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EFFECTS OF INADEQUATE COLD CHAIN MANAGEMENT ON VACCINE EFFICACY IN NIGERIA'S IMMUNIZATION PROGRAMS

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ABSTRACT

Background: Vaccination is among the most cost-effective public health interventions globally, yet its impact depends entirely on the potency of vaccines at the point of administration. In Nigeria, inadequate cold chain management—characterized by erratic electricity supply, aging equipment, and variable health worker practices—threatens vaccine integrity and undermines immunization program outcomes. **Objective:** This study aims to (1) assess cold chain infrastructure status and equipment functionality in health facilities in Kano, Lagos, and Enugu States; (2) evaluate health worker knowledge, attitudes, and practices (KAP) regarding cold chain management; (3) examine associations between cold chain management practices, vaccine potency indicators, and immunization coverage; and (4) identify contextual factors and stakeholder perspectives that inform strategies for cold chain system strengthening.**Methodology**: A convergent parallel mixed-methods design with an embedded proxy sub-study will be employed. Quantitative data will be collected from 384 health workers across 48 facilities in three purposively selected states (Kano, Lagos, Enugu) using validated structured questionnaires and facility observation checklists. Vaccine potency will be assessed using validated proxy measures including Vaccine Vial Monitor (VVM) staging and digital temperature logger data (LogTag TRID30-7R). Qualitative data will be gathered through 24 key informant interviews. Data integration will employ joint display tables and mixed-methods framework analysis. **Results:** Findings will provide multi-state empirical evidence linking cold chain management to vaccine potency outcomes, inform national policy on immunization logistics, and guide strategic investment in infrastructure, training, and monitoring systems across Nigeria's geopolitical zones.**Conclusion:** The study revealed that mobile phones of healthcare providers have high bacterial contamination and can harbor varied bacterial species and serve as a fomite in self- and cross- patient transmission of hospital acquired infections. Guidelines on standard precautions must be instituted in various healthcare settings as a way to curb the high prevalence of nosocomial infections

Keywords: Cold chain management; Vaccine efficacy; Immunization; Vaccine potency; Health worker KAP

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INTRODUCTION

1.1 Background

Vaccination—the administration of antigenic material to stimulate adaptive immunity—remains one of the most cost-effective public health interventions, preventing an estimated 4–5 million deaths annually from vaccine-preventable diseases (VPDs) [1]. However, vaccine efficacy depends on maintaining potency throughout the supply chain, from manufacture through administration. The vaccine cold chain refers specifically to the temperature-controlled supply chain (typically 2–8°C for traditional vaccines) that preserves vaccine integrity [2]. Breaks in this chain—whether from heat exposure, freezing, or light—can irreversibly degrade vaccine components, leading to loss of potency and reduced protective efficacy [3].

In low- and middle-income countries (LMICs) such as Nigeria, maintaining an uninterrupted cold chain is operationally challenging. Geographic dispersion of facilities, unreliable electricity, long travel distances and rough roads, aging equipment, and shortages of trained personnel produce multiple points where temperature excursions—both heat and freeze events—occur [4]. When temperature excursions are frequent or prolonged, vaccine potency may decline, reducing vaccine effectiveness at the individual level (primary vaccine failure) and diminishing herd immunity at the population level, thus raising the risk of outbreaks despite apparently high nominal coverage rates [5].

Nigeria's immunization program is large and complex. The Expanded Programme on Immunization (EPI) and its implementing agencies—including the National Primary Health Care Development Agency (NPHCDA) and state and local health authorities—manage procurement, storage, distribution, and administration of multiple vaccines for tens of millions of infants and children annually. Over the past decade, Nigeria has invested in cold-chain expansion and modernization, including procurement of WHO-prequalified cold-chain equipment and the introduction of solar direct-drive (SDD) refrigerators for off-grid facilities [6]. Despite these investments, systematic assessments and field studies show that cold-chain failures remain common at subnational levels, particularly at last-mile and facility levels where fragile infrastructure and human-resource gaps persist [7].

1.2 Statement of the Problem

Despite national immunization program investments, the relationship between cold chain system performance and immunization outcomes remains unquantified across diverse Nigerian contexts (see Section 2.9 for evidence gaps). Nigeria continues to experience outbreaks of VPDs—including measles, diphtheria, and circulating vaccine-derived poliovirus type 2 (cVDPV2)—despite substantial coverage-reporting from the EPI [5]. Studies have shown that up to 30–40% of vaccines administered in LMICs may lose potency before reaching recipients due to exposure to inappropriate storage conditions [8].

Vaccines that have lost potency due to improper storage or transport may fail to elicit protective immunity, resulting in primary vaccine failure [9]. Such failures are often invisible in routine service delivery because potency testing is not conducted at the facility level. This means children can be vaccinated without actually being immunized, creating a dangerous gap between reported coverage and actual protection [10]. Furthermore, poor cold chain management has serious economic and social implications: compromised vaccines represent wasted health resources and erode public trust in immunization programs [11].

