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## Thermostable Vaccines in the Optimization of African Vaccine Supply Chain, the Perspective of the Nigerian Health Supply Chain Professionals

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### Abstract

This study captures the perspectives of stakeholders on optimization of Nigeria vaccine supply chain with thermostable vaccines. Temperature excursion, cold chain maintenance and the attendant issues of maintaining vaccine integrity across the supply chain network till the last mile remain a critical bottleneck to immunization and vaccine coverage. Therefore, the study takes a pragmatic approach to understand supply chain professionals' perspective regarding their awareness, acceptability, feasibility, and preparedness to take up innovations to optimize the vaccine supply chain and immunization coverage. An electronic questionnaire was used to reach different public health supply chain professionals in Nigeria. A community of professionals whose works relates to the supply chain of public health commodity was selected as the sampling frame. This community includes some supply chain professionals in Nigeria who have identified as part of the International Association of Public Health Logisticians. There were 200 valid responses of which 70.5% were males and 29.5% were females. The most frequent age group was 31 – 40 (56.5%). Among respondents, 86.0% had good experience in the vaccine supply chain but only 41.0% had good knowledge/awareness of thermostable vaccines. The overall acceptability and feasibility of thermostable vaccines were 97.5% and 95.0% respectively. Preparedness of Nigeria vaccine supply chain to take up thermostable vaccines was rated 96.0% for international political will, 82.0% for private sector involvement and collaborations, 76.5% for readiness in regulatory and policy, 73.0% for workforce know-how and 54.0% for national political will. Though respondents generally had poor knowledge of thermostable vaccines, yet, they recognized its importance in optimizing Nigeria vaccine supply chain. Acceptability and feasibility of thermostable vaccines were generally high among professionals. We also found that the level of preparedness to take up new innovation product design and formulation was significantly high across all categories of professionals.

**Keywords:** Vaccine, supply chain, thermostable, acceptability, feasibility.

## 1.0 Introduction

Each year, a significant portion of vaccines lose their potency, become ineffective, or can become hazardous due to temperature-related problems in transportation and storage. This failure adds to the overall cost of vaccines, limits availability, and threatens vaccine coverage and public safety. There is a current challenge of keeping vaccines cold in high temperature environment due to irregular electricity supply and this limits vaccine coverage in low and middle-income countries (LMICs) [1]. Majority of vaccines lose their potency in a temperature-dependent manner<sup>2</sup>. Refrigerating mostly within 2°C to 8°C is commonly used to preserve vaccine potency through a cold chain system [2]. It is however common to see cases of temperature excursion in moving vaccine through its supply chain [2]. This experience poses a significant quality problem of loss of potency and potential vaccine failure to prevent/control epidemics and vaccine-preventable deaths. Greater vaccine thermostability is generally touted as the obvious solution [1].

The total established world vaccine market was approximately \$33B in 2014 and projected to be \$100B by 2025 [3,4]. From this huge market, LMICs accounts for 18% in value and 80% in volume. The large majority of vaccines in the LMICS require “cold chain” transportation to remain viable. A break in the cold chain can lower the potency of a vaccine and in some cases can result to toxicity or constitute public safety concerns [5]. In addition to maintaining the cold chain, there is a separate challenge of verifying any lapses in the chain and in testing the viability of the vaccine before it is administered, particularly in poor or remote areas [6].

According to Ogboghodo *et al.* [7], for vaccine delivery system to be successful, the essential vaccine needs to be available and of good quality. They further argued that the quality of vaccines can only be ensured by a functional cold chain system because vaccines are highly thermo-sensitive substances which have a fixed shelf life that loses viability over time. This loss is irreversible and accelerated if proper storage and temperature conditions are not maintained [7]. The efficacy of vaccines can be completely and permanently damaged if exposed to heat or freezing; this can also increase the risk of side [8]. Administration of vaccines that are not potent will lead to failed immunization of the individual against vaccine-preventable diseases [7]. The CDC has estimated that each year, 300 million pounds worth of vaccines alone are destroyed globally due to improper storage and distribution [9].

