.5ml	Intramuscular	Antero- lateral aspect of Right thigh
	OPV1	2 drops	Oral	Mouth
6 weeks	**Rota 1**	**0.5ml**	**Oral**	**Mouth**
	Pentavalent (DPT, Hep B and Hib) 2	0.5ml	Intramuscular	Antero-lateral aspect of left thigh
	Pnemococcal Conjugate Vaccine 2	0.5ml	Intramuscular	Antero- lateral aspect of Right thigh
	OPV2	2 drops	Oral	Mouth
10 weeks	**Rota 2**	**0.5ml**	**Oral**	**Mouth**
	Pentavalent 3 (DPT, Hep B, and Hib)	0.5ml	Intramuscular	Antero-lateral aspect of left thigh
	Pnemococcal Conjugate Vaccine 3	0.5ml	intra muscular	Antero- lateral aspect of Right thigh
	OPV3	2 drops	Oral	Mouth
	Rota 3	**0.5ml**	**Oral**	**Mouth**
14 weeks	IPV	0.5ml	Intramuscular	Antero- lateral aspect of Right thigh (2.5cm apart from PCV)
6 months	Vitamin A 1st dose	100,000 IU	Oral	Mouth
	Measles 1st dose	0.5ml	Subcutaneous	Left upper arm
9months	Yellow Fever	0.5ml	Subcutaneous	Right upper arm
	Meningitis Vaccine	0.5ml	Intramuscular	Antero- lateral aspect of Left thigh
12 months	Vitamin A 2nd dose	200,000 IU	Oral	Mouth
15 months	Measles 2 dose (MCV2)	0.5ml	Subcutaneous	Left upper arm
9 – 13 years	HPV (to be introduced 2021)	0.5ml	Intramuscular	Deltoid muscle (upper arm)

Table 9: Td immunisation schedule for women of childbearing age

Doses	When to give	Expected duration of protection
Td1	At first contact or as early as possible in pregnancy	None
Td2	At least 4 weeks after Td1	1-3 years
Td3	At least 6 months after Td2 or during subsequent pregnancy within 3 years.	5 years
Td4	At least 1 year after Td3 or during subsequent pregnancy	10 years
Td5	At least 1 year after Td4 or during subsequent pregnancy	All the childbearing years

3.5 Integrated service delivery strategy

In Nigeria, vaccination particularly new vaccine introductions have contributed to strengthening the delivery of Primary Health Care services. New vaccine introduction has been catalytic in attracting funding and high-level commitments to strengthen primary health care. Strategies for improving vaccine access and coverage such as the Reach Every Community (REC), Optimized Integrated Routine Immunisation Sessions (OIRIS), Immunisation Plus Days (IPDs), Local Immunisation Days (LIDs) and Integrated Maternal, Neonatal and Child Health (IMNCH) weeks, all focus on delivering integrated services at the health facility level. These strategies drive community participation, foster community ownership and wider stakeholder engagement in primary healthcare service delivery. Investments in logistics and data management systems during new vaccine introduction have further contributed to strengthening the primary healthcare infrastructure.

The introduction of rotavirus vaccines will be integrated with other planned vaccine introductions (COVID19 vaccine) where feasible and also into existing RMNCH and immunisation programs such as MNCH week, IPDs, SODs, and LIDs. These programs will be utilized as an avenue to reach more children within the target age with rotavirus vaccines and other services to prevent and manage diarrhoea. Aligning with the WHO/UNICEF Integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD) 1, the GoN will strengthen the use of an integrated approach to protecting, preventing and treating of pneumonia and diarrhoea in all health facilities. The NPHCDA will work closely with existing coordination bodies across the maternal and child health program such as WASH, RMNCH + N, CHIPS, family health etc. to strengthen coordination.

Through integrated messaging, communication on Rotavirus vaccine and diarrhoeal intervention strategies will be strengthened. The training of Health Care Workers (HCWs) in preparation for Rotavirus vaccine introduction will be utilized as an opportunity to train/ retrain HCWs on

- Promoting exclusive breastfeeding in the first six months of life
- Vitamin A supplementation
- Hand-washing, sanitation and other key household practices

- Case management including the use of zinc- ORS to prevent dehydration, continued feeding, and treatment services for pneumonia

Nigeria will strengthen integrated outreach and mobile immunisation services and will integrate these outreaches with other PHC services and diarrhoea intervention strategies. During these outreaches, health care workers will educate mothers on basic diarrhoea prevention strategies and management using zinc and ORS.

Barriers to integration and planned mitigating processes are described below:

1. Vertical Program implementation: Implementation of vertical programs in different domains is a barrier to integration.

   Mitigating strategy: Interventions to promote breastfeeding, handwashing and improved water supply and sanitation services, prevention and management of pneumonia and diarrhoea including the introduction of rotavirus vaccines will be implemented mainly at the Primary Health Care Level. Given the improvements in management and coordination of Primary Health Care activities through the State Primary Health Care Boards and the implementation of the PHC under one roof, the effect of vertical program implementation will be minimized. Integration of RI with other PHC services and commodities will be further strengthened.

2. Parallel logistics systems: Parallel logistics management system exist between programs within the PHC at various levels. Supply chain integration across programs is weak.

   Mitigating Strategy: A common logistics system for all health commodities in the country is already in the process. Efforts are in progress through NSCIP to improve logistics for health commodities. NSCIP has been established to effectively and efficiently integrate health product management services in the country.6 zonal hubs have been identified in Lagos, Abuja, Gombe, Imo, Sokoto, and Calabar. Implementation is in 14 states with plans ongoing to scale up to the rest of the country.

4 Resources, costs, financing, and sustainability

The Government of Nigeria with the support of partners and donors funds the immunisation program. Nigeria pays for traditional vaccines (BCG, Hep B, bOPV, Yellow Fever) while new and underused vaccines (Pentavalent, Men A, measles 2nd dose, IPV, PCV) are procured through a co-financing mechanism between government and Gavi. This co-financing mechanism has helped government demonstrate ownership and to be better prepared to fully fund new vaccines. The NSIPSS further outlines Nigeria's commitment to fully fund vaccines culminating in the transition from Gavi co-financing by 2028. 10,897,032

Additional resources have been allocated in the immunisation program through the Basic Health Care Provision Fund (BHCPF). The Private Health Sector Health Alliance is also being engaged to support the immunisation program at various levels. To further guarantee the sustainability of the immunisation program, Nigeria has committed additional 2.7 billion dollars for the implementation of the 10-year NSIPSS plan.

4.1 Estimated costs of Rota vaccine introduction

The Government of Nigeria (GoN) is requesting support from Gavi for three doses of Rotavirus vaccines with country co-financing. The quantity of vaccines and associated costs is as depicted in table 8. The GoN also requests to receive the Vaccine Introduction Grant (VIG) of USD 4,234,993.62 at USD 0.60 per child for the first-year birth cohort. These funds, in addition to leveraging existing resources and partnerships, will be important for rotavirus introduction preparatory activities described in the introduction plan. Note that the total target population and estimated coverage will be reached within 12 months of introduction, and not by the end of the 2021 calendar year.