Despite recognition of these challenges, there remains a paucity of integrated, multi-state evidence in Nigeria linking infrastructure gaps, health worker KAP, and documented vaccine potency losses to immunization outcomes. Without a robust evidence base, policymakers face difficulty in prioritizing interventions—whether in equipment procurement,

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workforce development, monitoring systems, or contingency planning. This study addresses that gap.

1.3 Research Questions

This study addresses the following research questions:

What is the status of cold chain infrastructure and equipment functionality in health facilities across Kano, Lagos, and Enugu States?

What are the levels of knowledge, attitudes, and practices regarding cold chain management among health workers in the study facilities?

What associations exist between cold chain management practices, vaccine potency indicators (VVM status, temperature excursion rates), and immunization coverage?

What are the contextual barriers and facilitators to effective cold chain management from the perspective of program managers and cold chain officers?

1.4 Significance of the Study

This study is significant on multiple grounds. First, it will generate multi-state empirical evidence linking cold chain system performance to vaccine potency indicators and immunization outcomes addressing a critical gap in the Nigerian evidence base. Second, it will provide context-specific data to inform programmatic reforms in cold chain monitoring, equipment procurement, and workforce training. Third, it will contribute to Nigeria's progress toward Sustainable Development Goal (SDG) 3 on health and well-being by supporting evidence-based strategies that ensure every administered vaccine is potent, safe, and effective. Finally, findings will offer lessons applicable to other sub-Saharan African countries facing similar cold chain challenges.

1.5 Aim and Objectives

This study aims to assess the relationship between cold chain management practices and vaccine potency indicators in selected health facilities in Nigeria.

The specific objectives are to:

1. Assess cold chain infrastructure status and equipment functionality in health facilities in Kano, Lagos, and Enugu States.
2. Evaluate health worker knowledge, attitudes, and practices regarding cold chain management.
3. Examine associations between cold chain management practices, vaccine potency indicators, and immunization coverage.
4. Identify contextual factors and stakeholder perspectives that inform strategies for cold chain system strengthening.

1.6 Expected Contributions

This study is expected to:

Provide empirical, multi-state evidence on the association between cold chain management practices and vaccine potency indicators in Nigeria.

Identify systemic gaps in cold chain infrastructure and workforce capacity across diverse geographic and socioeconomic contexts.

Contribute to national policy formulation on immunization logistics, equipment investment, and health worker training.

Strengthen Nigeria's capacity to achieve SDG 3 targets on reducing child mortality and ensuring universal access to effective immunization.

2: Literature Review

2.1 **Global Cold Chain Overview**

The cold chain system is critical to preserving vaccine integrity, requiring that most vaccines be stored between 2°C and 8°C throughout their supply chain journey [12]. Any breach in the cold chain can lead to significant loss of vaccine potency, resulting in vaccine failure, wasted resources, and potential outbreaks of VPDs. Globally, it is estimated that 25% of vaccines are wasted due to cold chain failures, with developing countries accounting for a significant share [13].

Globally, low-resource countries face significant challenges in maintaining effective cold chain systems. Studies in Bangladesh and India have revealed frequent temperature excursions during vaccine transportation and storage [14]. WHO and partners have promoted innovations such as the Controlled Temperature Chain (CTC) approach for selected vaccines, allowing time-limited exposure at higher temperatures under controlled protocols to facilitate

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reach in hard-to-serve communities [10]. UNICEF's Cold Chain Equipment Optimization Platform (CCEOP) has also supported procurement and deployment of SDD refrigerators and other modern cold-chain equipment suited to off-grid contexts [15].

2.2 African Context

In sub-Saharan Africa, electricity shortages and inadequate refrigeration equipment contribute significantly to vaccine potency loss [16]. Assessments across sub-Saharan Africa indicate that inadequate cold-chain systems contribute to variable vaccine effectiveness, despite standardized manufacturing quality [17]. Countries with stronger cold-chain monitoring and infrastructure—such as Rwanda and Ghana—demonstrate higher and more consistent vaccine effectiveness compared to countries with weaker systems [18]. These continental comparisons underscore that infrastructure investment alone is insufficient without robust monitoring, trained personnel, and reliable energy solutions.

2.3 Nigeria's Immunization System

Nigeria introduced the Expanded Programme on Immunization (EPI) in 1979 to address VPDs such as measles, tuberculosis, and polio [19]. Despite the program's achievements, challenges persist in ensuring universal immunization coverage, with national coverage for key antigens remaining below the global target of 90% [20]. The NPHCDA coordinates immunization activities nationally, managing procurement, storage, distribution, and administration of multiple vaccines for tens of millions of infants and children annually. Data platforms such as DHIS2 dashboards have been adopted to improve logistics decision-making [6].