These conditions of failure of cold chain management have an end effect of causing wastage of vaccines which can be expensive and be in short supply [7]. Refrigerators for vaccines have reportedly been found to be used in storing other things like foodstuff, laboratory reagents and drugs in some private clinics in Lagos, Nigeria [10].

Some influential public health companies, including The Bill and Melinda Gates Foundation, have for a very long time been advocating for moves that will promote the development of thermostable vaccines [3]. However, the challenges of developing thermostable vaccines have been greater than expected [3]. Vaccines vary greatly in their ability to remain viable under fluctuating temperatures. The stability of a particular vaccine formulation depends on many factors including the type of antigen (active ingredient) and the presence of other vaccine components such as adjuvants, stabilizers and preservatives [3].

Apart from improving the cold chain system within the supply chain, thermostable vaccines have been argued as a possible way forward in managing these challenges [1,4]. All WHO prequalified vaccines currently require storage in refrigerators or freezers as exposure to higher temperatures may result in the denaturation of the proteins in the vaccine rendering them impotent. However, many vaccine supply chains in LMICs have shortages in refrigerated (or even lower temperature) storage and transport capacity to accommodate all of the vaccine doses that must eventually make it to the population [6,11]. Making certain vaccines thermostable would eliminate their need for cold chain, thus freeing up space for vaccines that still require cooler or cold temperatures. More vaccine doses reaching the population can protect more mothers and children from infectious diseases, thus saving medical costs and productivity losses [6]. Thermostable vaccines are therefore designed and developed to withstand different kinds of excursions to retain the vaccine potency for vaccine success [2,12]. Example of such technology and approach is the Freeze-Drying technology in the freeze-dried vaccines [12]. Sometimes, these are referred to as dried vaccines.

Among many potentials/benefits of thermostable vaccines, quick to note is the wide range of differences in the half-life of dry vaccines and the cold vaccines. This is exemplified in the influenza vaccines where the dry version is more stable with 10 times longer half-life [12]. According to Lee *et al.*[6], thermostable vaccines help in relieving many bottlenecks in the vaccine supply chain and cost-effectiveness and cost-efficiency. With these cost advantages, Lee *et al.* submitted that medical cost and productivity savings outweigh the premium cost of producing the thermostable vaccines. The thermostable vaccines also happen to be a working strategy for making vaccines available in the LMICs [1]. The novelty of the innovation of thermostable vaccines also has the potential of reducing vaccine wastage, conserving the integrity of the vaccines and increasing vaccination coverage in the time and space including emergency situations where access to power and cold chain may be challenging [2]. To our knowledge, no study to date has captured stakeholders or professionals' perspectives at thermostable vaccines in the optimization of Nigeria vaccine supply chain. This article summarizes the views of professionals in six professions, five levels of operation as related to vaccine supply chain in Nigeria. The results are meant to inform ongoing initiatives to improve vaccine distribution and storage through enhanced vaccine stability in Nigeria and LMICs.

## 2.0 Materials and Methods

An electronic questionnaire was used to reach different categories of public health supply chain professionals with experience in Nigeria's vaccine supply chain. The samples cut across different levels of operation, geography, and areas of practice. The population size of professionals in Nigeria's development/health public health was estimated at over 5000. A cluster of professionals whose works relates to the supply chain of public health commodity was selected as the sampling frame [13]. This study used a target sample frame, though growing population stands at 1,047 as at the time of this data collection in December 2017 [14]. This involved number of professionals in Nigeria who have been identified as part of the International Association of Public Health Logisticians, IAPHL. The IAPHL is an association of public logistician from all over the world coming together to share knowledge, best practices and network. Using this sample frame, sample size calculator was used to calculate the expected sample size [11].

The questionnaire was shared on the listserv of the IAPHL and other smaller internet-based social network (WhatsApp, Telegram and LinkedIn) and opened for one (1) calendar month after which it was closed to further responses. At the end of one-month time horizon, (December 3, 2017, to January 2, 2018) a total response of 201 was received. Following this stage, the data were harvested for onward analysis. Steps were taken to improve the response. These steps include; assuring confidentiality and providing a good introduction to the survey and how responses will shape a smarter supply chain. We also ensured that questionnaires were easy to use and understandable and only take 5-10 minutes of a participant's time. The permission and support of the administrator of the different platforms were also secured to give the process speed and credibility. This approach follows the strategy by Easterby-Smith *et al.*[13] on how to improve the response rate [13]. The data analysis combined SPSS version 25 and Microsoft Excel. With SPSS, we better managed data with case selection, file reshaping, and creating derived data. A metadata dictionary was stored with the data. Statistical analysis carried out included descriptive statistics and Chi-square test of significance.