Table 10: Cost of Rotavirus vaccines required

Requirements	2021 (Phase 1 & Phase 2)
Total infant population for under 1 (surviving infant)	7,184,217
Coverage Target for 3rd dose	40%
Coverage targets for 1st and 2nd doses	50%; 45%
Total number of doses to be administered	5,448,516
Estimated wastage rate	30%
Number of doses required (before buffer)	10,897,032
Buffer (50% of doses)	6,850,830
Total number of doses	20,552,489

Cost per dose	$ 0.85
Government co-financing (at 0.48 USD per dose)	$ 9,957,680.8
Gavi vaccine co-financing (at 0.37USD per dose)	$ 7,551,934.6
Doses Total Cost	**$ 17,469,615.4**

4.2 Financing of vaccine introduction

The government of Nigeria and Gavi will support rotavirus vaccine introduction with additional support from other partners. To ensure a successful introduction and a significant uptake of Rotavirus vaccine post introduction, the following responsibilities are expected from the different tiers of government: -

1. **Federal:** Provision of Rotavirus vaccines and distribution to state stores through the zonal stores. Other support includes coordination of Rota introduction, development of training materials and support for Health Care Worker (HCW) training, surveillance and research.
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 and new vaccines and ensure a successful introduction of Rotavirus vaccines into the EPI program. These efforts will be leveraged to help defray any additional non-vaccine costs for the introduction of the Rotavirus vaccine. The overall trend in the cost of vaccine procurement stratified by source of funding is outlined in figure 11.

Nigeria will require about $2.7 billion between 2018 and 2028 for RI vaccine financing. Of this amount, the country will provide $1.95 billion (78%) through budgets and other sources and request $773.2 million (22%) from Gavi. Post transition (from 2029), the country will require at least $295 million to procure vaccines each year.

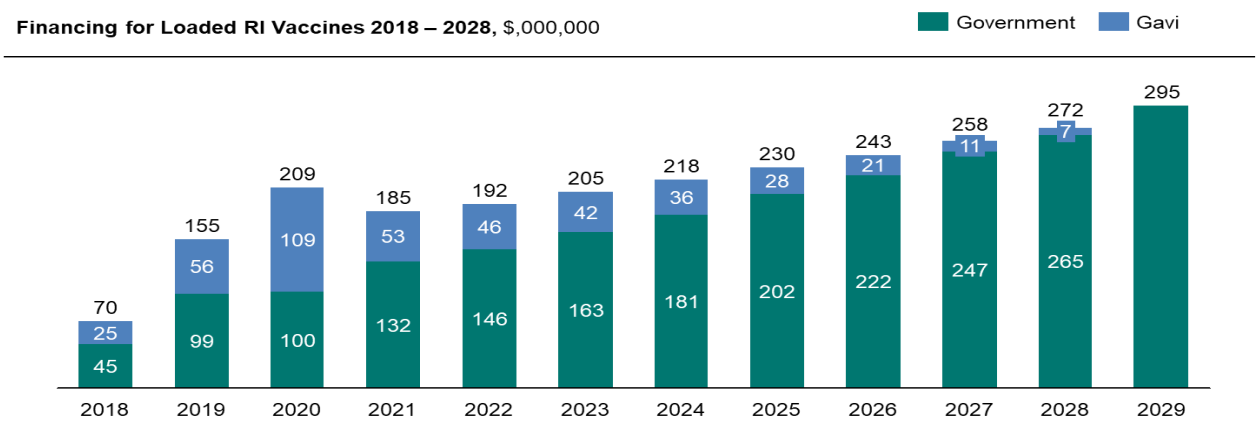


Figure 12: Financing for loaded routine immunisation vaccines 2018 – 2029

However, all other operational activities leading to the rotavirus vaccine introduction like health care workers trainings at national, state, LGA and ward levels, ACSM activities as well as monitoring and supervision will be solely funded through the GAVI vaccines Introduction Grant. Thus, there won't be need for any additional counterpart funding from the Federal or state Governments.

4.3 Cost-effectiveness

While there are no specific cost-effectiveness studies for rotavirus vaccines in Nigeria, rotavirus vaccine has shown to be lifesaving and cost-effective public health intervention in Africa and other high-mortality regions. In Ethiopia, the introduction of rotavirus vaccines is estimated to save 3,700 lives and US$800,000 in household expenditures annually.[27] Similarly, in Ghana, rotavirus vaccines are predicted to save 1,554 lives and 53% of rotavirus treatment costs. [28] If Rotavirus vaccine is used in all Gavi-eligible countries; rotavirus vaccines could prevent an estimated 180,000 deaths and avert 6 million clinic and hospital visits each year, thereby saving US$68 million annually in treatment costs. [29]

[27] Verguet S, Murphy S, Anderson B, et al. Public finance of rotavirus vaccination in India and Ethiopia: An extended cost-effectiveness analysis. Vaccine. 2013.

[28] Abbott C, Tiede B, Armah G, and Mahmoud A. Evaluation of cost-effectiveness live oral pentavalent reassortant rotavirus vaccine introduction in Ghana. Vaccine. 2012;30:2582–2587.

[29] Atherly DE, Lewis KDC, Tate J, Parashar UD, Rheingans, RD. Projected health and economic impact of rotavirus vaccination in GAVI-eligible countries: 2011- 2030. Vaccine. 2012;30 (Suppl 1):A7–A14).

Accelerating access to rotavirus vaccines will not only save the lives of African children but also lessen the tremendous economic and health burden of rotavirus disease, thereby contributing to poverty reduction and economic growth. Gavi and its partners planned to support the introduction of lifesaving rotavirus vaccines in more than 30 of the world's poorest countries by 2015. In country analysis shows that the cost of treating for a Nigerian child for Rotavirus Diarrhoea diseases is 250% of the cost of vaccinating with Rotavirus vaccines[30].

5. Strategies and activities for the vaccine introduction

In order to achieve the goals, objectives, and targets of the rotavirus vaccine introduction, the following key strategies will be implemented while the specific activities to implement these strategies are outlined in the Rotavirus vaccine introduction work plan.

5.1 Coordinating structures

The New Vaccine Strategy Task Team (NVSTT) is responsible for coordinating new vaccine introductions including the Rotavirus vaccine introduction. The NVSTT provides technical feedback on new vaccine introduction to the NERICC. It consists of technical experts from government and partners who meet regularly to design and guide the implementation of strategies for new vaccine introduction.

Immunisation operation rooms, situated at the NPHCDA and SPHCDAs are responsible for providing reports on the status of preparedness at all levels as per the chronogram. It serves as an information hub providing evidence in states to inform the SPHCDAs RI team and partners on progress and bottlenecks for appropriate and timely interventions. The introduction of rotavirus vaccine, in Nigeria will utilize these structures and collaborate with multiple stakeholders to ensure more effective introduction with greater efficiency in all states.