2.4 Cold Chain Challenges in Nigeria

Five major studies across northern and southern Nigeria document cold chain infrastructure deficits [21]. Key findings include: (1) power reliability averaging 6.2 hours daily in rural facilities; (2) functional cold chain equipment in approximately 45% of primary health centres (PHCs); and (3) VVM stage 2+ in 18% of vials assessed. These studies were single-state or facility-specific; none examined multi-state variation or linked infrastructure to coverage outcomes—the gap this study addresses.

A survey in northern Nigeria reported that over 25% of vaccine refrigerators experienced prolonged breakdowns, significantly affecting immunization coverage [22]. Moreover, limited use of data loggers and inadequate supervisory systems hinder effective monitoring [8]. Nigeria's experience with periodic measles and polio outbreaks has prompted investigators to examine supply-chain and cold-chain factors as contributors to outbreak persistence—not as sole causes, but as important enabling conditions that interact with access, demand, and surveillance gaps [23].

2.5 **Health Worker Knowledge, Attitudes, and Practices (KAP)**

Health worker competence and practices are central determinants of cold chain performance at the facility level. Studies in several Nigerian states have documented variable KAP profiles among vaccinators and logistics staff: while many workers understand basic temperature ranges and VVM functions, gaps remain in daily monitoring, interpretation of VVMs and freeze indicators, correct conditioning of ice packs, and contingency measures during prolonged power failure [24]. Only 55% of health workers surveyed were aware of correct storage temperature ranges [25].

These human-factor weaknesses are often compounded by weak supervision, limited refresher training, and constrained maintenance support for cold-chain equipment, creating systemic risk for temperature excursions that go unnoticed or uncorrected. Inadequate refresher training, limited supportive supervision, and poor accountability mechanisms exacerbate these challenges [26].

2.6 Temperature Excursions and Vaccine Potency

2.6.1 Vaccine Potency and Immunogenicity

Vaccine potency refers to the capacity of a vaccine to elicit its intended biological effect—namely, the induction of a protective immune response against a specific pathogen. Vaccines are inherently thermolabile biological products. Unlike most chemical pharmaceuticals, their active components—live

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attenuated organisms, inactivated pathogens, protein subunits, or toxoids—can undergo irreversible degradation when exposed to heat, freezing, or light [27]. Heat exposure may denature proteins or reduce viral viability, while freezing can disrupt emulsions, damage adjuvants, and alter antigen structure, especially in aluminum-adjuvanted vaccines [10]. When such degradation occurs, the vaccine may remain visually unchanged but lose potency, rendering it partially or completely ineffective.

Immunogenicity refers to a vaccine's ability to induce an immune response—both humoral (antibody-mediated) and cellular (T-cell mediated)—sufficient to confer protection against infection or disease [28]. A potent vaccine does not guarantee immunogenicity in all individuals, but loss of potency almost invariably reduces immunogenicity at the population level. Live attenuated vaccines such as measles, oral polio vaccine (OPV), and rotavirus vaccines are especially heat-sensitive; even brief exposure to elevated temperatures can significantly reduce viral viability and subsequent immune response [29].

2.6.2 Relationship Between Potency, Immunogenicity, and Efficacy

Vaccine efficacy is the clinical manifestation of vaccine potency and immunogenicity, representing the degree to which a vaccine prevents disease under ideal conditions, while effectiveness refers to performance under real-world conditions [2]. Loss of potency due to cold-chain breaches directly compromises immunogenicity, leading to reduced efficacy and effectiveness. This relationship can be summarized as follows:

Potent vaccine + intact cold chain → adequate immunogenicity → high efficacy.

Compromised potency (cold-chain failure) → reduced immunogenicity → vaccine failure.

Primary vaccine failure occurs when a vaccinated individual fails to develop protective immunity, often due to insufficient antigenic stimulation caused by degraded vaccines [9]. At scale, this leads to "silent susceptibility," where populations appear vaccinated based on coverage data but remain vulnerable to outbreaks [10].

2.6.3 Effects of Heat Exposure and Freeze Damage

Heat exposure is the most common cause of vaccine potency loss globally, particularly in tropical and low-resource settings. Prolonged exposure to temperatures above +8°C accelerates antigen degradation, especially for live attenuated vaccines [10]. Studies have shown that measles and OPV vaccines lose significant potency when exposed to temperatures above recommended ranges, even for short durations [30]. A study in South-East Nigeria evaluating measles vaccines collected from cold-chain facilities found that vaccines stored under proper conditions retained immunogenicity, while those exposed to suboptimal conditions showed reduced immune response potential [30].

Freeze damage is often underrecognized but equally destructive. Aluminum-adjuvanted vaccines such as DTP, hepatitis B, and pentavalent vaccines are particularly vulnerable to freezing. Freezing causes irreversible aggregation of adjuvants, reducing antigen adsorption and immune stimulation [27]. Unlike heat damage, freeze damage may not be detectable by VVMs, making it a hidden threat in cold-chain systems with unreliable temperature control.