## 3.0 Results and Discussion

### 3.1 Background information

There were 200 valid responses of which 141 (70.5%) were males and 59 (29.5%) were females (male: female; 2:1). The most frequent age group was 31 – 40 (113, 56.5%) followed by those above 41 years (48, 24.0%) while 21 – 30 recorded the least value of 39 (19.5%). Majority of respondents were Health/Public health development professionals (81, 40.5%) followed by 52 (26.0%) supply chain professionals only, 49 (24.5%) were into the supply chain and health/public health development. There were 8 (4.0%) financial/business and project managers, 7 (3.5%) were regulatory and safety professionals while IT professionals had the least number of 3 (1.5%). Respondents were from various specialties including technical/executive officers (82, 41.0%), middle managers (59, 29.5%), consultants (26, 13.0%), senior managers (25, 12.5%) and regulatory/policymakers (8, 4.0%). Fifty-

seven percent of the respondents had maximum of 5 years' experience in Nigeria supply chain/development, 57 (28.5%) had between 6 – 10 years' experience, 26 (13.0%) had between 11 – 20 years' experience while only 3 (1.5%) had more than 20 years' experience in Nigeria supply chain/development (Table 1).

**Table 1: Demographics with professional experience**

Parameter	Frequency	Percentage
<b><u>Gender</u></b>		
Male	141	70.5%
Female	59	29.5%
<b><u>Age category</u></b>		
21 - 30	39	19.5%
31 - 40	113	56.5%
41 and above	48	24.0%
<b><u>Profession</u></b>		
Supply Chain Professional Only	52	26.0%
Health/Public Health/Devt Professional Only	81	40.5%
Supply Chain and Health/Public Health/Devt	49	24.5%
IT professionals Only	3	1.5%
Financial/Business and Project Mgt	8	4.0%
Regulatory and Safety Professionals	7	3.5%
<b><u>Specialization</u></b>		
Consultant	26	13.0%
Middle Manager	59	29.5%
Regulatory and Policy Maker	8	4.0%
Senior Manager	25	12.5%
Technical/Executive Officer	82	41.0%
<b><u>Year of experience</u></b>		
≤ 5	114	57.0%
6 – 10	57	28.5%
11 – 20	26	13.0%
>20	3	1.5%

### 3.2 Respondents' experience in the supply chain with the awareness of thermostable vaccines

The experience of participants in the vaccine supply chain and level of awareness of thermostable vaccine was tested. All (100.0%) Information Technology (IT) professionals had good experience, approximately 96% each for supply chain professionals and supply chain and health/public health development, while the least value of 62.5% was noted among financial/business and project managers. No IT professional was aware of thermostable vaccine, only 28.8% of supply chain professionals were aware, 55.1% for Supply chain and health/public health/development professionals and 71.4% for regulatory and safety professionals. Most consultants (96.4%) had experience of vaccine supply chain but only 65.4% were aware of thermostable vaccine. Most middle managers (74.6%) had experience of vaccine supply chain and 42.4% thermostable vaccine awareness. Regulatory and policymakers had 75.0% and 37.5%, senior managers; 92.0% and 36.0% while technical/executive officers had 90.2% and 34.1% experience of vaccine supply chain and awareness of thermostable vaccines respectively. Experience of vaccine supply chain was 86.0% for those who had a maximum of 5 years working experience while it was 100% from 6 years upward whereas. In contrast, 42.1% of those who had a maximum of 5 years' experience were aware of thermostable vaccines, 31.6% for 6 – 10 years, 53.8% for 11 – 20 years and 66.7% for those who had over 20 years' experience (Table 2).