The NERICC/SERICC TWG is responsible for coordinating all routine immunisation activities at the national and sub-national levels. The NERICC/SERICC meet daily to deliberate on all issues related to specific activities requiring attention and report to the ICC. Other technical working groups such as RIWG, NLWG/SLWG, SMWG, FWG, MEWG meet on a routine basis to discuss immunisation related issues per ToR. These technical working groups will be instrumental to ensure a successful rollout of Rotavirus vaccine introduction across all states. The introduction of rotavirus vaccine in Nigeria will utilize these structures and enhance this partnership in ensuring a more effective introduction with greater efficiency and minimize bottlenecks. This impact and investment in the health system will further strengthen routine immunisation performance thereby contributing to an increase in overall coverage of RI antigens nationwide.

[30] CHAI analysis- Cost benefit of PCV and Rotavirus vaccine introductions

5.1.1 Licensure and procurement procedure

The choice of the Rotavirus vaccine to be introduced in Nigeria is the liquid Rotavac and is prequalified by WHO.

Rotavac vaccine is licensed in the country along with other rotavirus products GlaxoSmithKline Biologicals (Rotarix™) and Merck (Rotateq™) which are in use in the private sector. Once a product is registered in the country, no specific local customs regulations, requirements for pre-delivery inspection, or special documentation requirements are required whereas vaccines with waivers undergo pre-delivery inspection by the National Agency for Food and Drugs Administration and Control (NAFDAC). NAFDAC also makes provision for a waiver to be granted for the importation of WHO prequalified vaccines, which is the current practice for many prequalified vaccines in the Nigerian EPI.

5.1.2 Shipping and distribution

All vaccines for the country are purchased through UNICEF. The detailed procurement procedure is in line with the existing SOPs. The vaccines come in by airfreight and at the point of entry, the vaccines are cleared through customs using standing waiver for vaccines which exempt it from duty fees. However, clearing cost is collected at specific rates appropriate for the volume. This is difficult to determine but programmatically 3-5% of vaccine cost suffices.

Rotavirus vaccines, along with other routine vaccines will be received in 4 shipments per annum at the National Cold Stores and distributed to the zonal and state stores every quarter for onward distribution and further to the LGA stores every month. The LGA stores will supply the health facilities week as stipulated by the Standard Operating Procedures.

Presently, at the national level, vaccines are transported by trucks using cold boxes and ice packs from the National Strategic Cold Store (NSCS) to the six zonal stores nationwide which are part of the national cold store. In addition, third-party transport providers are routinely contracted to distribute vaccines and dry materials, especially during campaigns when large volumes are involved. A combination of push and pull vaccine distribution systems are currently in operation to distribute vaccines and dry materials from states to LGA levels on a monthly basis using program vehicles, and other means of transportation. The health facilities collect vaccines on scheduled immunisation days using either cold boxes or Giostyle vaccine carriers where storage facilities are not available at the Health Facility. In Health Facilities with cold storage capacity, vaccines are collected on a monthly basis and stored for use during sessions. Most Health Facilities use motorcycles for vaccines collection and in some case bicycles are also used.

The country is also moving towards streamlining Vaccine supply chain architecture by transitioning to the 3-hub structure at National level (Abuja, Kano and Lagos). These hubs once instituted will now receive vaccine shipments from outside the country and deliver directly to the states. The state stores further reduce vaccine transition time by delivering vaccines directly to one cold chain equipped health facility per ward. Other health facilities will receive their vaccines from this designated ward health facility. This initiative further strengthens cold chain storage and distribution reducing transit time for vaccines and resources required to operate the current zonal

and LGA cold stores. The rotavirus vaccine introduction will leverage on the improved efficiency of this Vaccine supply chain system. Inversely, the investments in the Routine Immunisation system with the rotavirus introduction will also contribute in improving and strengthening this supply chain system.

5.2 Cold chain, logistics and vaccine management

5.2.1 Current cold chain capacity at different levels

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. 34,173 (22,850 public and 11,323 private hospitals) health facilities provide routine immunisation services. The NSCS and the zonal cold stores constitute the national level cold storage capacity which operates as a single entity.[31]

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 10). These zonal stores which are part of the national strategic cold store, provide the total nationally available cold storage capacity of 290,269 Litres positive storage and 104,851 Litres negative storage. Vaccines and dry materials are distributed to the thirty-six States and the Federal Capital Territory from the zonal stores, coordinated by the NSCS. The routine immunisation buffer stock (3 months 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 are integrated with the NSCS and distribution to state stores occurs quarterly based on state requests determined by current stock levels in state stores. 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.

Table 12: Cold chain capacity of national level stores

Level	Available Net storage Litres (+2°C to +8°C)	Available Net storage Litres (-15°C to -25°C)
NSCS, Abuja	90,268	28,871
SW Zone, Lagos	84,286	7,407
NC Zone, Minna	31,429	11,429

[31] Cold chain capacity assessment, 2018

SS Zone, Warri	31,429	11,429
NE Zone, Bauchi	15,714	17,143
SE Zone, Enugu	25,714	17,143
NW Zone, Kano	11,429	11429
TOTAL	**290,269**	**104,851**

Some of the negative storage is flexible in the sense that it can be converted to positive storage anytime the need arises.

State Cold Stores:

Each State and the Federal Capital Territory (FCT), Abuja in Nigeria has a functional cold store which is run and maintained by the State. The cumulative total functional capacity of the cold chain system in all 36 states and FCT is 482,927 and 110,492 Litres for positive and negative volumes respectively. [32]

LGA Cold Stores:

All 774 LGAs have cold chain stores. LGAs are typically equipped with electric refrigerators, deep freezers and solar refrigerators. Frequent power outage is a major challenge and the LGAs have back-up electric power generators to provide energy during a power outage.

Health Facility Level:

Government policy specifies that at least 1 HF in each of the 9,572 political wards nationwide must be fully equipped to provide regular routine immunisation services. As of 2015, 47% of wards had at least one health facility equipped with a refrigerator. This was after the installation of 1,656 solar direct drive refrigerators.