2.7 Impact on Immunization Outcomes

Failure to maintain vaccine potency has far-reaching consequences, including increased child morbidity and mortality, loss of public confidence in immunization programs, and financial wastage. The consequences of inadequate cold chain management in Nigeria extend beyond individual vaccine failures. At the population level, attenuated vaccine potency can reduce effective coverage and increase susceptibility pockets; this, in turn, makes outbreaks more likely and can increase the scale and cost of outbreak response campaigns [23].

Beyond health outcomes, poor cold-chain management has serious economic and social implications. Vaccines represent a significant proportion of health budgets and donor funding. When

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potency is lost due to exposure outside recommended temperature ranges, these resources are effectively wasted. Moreover, administering compromised vaccines erodes public trust in immunization programs. Caregivers who see vaccinated children still falling ill may lose confidence in vaccination, fueling hesitancy and resistance [11].

2.8 Interventions and Strategies

Global best practices for strengthening cold chain systems include the use of solar-powered SDD refrigerators in off-grid areas, installation of continuous temperature monitoring devices (data loggers), regular maintenance of cold chain equipment, training and retraining of health workers on effective vaccine management, and implementation of data-driven decision-making using remote temperature monitoring systems [31]. Global initiatives such as WHO's Effective Vaccine Management (EVM) framework emphasize these components as essential to safeguarding vaccine quality and maximizing immunogenicity [10].

Digital monitoring platforms—such as remote temperature sensors integrated with DHIS2—and standard operating procedures (SOPs) with preventive maintenance contracts and regular training are recommended to reduce human errors and ensure equipment uptime [32]. As Nigeria expands its immunization portfolio (including new vaccines and potential malaria vaccine rollouts), safeguarding cold-chain integrity will be essential to translate vaccine availability into population-level protection.

2.9 Gaps in Evidence

Despite recognition of these challenges, there remains a paucity of integrated, multi-state evidence in Nigeria linking infrastructure gaps, health worker KAP, and documented vaccine potency losses to immunization outcomes. Most available studies are localized audits or cross-sectional surveys, which, while informative, do not provide a comprehensive picture of how systemic weaknesses interact to affect vaccine efficacy across regions. Moreover, while global frameworks such as the WHO's EVM assessment tools exist, their application in Nigeria has been inconsistent and results underutilized in guiding state-level investments [10]. This study directly addresses these gaps through a multi-state, mixed-methods design with integrated proxy potency assessment.

2.10 Conceptual Framework

This study is guided by the World Health Organization Effective Vaccine Management (EVM) Framework, which provides a comprehensive model for assessing immunization supply chain performance [13]. The EVM framework identifies nine critical components of vaccine management systems, organized into three functional domains: Supply Chain Strategy, Supply Chain Operations, and Supply Chain Controls.

The study-specific adaptation focuses on cold chain integrity as the central mediating variable between system inputs and immunization outcomes:

Input Variables:

Cold Chain Infrastructure (Equipment, Power, Storage) + Health Worker KAP + Policy/Programmatic Factors

↓

Mediating Variable: Cold Chain Integrity (Temperature Stability, VVM Status)

↓

Outcome Variables: Vaccine Potency (VVM stage, temp excursion) + Immunization Coverage + VPD Incidence

Table 1: EVM Framework Components and Study Operationalization

EVM Domain	Component	Study Operationalization
Supply Chain Strategy	Cold Chain Equipment	Equipment audit checklist (Appendix III)
Supply Chain Operations	Buildings & Facilities	Infrastructure assessment
Supply Chain Operations	Program Management (SOPs)	SOP availability, supervision frequency
Supply Chain Operations	Personnel	KAP survey (Section B)
Supply Chain Controls	Vaccine Stock Management	Stock records, wastage rates
Supply Chain Controls	Vaccine Distribution	Cold box usage, transport times
Supply Chain Controls	Vaccine Management	Temperature monitoring, VVM checks

3: Methodology

3.1 Research Design

This study will employ a convergent parallel mixed-methods design with an embedded proxy sub-study [33]. This design is selected to obtain complementary quantitative and qualitative data on cold chain management practices while independently assessing vaccine potency through validated proxy measures.

Phase 1: Concurrent Data Collection (Months 12–18)

Three data streams will be collected simultaneously:

Quantitative Strand: Cross-sectional health worker survey (n=384) assessing knowledge, attitudes, and practices regarding cold chain management. Data will be collected at a single time point across 48 health facilities in three states.

Qualitative Strand: In-depth key informant interviews (n=24) with cold chain officers, immunization program managers, and facility administrators to explore contextual barriers and facilitators to cold chain maintenance.

Proxy Sub-Study: Vaccine potency assessment of vaccine vials from participating facilities using validated proxy measures (VVM staging and temperature logger data) in lieu of full laboratory potency testing, due to PhD timeline and budget constraints.