**Table 2: Respondents' experience in vaccine supply chain with awareness of thermostable vaccines**

Profession/Experience	Vaccine Supply Chain Experience			Awareness of Thermostable Vaccine		
	Experienced	No Experience	p	Good Awareness	Poor Awareness	P
<b>Profession</b>						
Supply Chain Professional Only	50 (96.2%)	2 (3.8%)	<b>0.001*</b>	15 (28.8%)	37 (71.2%)	<b>0.022*</b>
Health/Public Health/Dev't Professional Only	61 (75.3%)	20 (24.7%)		32 (39.5%)	49 (60.5%)	
Supply Chain and Health/Public Health/Dev't	47 (95.9%)	2 (4.1%)		27 (55.1%)	22 (44.9%)	
IT professionals Only	3 (100.0%)	-		-	3 (100.0%)	
Financial/Business and Project Mgt	5 (62.5%)	3 (37.5%)		3 (37.5%)	6 (62.5%)	
Regulatory and Safety Professionals	6 (85.7%)	1 (14.3%)		5 (71.4%)	2 (28.6%)	
<b>Specialization</b>						
Consultant	25 (96.2%)	1 (3.8%)	<b>0.022*</b>	17 (65.4%)	9 (34.6%)	<b>0.080</b>
Middle Manager	44 (74.6%)	15 (25.4%)		25 (42.4%)	34 (57.6%)	
Regulatory and Policy Maker	6 (75.0%)	2 (25.0%)		3 (37.5%)	5 (62.5%)	
Senior Manager	23 (92.0%)	2 (8.0%)		9 (36.0%)	16 (64.0%)	
Technical/Executive Officer	74 (90.2%)	8 (9.8%)		28 (34.1%)	65 (65.9%)	
<b>Year of experience</b>						
≤ 5	86 (86.0%)	28 (24.6%)	<b>&lt;0.001*</b>	48 (42.1%)	66 (57.9%)	<b>0.191</b>
6 – 10	57 (100.0%)	-		18 (31.6%)	39 (68.4%)	
11 – 20	26 (100.0%)	-		14 (53.8%)	12 (46.2%)	
>20	3 (100.0%)	-		2 (66.7%)	1 (33.3%)	
<b>Overall</b>	<b>172 (86.0%)</b>	<b>28 (14.0%)</b>		<b>82 (41.0%)</b>	<b>118 9.0%)</b>	