Table 13: Storage Capacities compared to needs

	National	States	LGAs	HFs
Target population	8,036,746	8,036,746	8,036,746	8,036,746
Frequency of shipments/annum	4	4	12	26
Positive Storage Space available (L) as at May, 2021	290,269	535,348	-	-

[32] Cold chain inventory, 2018

2023 Planned cold chain expansion- positive storage	519,000	4,632	149,556	187,150
Total capacity anticipated from now till 2023 is given in the next few rows…. Initial support phase Priority 1 70L TCW 2043 No of equipment 303	-	-	-	21,210
Initial support phase (102L) VC150 SDD No of equip 1154	-	-	115,400	-
Initial support phase Priority 3 (70L) TCW2043 No of equip 153	-	-	-	10,710
Initial support phase Priority 4 (70L) TCW2043 No of equip 36	-	-	-	2,520
Secondary TCW40 SDD (36L) No of equipment 96	-	-	3456	-
Secondary TCW2043 (70L) SDD No of equipment 10	-	-	700	-
Tertiary VC225 (122) No of equipment 38	-	4632	-	-
175 cubic m cold house at NSCS (GAVI HSS 2)	519,000	-	-	-
Scale up phase to equip additional PHC in compliance with reaching every child 472 TCW 2043	-	-	-	33,040
Replacement of cold chain Equipment that will be greater than ten years at HFS and LGAs 2827	-	-	-	101772
Replacement of CCE that will be greater than 10 years at additional HFS TCW40 (36) 443 VC150 SDD (102L) 9 TCW2043 (70) 15	-	-	-	15,948 900 1,050

To meet new vaccine introduction requirement at LGA stores VC225llll 300 (100L)	-	-	30,000	-
Installation of yet-to-be installed CCEs	-	5,792	1,242	5770

Figure 13: Cold Chain Storage capacity; There is adequate storage capacity for RI and Rotavirus vaccine introduction in Nigeria. There is adequate storage capacity to accommodate the planned introduction of new vaccines including rotavirus vaccine for routine immunization at the National level in 2021. At the State, LGA and health facility levels, the general outlook is that adequate capacity is available for new vaccines introduction in 2021. Deployment of cold chain under CCEOP will further enhance the storage capacity. Where capacity may be inadequate due to unforeseen events for example, breakdowns. Supply chain characteristics will be revised for these States to accommodate the new vaccines.

Strategies that will be employed include increasing the frequency of supplies to these states and LGAs based on available capacity and use the zonal cold stores or state stores as reserve depots. This will ensure that the vaccines are available in close proximity to these states or LGAs with inadequate capacities. Additional measures will be using available negative storage capacities for the storage of lyophilized vaccines.

CCEOP

The ongoing cold chain expansion through the CCEOP will provide additional positive cold chain storage capacity at national, state and LGA/Ward levels, respectively. So far, first tranche of CCEOP was deployed and installed and second tranche of phase 1 CCEOP (6,395 CCEs) were deployed to the states and installation is ongoing with 6,899 units in-country and being installed.

In addition to the above the ongoing COVID-19 vaccine introduction has provided another opportunity to synergize efforts and states were tasked to review their cold chain system as a prerequisite for the COVID-19 vaccine deployment to the state. This activity was prioritized by the states and all the 36 states and FCT were able to fix any major challenge/gap in CCE. This is especially pronounced at the state level. Some of the states that make major changes include Adamawa, Cross River, Edo and Kogi states. At the national level ultra-cold chain system (UCCS) was procured and installed and at the state level the government of Bauchi state was able to procured and installed UCCS in preparation for the COVID-19 vaccine introduction.

Efforts at improving the cold chain maintenance culture are currently ongoing. The development of SOPs, total cost of ownership approach in procurement and a planned preventive maintenance manual are some of the ongoing activities in this regard. Provision of funds for guaranteed cold chain equipment maintenance contracts has been made through GAVI HSS.

Table 14: Post-2022 Cold Chain Storage Capacity Projection (L)

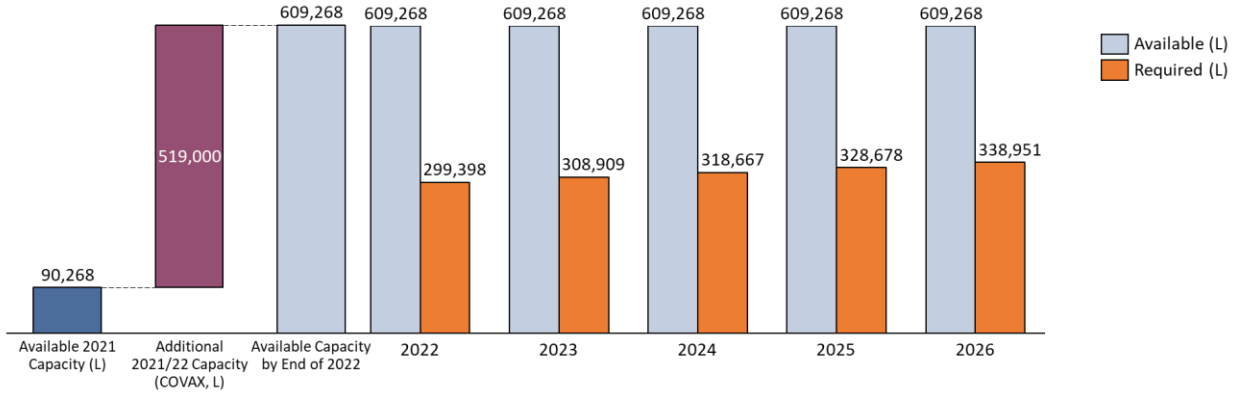


Table 14 shows the incremental capacity that will be added at the National Strategic Cold Store (NSCS) through the initial COVAX support of three 175 cubic meter Walk-In Cold Rooms in 2021/2022. This initial installation will add a total of 519,000L to the national store's capacity which will bring us up to 609,268L by 2022 when all the installations would have been concluded. The table above also shows that the 609,268L is sufficient to meet our projected national level requirements of 299,398L, 308,909L, 328,678L and 338,951L respectively required for 2022 to 2026.

However, pending the arrival and subsequent installations of these initial COVAX WICRs in 2021, the zonal stores (who are also part of the national structure) will be leveraged to transduck shipments that will be followed by immediate distribution to states.

5.2.2 Current vaccine stock management systems

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, LGA and health facility levels. In addition, the vaccine management tools (VM tools) are used to record vaccine movement between the LGA and the HFs. The DHIS2 is a platform for monitoring vaccine utilization at the LGA and health facility levels. Stores requisition, issue and receipt vouchers are used for documenting movement of vaccines and other immunisation supplies.

Other tools used include the monthly stock balance reporting forms which track vaccine balances at the state level including temperature of vaccines within the month. The DHIS 2 also reports vaccines received, used and balance from the LGA. 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 DHIS 2 along with the immunisation coverage data for the month.

5.3 Training and supervision

Training of health workers (HWs) and supportive supervision across all levels of the immunisation program is a top priority in Nigeria.[33] The introduction of Rotavirus vaccine offers an opportunity to close capacity gaps amongst health workers and EPI managers. The training process will leverage lessons learned during the pentavalent, PCV and IPV introduction training. One overarching objective of NSIPSS is to strengthen EPI and PHC workforce. The NERICC and Technical Support Unit (TSU) are currently implementing various capacity building approach such as OIRIS, Peer-led learning, leadership development academy (LDA) and Growing Expertise E-health Knowledge and Skills (GEEKS).