Phase 2: Integration and Interpretation (Months 19–21)

Quantitative and qualitative datasets will be analyzed independently, then merged through joint display tables comparing statistical findings with thematic categories, side-by-side matrix analysis at facility level, and meta-inferences drawing conclusions from both datasets. The proxy sub-study results will be compared against KAP survey findings and qualitative themes to assess convergence between reported practices and measured potency indicators.

The convergent parallel design is appropriate when quantitative and qualitative data are given equal priority, collected concurrently, and integrated to provide a comprehensive

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understanding of the research problem [34]. This design addresses the limitation of cross-sectional surveys alone, which cannot capture contextual processes or explain statistical associations.

3.2 Study Area and State Selection

This study will be conducted in Kano State (North-West), Lagos State (South-West), and Enugu State (South-East). These states were selected using maximum variation purposive sampling to capture the full spectrum of cold chain performance contexts in Nigeria [35].

Table 2: State Selection Criteria and Justification

Criterion	Kano	Lagos	Enugu	Data Source
Geopolitical Zone	North-West	South-West	South-East	Nigerian Federal Structure
Penta3 Coverage (2021)	48%	76%	62%	NPHCDA/UNICEF MICS 2021
CCE Functionality	34%	71%	52%	WHO EVM Assessment 2022
Power Supply (hrs/day)	4.2	18.5	8.3	World Bank Energy Access 2022
Climate Zone	Sahel (hot/dry)	Coastal (humid)	Humid tropical	Köppen Classification
Total Health Facilities	1,247	2,156	978	State HMIS

Kano State represents high-burden, low-resource settings with significant cold chain deficits. Low Penta3 coverage (48%) and equipment functionality (34%) create high risk for vaccine potency compromise. The hot, dry climate (average 35°C) stresses cold chain systems. Lagos State represents high-capacity urban infrastructure with functional cold chain systems. High coverage (76%) and equipment functionality (71%) provide a comparative benchmark for best practices. Enugu State represents middle-performing systems with moderate infrastructure and coverage (62%), offering a “typical” Nigerian context between the extremes of Kano and Lagos.

3.3 Study Population

The study population comprises health workers responsible for vaccine storage and administration at primary health centres (PHCs), secondary facilities (district/state general hospitals), and tertiary facilities (federal hospitals and teaching hospitals) involved in routine immunization in the three selected states.

3.4 Within-State Sampling

Table 3: Within-State Sampling Framework

State	LGAs Selected	Facilities/LGA	Total Facilities	Workers/Facility
Kano	Dala, Fagge, Gwale, Tarauni	4	16	6–8
Lagos	Alimosho, Ikorodu, Eti-Osa,	4	16	6–8

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	Surulere			
Enugu	Enugu North, Enugu South, Nsukka, Udi	4	16	6–8
Total	12 LGAs	—	48	384

Within each state, LGAs were purposively selected to include two high-density urban LGAs and two peri-urban/rural LGAs. Facility level distribution will be: Primary Health Centers 60% (n=29), Secondary Facilities 30% (n=14), Tertiary Facilities 10% (n=5).

3.5 Sample Size Calculation

A. Health Worker Sample (Individual Level)

Using Cochran's formula for proportions 36:

$n_0 = Z^2 \times p \times q / d^2 = (1.96)^2 \times 0.5 \times 0.5 / (0.05)^2 \approx 384$

Where Z = 1.96 (95% confidence level), p = 0.5 (conservative estimate), q = 1−p, d = 0.05 (5% margin of error). Finite population correction (N ≈ [15],000 health workers in three states) yields n ≈ 374, rounded up to 384 for margin. Accounting for a 10% non-response rate gives a final target of 422 respondents.

B. Health Facility Sample (Cluster Level)

Since health workers are nested within facilities, the facility sample size was calculated using design effect correction for cluster sampling 37:

$DE = 1 + (m - 1)\rho = 1 + (8 - 1) \times 0.05 = 1.35$

$n_facilities = 384 / (1.35 \times 8) \approx 36 \rightarrow$ rounded up to 48 facilities

Where m = 8 workers per facility and ρ = 0.05 (intraclass correlation coefficient). The sample of 48 facilities (16 per state, 4 per LGA) provides adequate power (≥80%) for facility-level regression analyses.

C. Vaccine Vial and Qualitative Samples

For the proxy sub-study: 2 vials assessed per facility per vaccine type (measles, BCG, DPT) gives 48 facilities × 3 types × 2 vials = 288 vial assessments. For qualitative interviews: 8 key informants per state (cold chain officers, program managers, facility heads) gives n = 24 total interviews, sufficient for information saturation [38].

Table 4: Sample Size Summary

Level	Unit	Sample Size	Calculation Method
State	Geopolitical zone	3	Purposive (maximum variation)
LGA	Administrative unit	12	4 per state (purposive)
Facility	Health facility	48	Design effect correction
Individual	Health worker	384	Cochran's formula
Vaccine	Vial assessment	288 (proxy)	Power analysis
Qualitative	Key informant	24	Saturation criterion

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3.6 Vaccine Potency Proxy Measures

Given feasibility constraints for laboratory potency testing within the PhD timeline and budget, this study will employ validated proxy indicators of vaccine potency and cold chain integrity 13:

Primary Proxy Measures

Vaccine Vial Monitor (VVM) Stage Classification: Visual inspection of all vaccine vials at sampled facilities, categorized as Stage 1 (no heat exposure) versus Stages 2–4 (progressive heat damage). VVM Stage 3+ correlates with >25% potency reduction [39].

Digital Temperature Logger Data: 30-day continuous monitoring using LogTag TRID30-7R data loggers placed in cold chain equipment. Outcome: excursion rate (% time outside 2–8°C). Threshold: >5% excursion time is associated with unacceptable potency loss [27].

Cold Chain Equipment Performance Score: WHO EVM assessment tool covering Equipment, Stock Management, Distribution, Personnel, and Vaccine Management domains. Validated score: <80% EVM compliance is associated with VVM stage advancement [40].

Secondary Proxy

Administrative Data Linkage: DHIS2 data extraction for VPD incidence (measles, pertussis) by LGA and coverage estimates from NPHCDA administrative data, statistically linked to facility-level cold chain assessment scores.

These proxy measures have demonstrated correlation with laboratory potency in African settings: a study in Cameroon found VVM status correlated with measles IgG seroconversion ($r = 0.72$, $p < 0.01$) [41]. The Nigeria EVM assessment 2019 found that facilities with <90% EVM compliance had 3.2× higher vaccine wastage rates [42].

3.7 Data Collection Instruments and Validation

3.7.1 KAP Questionnaire Development and Validation

The structured questionnaire (Appendix II) was developed through: literature synthesis of existing KAP tools in immunization 24; EVM framework mapping (Section 2.10); and local adaptation for the Nigerian context (terminology, cadre structures, equipment types). Expert panel content validity review was conducted by seven specialists (two immunization program managers, two cold chain specialists, two academic researchers, one health economist). The Scale-level Content Validity Index (S-CVI) achieved was 0.93, with 42 of 45 items meeting the retention criterion (≥0.78 I-CVI). Three items were revised for clarity.

Pilot testing was conducted in Nasarawa State (a non-study state with similar characteristics) with 20 health workers over two weeks. Results: average completion time 28 minutes; missing data rate 3.2%; Cronbach's alpha 0.84 (knowledge), 0.79 (attitudes), 0.81 (practices); inter-rater reliability (Kappa) 0.88. Four items were reworded; skip logic was adjusted; "Don't know" options were added to three knowledge items.

3.7.2 Facility Observation Checklist

The facility observation checklist (Appendix III) was adapted from the WHO EVM Assessment Tool 2.0 (public domain, permission obtained) and validated by the same expert panel. The checklist covers five sections: cold chain equipment (12 items, EVM Component 2), temperature monitoring (8 items, Component 9), storage practices (10 items, Component 7), vaccine handling (6 items, Component 8), and infrastructure (5 items, Component 3). Inter-rater reliability: Kappa = 0.91.

3.7.3 Qualitative Interview Guide

The semi-structured interview guide comprises 12 core questions with probes covering cold chain challenges, solutions, policy gaps, and training needs. It was developed from literature gaps and EVM framework

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Component 5 (Program Management). Validation involved expert review by an independent qualitative methodologist and cognitive interviewing with three cold chain officers to test question interpretation and local idiom.

3.7.4 Temperature Logger Protocol

Table 5: Temperature Logger Specification

Parameter	Specification
Device	LogTag TRID30-7R (validated against WHO PQS standards)
Placement	Cold box, refrigerator, and freezer at each facility
Duration	30 days continuous monitoring
Download	Monthly via LogTag Analyzer software
Outcome Measure	Excursion rate (% time outside 2–8°C)
Validation	Devices calibrated against reference thermometer pre-deployment

3.8 Data Analysis Plan

3.8.1 Quantitative Analysis

Software: SPSS Version 28 (IBM Corp) and Stata 17 (StataCorp). Descriptive analysis will include frequencies and percentages for categorical variables, means and standard deviations (or medians and IQR) for continuous variables, and stratification by state, facility level, and geopolitical zone.

Primary regression model: Dependent variable – Cold Chain Performance Score (CCPS, composite from observation checklist, categorized as Adequate ≥80% vs. Inadequate <80%). Independent variables: health worker KAP score (continuous), infrastructure index (0–10), training received (binary), facility level (categorical), and state (categorical). Logistic regression with the form: $\text{logit}(P(\text{CCPS_adequate})) = \beta_0 + \beta_1(\text{KAP}) + \beta_2(\text{Infrastructure}) + \beta_3(\text{Training}) + \beta_4(\text{Level}) + \beta_5(\text{State}) + \varepsilon$. Secondary analyses include multilevel logistic regression if ICC >0.05, Pearson correlation between CCPS and temperature excursion rates, and linear regression with immunization coverage as dependent variable.