The NPHCDA will work with SPHCDAs and partners to ensure at least 2 HCWs are trained per facility on Rotavirus vaccines administration, vaccine management, exclusive breastfeeding, preparation/administration of ORS, administration of zinc as part of the holistic approach in line with GAPPD.

The Rotavirus vaccine introduction training will be leveraged to train HCWs on other PHC services. This will include the following:

- Vaccine administration and injection safety requirements
- Vaccine management and ensuring only potent vaccines are issued

- Vaccines accountability and multi-dose vial policy
- Identification, management, and reporting of Adverse Events Following Immunisation (AEFI) with Rotavirus vaccines
- Diarrhea prevention and PHC interventions
- Data monitoring and reporting
- Advocacy, communication, and social mobilisation
- COVID-19 IPC and COVID-19 vaccine introduction refresher modules

Approaches to training with regard to Rotavirus vaccine introduction such as practical demonstrations, role-play, hands-on, reading comprehension, video-learning and other innovative adult learning mentoring techniques such as on-the-job mentoring, peer to peer learning will be incorporated if COVID-19 cases drop significantly. The current situation regarding the COVID-19 pandemic has transformed learning approaches across the EPI and PHC as a whole. Through virtual means, the team can pull off training HCWs on Rotavirus vaccine introduction effectively. 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 interpersonal communication as a key vaccinator skill.

[33] NSIPSS 2018-2028

The Rotavirus vaccine introduction training will be conducted in synergy with other ongoing or future health worker capacity building efforts. The planned refresher training for COVID-19 vaccines roll-out (phases 2-4) and IPV2 introduction will be leveraged to commence the sensitization on Rotavirus vaccines and strengthen capacity of health care workers on general vaccines handling, administration and management.

Training materials:

A technical and an operational manual that covers policy, scientific, and operational aspects related to the introduction of Rotavirus vaccine; a handbook for HWs; FAQs and fact sheets, case-studies on introduction experience from other settings; training videos; and posters. *Technical assistance from partners will be required* with preparations of training videos and message development.

Continuous Education on Routine Immunisation:

The NPHCDA and partners are supporting state governments to implement monthly continuous education on RI service delivery and vaccine management in health facilities. This occurs 30-60 minutes before routine immunisation sessions to strengthen key messages around vaccine management and immunisation best practices at the provider levels. These peer-led learning sessions. The 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.

The conduct of supportive supervision during Rotavirus Introduction will reinforce the messages provided during the training to health workers. Emphasis will be on skill improvement for the staff to ensure the provision of quality services, assessment of the performance and provision of feedback including on-the-job mentoring, while ensuring all COVID-19 IPC measures are in place and strictly adhered to. Each supervisory team is expected to carry out a debriefing to facility staff at the end of each visit. The national level should undertake supervision at least once every month, states twice a month and LGAs three times a month. The supervisory visits will include a review of the monitoring data, social mobilization, logistics, stock management, and vaccine handling practices at the healthcare center.

6 Monitoring and evaluation

6.1 Data management

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. This section provides a broad overview of plans for monitoring and evaluation in the context of the Rotavirus vaccine introduction. As with other new vaccines that are introduced, the GoN emphasizes the need to evaluate administrative data to document trends in accountability indicators of routine immunisation. Identifying other indicators relevant to the Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea (GAPPD), it will be necessary to

demonstrate the progress being achieved in this direction. These indicators such as number of diarrhoeal cases per thousand live births will form a core part of reporting rotavirus vaccine introduction progress. Other key predictors of RI strengthening will be important through a combination of evaluation designs such as surveys of caregivers, health workers, immunisation managers, and key informants; ecologic evaluations of environment; 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 immunisation coverage.

6.1.1 Plans for updating monitoring tools

During previous vaccine introductions, the NPHCDA and Partners updated the immunisation forms, vaccination cards, electronic databases used for recording and reporting vaccine administration, forms for ordering vaccines, vaccine stock ledgers, and any other forms that list the national immunisation program vaccines to include rotavirus vaccine. These includes:

- Child immunisation registers
- Child health cards
- Tally sheets
- Summary sheets
- Stock ledgers
- Vaccine Management Tools
- Web-based databases e.g. DHIS 2

The National level will print and distribute all the available data tools to the States, LGAs and health facilities. The main recording tools that are used for immunisation-related activities have been adapted to include the Rotavirus vaccine as follows.

- Immunisation or child health card: The Rotavirus vaccine dose would be recorded on the child's health card, which is kept with the child to report their vaccination status, and other information such as growth monitoring. The updated card will clearly indicate the clinic **where the Rotavirus vaccine dose was received,** and the **date of administration** would be entered. If a child already has an older card without space for recording Rotavirus vaccine administration, the information would be transferred to a new and updated card.
- Tally sheet: Tally sheets are used to record children vaccinated during an immunisation session. Data from the tally sheet is summarized into the monthly summary form.

- Immunisation Register: a column for Rotavirus vaccine has been provided for recording the date when the Rotavirus vaccine is administered, alongside all other vaccines at the same contact.

- Vaccine Stock ledger: Accurate vaccine forecasting, and ordering depend on knowing the quantity of vaccines in stock at all times. The ledger has also been updated to include Rotavirus vaccine.

- Vaccine Management forms (VM1a &1b, VM monthly summary) These forms have been updated to capture data on Rota vaccine and devices utilization.

Monitoring the introduction of the Rotavirus vaccine 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 ROTAVIRUS VACCINE immunisation plan to identify achievements and gaps that need to be addressed. These core indicators will include:

    - Rotavirus vaccine doses administered in relation to the target population under 1
    - Vaccine stock management & wastage
    - Rota vaccine dropout rates

Evaluation of Rotavirus vaccine introduction will be based on monitoring vaccine coverage and other indicators of successful introduction activities (e.g vaccine stock-outs, wastage) and not only on disease burden.

6.2 Impact and safety monitoring

6.2.1 Adverse Events Following Immunisation (AEFI) monitoring

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

The following developments have so far been recorded in AEFI surveillance in the country during the introduction of new vaccines (pentavalent vaccine, PCV, MenAfriVac and MCV2 vaccines) since 2012.

- A national expert committee on AEFI case review and causality assessment was inaugurated with the commencement of MenAfriVac campaigns in 2011.
- The committee was strengthened during the pentavalent vaccine introductions and the MenAfriVac campaigns in 2012, 2013 and 2014. The Expert Committee is responsible for causality assessments of all reported AEFIs and has been actively carrying out causality assessments regularly, especially after mass campaigns.
- State AEFI committees were established, trained and reoriented on advanced concepts on AEFI and the principles of causality assessments from 2012 to 2014.

The AEFI surveillance guidelines were reviewed in 2019, in line with recent global advances in AEFI surveillance. National AEFI training was conducted in 2019. Currently, States are cascading training to the health facilities.