3.8.2 Qualitative Analysis

Software: NVivo 14 (QSR International). Analytical approach: Framework Analysis [43], selected for policy-relevant research questions, pre-defined themes from the EVM framework, and need for comparison across cases (states). The five stages are: (1) familiarization, (2) identifying thematic framework, (3) indexing, (4) charting, and (5) mapping and interpretation. A priori codes derive from EVM domains (Equipment, Personnel, Procedures, Policy); emergent codes will be identified from the data.

3.8.3 Mixed-Methods Integration

Integration strategy: Convergence and Expansion [34]. Technique 1 (Joint Display) will compare quantitative findings with qualitative themes to identify convergence or discordance. Technique 2 (Expansion) will use qualitative findings to explain unexpected quantitative results—for example, if regression shows no association between training and CCPS, qualitative data may reveal that training is theoretical without practical application. Technique 3 (Data Transformation) will convert qualitative themes to frequency counts for comparison and quantitative facility scores to case profiles for rich description.

3.9 Ethical Considerations

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Ethical approval will be obtained from the National Health Research Ethics Committee (NHREC) and relevant State Health Research Ethics Committees in Kano, Lagos, and Enugu. NAFDAC research clearance will also be sought. Informed consent will be secured from all participants before data collection. Confidentiality and anonymity will be maintained throughout: data will be coded and stored securely, with access limited to the research team. Participation is entirely voluntary; participants may withdraw at any time without penalty.

Table 6: 36-Month PhD Research Work Plan [44]

Activity	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)
Comprehensive literature review	■■■		
Research proposal development	■■■■■		
Ethical approval submission & receipt	▒	■■	
Instrument finalization & pilot study		■■■■	
FIELDWORK: Quantitative (Kano)			■■■■
FIELDWORK: Quantitative (Lagos)			■■■■
FIELDWORK: Quantitative (Enugu)			■■■■
FIELDWORK: Qualitative interviews (all states)			▒■■■■■
Temperature logger deployment (12 months)			■■■■■■■■■■
VVM assessment / proxy data collection			■■■■■■
Quantitative & qualitative data analysis			▒■■■■■
Thesis writing & submission			▒▒▒■■■■
Journal article & dissemination			▒▒▒▒▒▒■■

3.10 Validity and Reliability

Content validity is ensured through expert panel review (S-CVI = 0.93) and pre-testing of all instruments in a non-study state. Internal consistency reliability is confirmed through Cronbach's alpha values exceeding the acceptable threshold of 0.70 for all questionnaire subscales. Inter-rater reliability (Kappa ≥0.88) ensures consistency across data collectors. Qualitative trustworthiness will be enhanced through member checking, reflexive journaling, and peer debriefing.

3.11 Work Plan (Gantt Chart)

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Legend: ▉ = Active work period; ▒ = Buffer/contingency time. Bold "FIELDWORK" rows indicate activities requiring inter-state travel. Fieldwork period: quantitative data collection April–September 2026; qualitative interviews June–November 2026; temperature monitoring April 2026–March 2027.

3.12 Budget Justification

Table 7: Detailed Research Budget (36 Months)

Item	Unit Cost (₦)	Total (₦)	Justification
A. PREPARATION PHASE		275,000	Literature, printing & binding
B. ETHICAL & REGULATORY		215,000	NHREC, 3 state ethics, NAFDAC
C. PERSONNEL (PI stipend, 2 RAs, 3 field supervisors, transcriptionist)	Variable	3,600,000	36-month staffing costs
D. DATA COLLECTION (transport, accommodation, per diem)	Variable	4,560,000	3 states × 60 nights + per diem
E. EQUIPMENT (loggers, laptops, tablets, cold boxes, stationery)	Variable	2,440,000	LogTag TRID30-7R, KoboCollect tablets
F. PROXY MEASURES (VVM cards, logger software, calibration)	Variable	2,625,000	450 VVM cards + calibration
G. DATA ANALYSIS SOFTWARE (SPSS, NVivo, Stata, statistician)	Variable	450,000	Licensed software + expert support
H. DISSEMINATION (thesis, OA publication fees, conferences, briefs)	Variable	1,335,000	2 OA articles + 2 conferences
I. CONTINGENCY (10%)		1,550,000	Inflation, delays, equipment failure
TOTAL BUDGET		₦17,050,000	≈11,400 USD @ ₦1,500 = $1

Funding Sources:

Nasarawa State University Postgraduate Scholarship: ₦5,000,000

TETFund Institutional Research Grant (applied): ₦10,000,000

Personal contribution: ₦2,050,000

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Appendix I: Informed Consent Form

I am Awoleye, David Olusegun (B.Sc., M.Sc.), a PhD candidate at the Department of Public Health, Global Health and Infectious Disease Institute, Nasarawa State University, Keffi, Nasarawa State. I am conducting research titled "Effects of Inadequate Cold Chain Management on Vaccine Efficacy in Nigeria's Immunization Programs."

You are invited to participate in a research study that aims to explore how inadequate cold chain management is associated with the efficacy of vaccines used in Nigeria's immunization programs. Please read this form carefully and ask any questions you may have before deciding whether to participate.

Purpose of the Study:

Assess cold chain infrastructure status and equipment functionality in health facilities in Kano, Lagos, and Enugu States.

Evaluate health worker KAP regarding cold chain management.

Examine associations between cold chain management practices, vaccine potency indicators, and immunization coverage.

Identify contextual factors that inform strategies for cold chain system strengthening.

Participation:

Your participation is entirely voluntary. You may withdraw at any time without penalty. If you agree to participate, you will be asked to complete a structured questionnaire taking approximately 28–30 minutes.

Inclusion Criteria:

Immunization health workers at primary, secondary, and tertiary levels of health facility structure involved in vaccine storage or administration.

Exclusion Criteria:

Facility attendants and cleaners at all health facility levels.

Confidentiality:

All information collected will be kept strictly confidential. Your name or any personal identifier will not appear in any reports or publications. Data will be coded and stored securely, accessible only to the research team.

Risks and Benefits:

There are no foreseeable risks associated with your participation. While there may be no direct benefit to you, your input will help identify challenges in cold chain management and support recommendations that can strengthen Nigeria's immunization programs.

Compensation:

There is no monetary compensation for participating in this study.

By signing below, you confirm that you have read and understood the information, have had the opportunity to ask questions, and voluntarily agree to participate.

Participant's Name: _____

____ Signature: _____

Date: _____

Researcher's Name: _____

____ Signature: _____

Date: _____

Appendix Ii: Kap Questionnaire

Effects of Inadequate Cold Chain Management on Vaccine Efficacy in Nigeria's Immunization Programs

INSTRUCTION: Kindly tick the appropriate boxes and fill in the blanks.

SECTION A: Demographic Information

1. Age: _____
2. Gender: □ Male □ Female □ Other
3. Profession: _____
4. Job title/designation: _____
5. Years of experience: □ <1 year □ 1–3 years □ 4–6 years □ 7+ years
6. Type of facility: □ PHC □ General Hospital □ Tertiary Hospital □ Private □ Other: _____
7. State/Location: _____

SECTION B: Cold Chain Infrastructure Assessment (Objective 1)

8. Does your facility have a functioning cold chain system? □ Yes □ No
9. What cold chain equipment is available? (check all that apply): □ Refrigerators □ Freezers □ Cold boxes □ Vaccine carriers □ None
10. How reliable is the power supply? □ Very reliable □ Moderately reliable □ Poor □ Very poor
11. Backup power source: □ Generator □ Solar □ Inverter □ None
12. Frequency of equipment maintenance: □ Monthly □ Quarterly □ Annually □ Never

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13. Equipment breakdown in last 6 months? □ Yes □ No If yes, how often? _____ times

SECTION C: Health Worker KAP (Objective 2)

14. Received formal training on cold chain management? □ Yes □ No

15. Last training: □ Within 6 months □ 6–12 months ago □ Over 1 year ago

16. Knowledge of storage temperature (2–8°C): □ Excellent □ Good □ Fair □ Poor

17. Do you regularly monitor and record storage temperatures? □ Yes □ No

18. Frequency of temperature checks: □ Every shift □ Daily □ Weekly □ Rarely

19. Vaccines discarded due to temperature excursions? □ Yes □ No If yes, how often? _____

20. Confidence in vaccine handling: □ Very confident □ Somewhat confident □ Not confident

21. Do you believe cold chain failure affects vaccine potency? □ Yes □ No □ Not sure

SECTION D: Impact on Vaccine Potency and Immunization Outcomes (Objective 3)

22. Observed vaccine failures (children ill despite immunization)? □ Yes □ No

23. Suspect cold chain failure as a cause? □ Yes □ No

24. Consequences of inadequate cold chain (check all): □ Loss of potency □ Disease outbreaks □ Resource wastage □ Loss of public trust □ None

25. Reports of expired/compromised vaccines administered? □ Yes □ No □ Not sure

26. Frequency of vaccine quality assessments: □ Regularly □ Occasionally □ Rarely □ Never

SECTION E: Recommendations (Objective 4)

27. Challenges in maintaining cold chain (check all): □ Inadequate equipment □ Unreliable power □ Lack of training □ Inadequate funding □ Poor transport logistics □ Others: _____

28. Suggested improvements: □ More training □ Better equipment □ Reliable power backup □ Regular supervision □ Increased funding □ Others: _____

29. Are cold chain systems in Nigeria improving? □ Yes □ No □ Not sure

30. Primary responsibility for improvement: □ Federal Government □ State Government □ Facility Managers □ Donor Agencies □ Others: _____

Thank you for your participation. This questionnaire is for academic research purposes only. All responses are strictly confidential.

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