According to the national AEFI policy, the following events should be reported immediately by the health worker:

1. Serious AEFI (i.e., an 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 immunisation error.
4. Significant events of unexplained cause occurring with 30 days after 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 (for injectable vaccines)

Additionally, a surveillance mechanism will be established to determine the zero rate for intussusception (IS) and monitor post introduction. This is to make sure that cases are reported promptly to help identify any signal and also to assist management of any community or media misinterpretation of IS cases that will occur, irrespective of rotavirus vaccination. AEFI surveillance cascade training will be integrated with the rotavirus introduction training at the National, State and LGA levels. This training shall be supported by the National and State EPI program officers at all levels. At the lowest levels frontline health facility workers shall be trained.

The detection, reporting, investigation, and management of AEFIs shall be carried out by caregivers, vaccinators, State AEFI team/National AEFI team and the health facility workers as found in the AEFI surveillance guidelines.

Although serious AEFI caused by Rotavirus vaccine are extremely rare, the coincidental occurrence of a serious AEFI and sensational media coverage may seriously undermine immunisation 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 National AEFI 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, information, 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;
- Having an AEFI action plan with specific roles for immunisation program partners.

Real-time data on the rotavirus introduction indicators e.g., coverage, quantity of vaccine used, wastages etc. will be available on the DHIS2 platform.

6.2.2 Impact and safety monitoring

Impact:

Post licensure impact of rotavirus is important to monitor because this is an oral vaccine and several factors may adversely affect vaccine performance. In addition, the benefits data have been proven to be successful in appropriately evaluating risk: benefit ratios in the occurrence of any emerging adverse event information post-vaccination. This section outlines evaluations to assess the impact of the introduction of rotavirus vaccines in Nigeria, one of the countries with the highest rotavirus morbidity and mortality worldwide that will include the vaccine into the routine childhood immunisation program. Demonstrating impact of the vaccine through its routine use in the public sector will provide essential information to the GoN to assess the potential health benefits of vaccination. In addition, these data will have relevance to the global community, as it will demonstrate potential impact of introduction of rotavirus vaccines in the national immunisation program.

We propose a program evaluation to assess the impact of the rotavirus vaccine introduction in Nigeria, which will include assessing vaccine effectiveness through a case-control assessment,

monitoring diarrhea and rotavirus disease trends in terms of hospitalizations and deaths, and monitoring strains after the introduction of vaccine. Active surveillance sites will provide cases of severe rotavirus disease to use in vaccine effectiveness studies using a case-control methodology. Potential uses of the program evaluation findings include:

(1) ensuring optimal effectiveness of rotavirus vaccines among children of Nigeria.

(2) making evidence-based decisions about implementing rotavirus vaccines into routine immunisation schedules in other middle and low-income countries.

(3) advocacy for further resources to introduce rotavirus vaccines in countries with the highest disease burden.

(4) identifying barriers that might affect the performance of rotavirus vaccines in a real-world setting. Local systems will be strengthened to enable the accurate identification of cases in a timely way at all levels of healthcare and appropriate treatment options.

Monitoring of diarrhoea hospitalization/mortality trends:

One aspect of impact monitoring will include analysis of all-cause diarrhoea deaths and hospitalization, among children <5 years before and after the introduction of the rotavirus vaccine in Nigeria. NPHCDA is identifying existing sources of national data for all-cause diarrhoea deaths and hospitalizations in children < 5 years to describe the epidemiology of rotavirus diarrhoea in Nigeria. These data will be utilized to assess impact and the analysis will include comparison of all diarrhoea visits data by month, stratified by age. Rotavirus testing data is unlikely to be widely available and thus the analysis will rely on modeling and reductions in incidence by age (<1 during the first year after introduction) and season (peak diarrhoea season in Nigeria is December–March) to assess impact. Vaccine coverage will be ascertained using NPHCDA survey and administrative EPI data.

Nigeria also has established active surveillance of rotavirus gastroenteritis in children <5 years of age in a few sentinel hospitals in Southeast, Northcentral Northeast and Northwest Nigeria. This active surveillance program is crucial to a vaccine program evaluation as it provides robust baseline data on severe rotavirus gastroenteritis and is an excellent platform for specialized epidemiologic studies to assess vaccine effectiveness and safety. With a demographic surveillance site in place, population-based data will be obtained. Surveillance coordinators at these sites will employ a standardized surveillance protocol that follows WHO guidelines. The GoN proposes enhancing active surveillance to other sentinel hospitals and initiating a case-control assessment after vaccine introduction, to implement this proposed program evaluation. The project proposed below will revolve around the surveillance efforts at sentinel sites.

6.2.3 Post Introduction Evaluations

In addition to the impact and safety evaluations described above, the NPHCDA will conduct a post-introduction evaluation 6 months after the introduction of rotavirus vaccine in order to assess and document lessons learned for improvement of strategies to improve vaccine uptake.

7. Advocacy, communications, and social mobilization (ACSM)

The development and implementation of a robust national and sub-national ACSM plan is an important component of the Rotavirus Introduction. The plan targets different audiences including partners, stakeholders, communities, and caregivers through a multiphase multichannel communication platform.

The ACSM plan and subsequent activities, materials, and messages will be most effective if they are informed by a desk review and subsequent study of the public's awareness, knowledge, attitudes, beliefs, and practices (AKABP) about rotavirus disease, rotavirus vaccine, and immunisation in general. AKABP studies can range from a series of focus group discussions to more involved community and household surveys. The SEM (socio-ecological model) will inform audience segmentation, social change and behavior change communication. The target audiences will include different groups, including community and opinion leaders, teachers, health workers, and parents/caregivers. The desk review and AKAPB study can identify gaps in the public's knowledge and attitudes about diarrhoea, misperceptions and concerns about receiving rotavirus vaccine, and other factors that may affect the public's acceptance and thus uptake of the vaccine, such as the influence of anti-vaccination publicity.

The Specific objectives of ACSM activities include:

i. To raise awareness on diarrhea and create demand for Rotavirus vaccine.
ii. To prevent rumors and misinformation (intussusception, porcine viral contaminations)
iii. To foster trust through securing relevant stakeholders buy-in for the vaccine uptake
iv. To create a positive attitudinal change towards immunisation service.
v. To improve interpersonal communication between health workers and caregivers.
vi. To improve crisis communication skills for health workers.
vii. To enhance the detection and reporting of potential AEFI
viii. To build strong community support and ownership for the immunisation and PHC program

The following strategies will be implemented at different stages during the Rotavirus Vaccine Introduction.

7.1 Pre-implementation Stage:

1. Conduct desk review on effective ACSM strategies for diarrhoeal diseases, other vaccine introductions and Rotavirus vaccine introduction.
2. Conduct rapid information needs assessment (AKABP study) for evidence based ACSM interventions and validation with key stakeholders.
3. Develop evidence based ASCM strategy, M&E plan, implementation plan for Rotavirus Vaccine introduction.
4. Development, printing, and distribution of evidence-based IEC-SBCC materials

5. Validation of ACSM strategy, plan, and dissemination to key stakeholders.
6. Organize three-day planning meeting with SHEOs (State Health Educator Officers) on Rotavirus introduction at the National level

    - Engagement of traditional and religious leaders
    - Workshops with members of scientific and professional organizations
    - Selecting and leveraging potential advocates for training (pediatricians, surgeons, researchers, civil society)—providing them advocacy, communications, and media relations training.
    - Engagement of civil societies, non-governmental organizations, CBOs and FBOs

7. Media engagement (radio and TV) and social media engagement
8. High-level Advocacy, Social mobilization and Partnership engagement

NB: Engagement meetings will be conducted both at National and State levels.

7.2 Implementation Stage:

Communication and Social Mobilization activities

- Advocacy visits to various stakeholders
- Implementation monitoring through clusters.
- Town Announcements
- H2H Mobilization
- Announcements in Religious Houses

Media Engagement and Community Mobilization and Education

- Organize special health features radio, television programs.
- Organize phone-in radio/television programs.
- Engage Social Media Influencers to Promote messages
- Hold a town hall meeting with community Leaders and WDC chairmen on the importance of the vaccine.
- Media monitoring
- Organize press conferences for vaccine introduction.
- Organize crisis information management workshop for commissioners of health and state spokespersons.
- Production of media kits
- Organize media orientation workshop for program managers and correspondence.
- Hold a media roundtable discussion on Rotavirus vaccine introduction.

Tracking and Monitoring

- Tracking the availability and use of IEC materials at all levels.

7.3 Post Implementation Stage

- Documentation of ACSM processes and lessons learned.
- Knowledge management activities including Spot Checks to test vaccine acceptance and knowledge, publications.
- Media field visit to cover post-introduction activities.
- Documentary on the Rota Virus vaccine.

7.4 Activities to reach zero dose children during Rotavirus vaccine introduction

- Analyze and quantify the available data (from RI LQAS, MICS-NICS) to map out reasons for zero dose children.
- Identify existing sources of RI information for caregivers and those who influence the decision of caregivers on whether to vaccinate children or not.
- Based on the analysis of available data on zero dose, develop key messages targeted at improving uptake of routine vaccines
- Leverage other diarrheal intervention programs to reduce the missed opportunity vaccination (M.O.V).
- Conduct targeted engagement of identified influencers of vaccine uptake such as religious leaders, community influencers, NGOs, FBOs (FOMWAN, Christian denominations) and CSOs using the result of analysis on zero dose mapping, and reasons for poor uptake, to ensure their buy-in
- Update materials on training HCWs and community mobilizers
- Translate key messages into the major local languages (Hausa, Igbo, Yoruba)
- Incorporate key messages into existing print communication channels such as IEC materials and FAQs on zero dose.
- Incorporate key messages into broadcast media such as radio jingles, tv programs
- Incorporate key messages into telecommunication channels through ring back tunes
- Launch (flag-off) introduction of rotavirus vaccine ACSM activities in rural communities with high burden of zero dose children.

Considering the fact that Penta and PCV vaccines are administered at the same time, the strategies itemized above to address zero dose will invariably improve PCV uptake. Given that rotavirus has been introduced as a routine vaccine, other RI vaccines will be administered during the introduction.

7.4 Synergy with other current or future ACSM activities

The ACSM activities for the Rota vaccine roll-out will be conducted in synergy with the routine. demand generation activities currently ongoing at the subnational level (state, LGA and ward) as well as those implemented as part of new vaccines introduction.

The demand generation activities (Advocacy, Communication, and social mobilization) being implemented as part of the ongoing COVID-19 vaccines roll-out and those planned for the IPV2 introduction will be leveraged to raise public awareness, foster trust, and create positive attitude towards immunization services. Thus, the ASCM activities for the Rota vaccine introduction will be tailored to focus on identified demand gaps (not addressed by both routine and new vaccines. introduction ACSM strategies) from a AKABP study.

7.5 Routine Immunization Intensification Activities

Period of Intensification of Routine Immunization activities following introduction of Rota vaccine

The GoN also proposes a period of routine intensification activities to increase number of vaccinated children. This would be planned for a week after the launch of Rota vaccine in selected local government areas across implementing states. This opportunity would be leveraged to continue tracking, identification and vaccination of all eligible children age of 0-23 months including zero dose children for the first, second and third dose of rota vaccine and other RI antigens. As part of the activities, caregivers, parents and immunization stakeholders would be sensitized on the need to ensure that their children receive the three doses of the vaccines. In addition, supportive supervision, monitoring and ACSM activities would be intensified to ensure the successful introduction of the vaccine across all levels.

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8 Annexes:

Annex 1: Lives saved

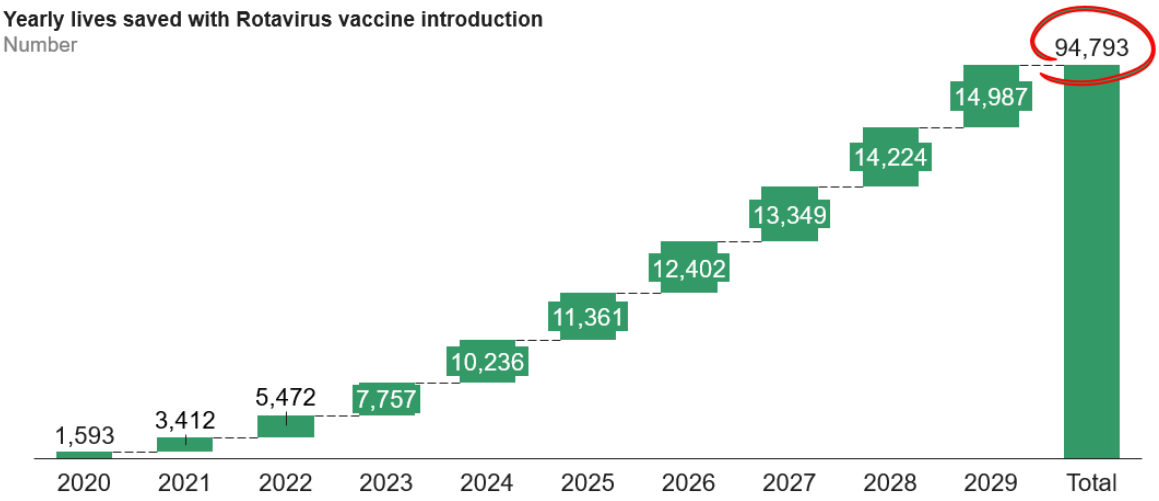

Figure 14: Additional Lives saved from Rotavirus Vaccination.

Annex 2: Phasing plan

Geopolitical Zone	State	No of LGA	State Target Population (2019)	Annual Rotavirus vaccine requirement (in doses)	Sufficient Cold chain capacity at state level for quarterly RI+PCV+IPV+ROTA shipment (Based on installed capacities)	Penta 3 covergae	% children under 5 who had diarrhoea in the 2 wks preceeding NDHS 2018 survey	Sufficient Cold chain capacity at state level for quarterly RI+PCV+IPV+ROTA shipment (Based on installed capacities)	% children under 5 who had diarrhoea in the 2 wks preceeding NDHS 2018 survey	Total score (Max score = 5	Percentage ranking
Data Source			Operational Population Figures 2018-2021: Projection figures 2020=1	NSIPSS projections	CCEOP and Cold Chain inventory	2018 NHDS	2018 NDHS	Scoring 1 (insufficient capacity) 2 (sufficient capacity)	Scoring: 3 (Diarrhoea incidence under >20% 2 (diarrhoea incidence over 10-20% 1 (diarrhoea incidence between 0-10%		
NC	FCT	6	100,399	748,206	yes	74.0%	8.2	2	1	3	60.0%
	Kwara	16	143,459	373,281	yes	55.0%	8.3	2	1	3	60.0%
	Plateau	17	136,833	481,805	yes	72.0%	13.3	2	2	4	80.0%
	Niger	25	261,390	116,062	No	39.0%	16.3	1	2	3	60.0%
	Nasarawa	13	101,886	293,336	yes	60.0%	5.7	2	1	3	60.0%
	Kogi	21	231,586	516,133	yes	56.0%	6.7	2	1	3	60.0%
	Benue	23	196,663	664,236	Yes	59.0%	11.2	2	2	4	80.0%
NE	Adamawa	21	112,798	492,486	Yes	66.0%	10.7	2	2	4	80.0%
	Bauchi	20	383,865	83,531	Yes	32.0%	34.1	2	3	5	100.0%
	Gombe	11	186,715	67,440	yes	26.0%	35	2	3	5	100.0%
	Taraba	16	203,670	40,993	YeSs	42.0%	23.1	2	3	5	100.0%
	Yobe	17	143,591	19,496	yes	29.0%	33.4	2	3	5	100.0%
	Borno	27	144,916	687,296	yes	36.0%	8.9	2	1	3	60.0%
NW	Jigawa	27	201,512	33,861	No	36.0%	19.1	2	2	4	80.0%
	Kaduna	23	637,536	169,482	yes	32.0%	11.8	2	2	4	80.0%
	Kano	44	742,842	177,405	yes	46.0%	17.7	2	2	4	80.0%
	Kebbi	21	154,559	59,705	yes	11.0%	9.6	2	1	3	60.0%
	Sokoto	23	244,916	29,153	yes	7.0%	18.5	2	2	4	80.0%
	Zamfara	14	132,848	26,362	yes	11.0%	3.9	2	1	3	60.0%
	Katsina	34	281,551	105,449	yes	34.0%	13.7	2	2	4	80.0%
SE	Anambra	21	312,390	1,004,843	No	87.0%	3.1	1	1	2	40.0%
	Enugu	17	197,078	802,679	yes	81.0%	4.1	2	1	3	60.0%
	Abia	17	123,649	423,556	yes	80.0%	3	2	1	3	60.0%
	Ebonyi	13	127,374	333,637	No	82.0%	10.5	1	2	3	60.0%
	Imo	27	253,308	394,421	No	80.0%	9.1	1	1	2	40.0%
SS	Akwa Ibom	31	221,511	1,015,960	yes	62.0%	8.1	2	1	3	60.0%
	Edo	18	101,879	763,567	No	81.0%	4.4	1	1	2	40.0%
	Rivers	23	331,230	1,343,847	yes	75.0%	9	2	1	3	60.0%
	Bayelsa	8	78,099	264,795	yes	55.0%	1.2	2	1	3	60.0%
	Delta	25	272,976	661,688	yes	72.0%	3.8	2	1	3	60.0%
	Cross River	18	172,432	702,380	No	64.0%	4.5	1	1	2	40.0%
SW	Ekiti	16	76,556	594,388	yes	93.0%	9.3	2	1	3	60.0%
	Lagos	20	560,365	2,277,884	yes	91.0%	4	2	1	3	60.0%
	Ondo	18	184,919	847,954	yes	77.0%	6.9	2	1	3	60.0%
	Osun	30	223,446	865,190	yes	84.0%	9	2	1	3	60.0%
	Oyo	33	357,176	925,777	No	44.0%	5.7	1	1	2	40.0%
	Ogun	20	225,974	603,531	No	50.0%	0.9	1	1	2	40.0%

Figure 15: Nigeria Rotavirus introduction plan

Annex 3: Coverage Targets

Table 14: Coverage Targets from other Countries

Intro			Year 1	Year 2	Year 3	
Country	**Product**	**Year of Intro**	**actual coverage**	**actual coverage**	**actual coverage**	**Penta3 coverage (actual)**
Kenya	Rotarix	2014	19%	66%	74%	89%
Tanzania	Rotarix	2013	85%	97%	98%	98%
Ethiopia	Rotarix	2014	56%	79%	80%	73%
Cameroon	Rotarix	2014	46%	73%	80%	85%
Burkina Faso	RotaTeq	2013	9%	91%	91%	91%
Mali	RotaTeq	2014	23%	35%	47%	69%

Sources of Data:

Target coverage data: Rota introduction proposals on Gavi country hub
Actual coverage data: WUENIC estimates
Note: for actual coverage data, year 1 does not necessarily capture a whole year since the introduction but rather is based on calendar year data

Annex 4: ACSM

KEY MESSAGES FOR HEALTH WORKERS

- Diarrhoeal disease remains a serious public health issue for children in Nigeria and across the globe.
- All eligible children should receive Rotavirus vaccine at 6, 10, and 14 weeks.
- A child must receive all doses of Rotavirus vaccine to be fully protected.
- Health workers should clearly communicate the time, date and location of the next immunisation visit, and encourage the caregivers to return as when due.
- Prevention of childhood diarrheal diseases also requires improvements in exclusive breastfeeding for 6 months, vitamin A supplementation, safe water, hygiene (such as handwashing with soap), and vitamin A supplementation.

- If the infant suffers from severe diarrhea, take him or her to the health center or community health worker immediately to get treatment – e.g. Zinc Oral rehydration solution (Zinc/ORS), and continued feeding.

- Breast milk is also an excellent rehydration fluid and should be given to infants still breastfeeding, along with Zinc/ORS. In addition to fluid replacement, children with diarrhea should continue to be fed during the episode.
- A comprehensive approach to diarrhoeal disease control should be implemented together with rotavirus vaccine introduction. This comprehensive approach strategy should include exclusive breastfeeding for 6 months, vitamin A supplementation, safe drinking water, hygiene (including hand washing with soap), and sanitation; treatment with zinc/ORS, and continued feeding.

- The Rotavirus vaccine protects the infant against one important cause of diarrhea, but not all causes. Therefore, a child vaccinated with Rotavirus vaccine may still get diarrhea from other agents.

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Annex 5: Contributors to Proposal Development

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