\* Significant at p = 0.005

### Acceptability and Feasibility of Thermostable Vaccines among Nigeria Vaccine Supply Chain professionals

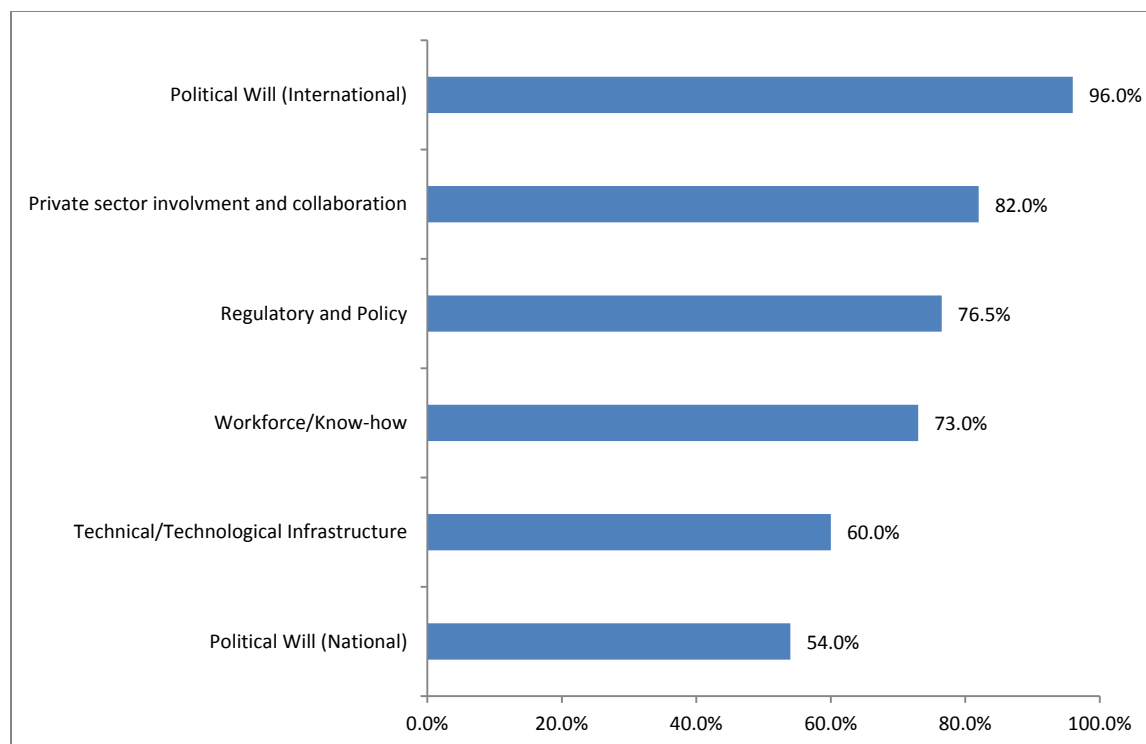
To overcome cold chain challenges, participants were asked whether thermostable vaccines are acceptable and feasible in Nigerian vaccine supply chain. All (100.0%) supply chain professionals only, IT professionals, Financial/business and project managers as well as all regulatory and safety professionals declared acceptance of Thermostable vaccine, while the level of acceptance was 93.9% and 90.0% among health/public health development professionals and supply chain & health/public health development respectively. Similarly, thermostable vaccine recorded 100.0% acceptability by middle managers, regulators, and policymakers as well as senior managers. The acceptability of thermostable vaccines among other specialists was at least 95%. Among experienced professionals, thermostable vaccines recorded 100% acceptability. The thermostable vaccine was also seen feasible among all professions, specializations as well as experience with minimum feasibility of 87% seen from financial/business and project managers while others rated thermostable vaccine feasibility above 90% (Table 3).

**Table 3: Acceptability and Feasibility of Thermostable Vaccines among Nigeria Vaccine Supply Chain professionals**

	<i>Parameter</i>	<i>Acceptability</i>	<i>Feasibility</i>
<b>Profession</b>	Supply Chain Professional Only	100.0%	94.2%
	Health/Public Health/Devt Professional Only	93.9%	92.4%
	Supply Chain and Health/Public Health/Devt	98.0%	100.0%
	IT professionals Only	100.0%	100.0%
	Financial/Business and Project Mgt	100.0%	87.5%
	Regulatory and Safety Professionals	100.0%	100.0%
<b>Specialization</b>	Consultant	96.2%	96.2%
	Middle Manager	100.0%	96.6%
	Regulatory and Policy Maker	100.0%	100.0%
	Senior Manager	100.0%	100.0%
	Technical/Executive Officer	95.1%	91.5%
<b>Year of experience</b>	≤ 5	95.6%	93.9%
	6 – 10	100.0%	94.7%
	11 – 20	100.0%	100.0%
	>20	100.0%	100.0%
<b>Overall</b>		<b>97.5%</b>	<b>95.0%</b>

#### **Preparedness to take up new technological innovations in Nigeria vaccine supply chain**

‘International political will’ was rated highest (96.0%) preparedness to take up new technologies/innovations in Nigeria vaccine supply chain followed by private sector involvement and collaboration (82.0%). Readiness in regulatory and policy was rated 76.5%, workforce know-how 73.0% while the national political will was rated 54.0%.



**Figure 1: Preparedness to take up new technological innovations in Nigeria vaccine supply chain**

## Discussion

While previous studies attempted to offset the paucity of data on the perceptions of country stakeholders regarding their challenges in maintaining vaccines in a 2–8°C temperature range and interest in purchasing and using vaccine products with improved stability [15], assessed vaccine cold chains [15,16], monitored temperatures during vaccine storage and distribution [17], and focused on the use of specific antigens in a CTC [18], our research attempts to capture the perspectives of vaccine supply professionals in using thermostable vaccines in the optimization of Nigeria vaccine supply chain.

Majority of the respondents were males and were mostly within the active labour force (age 31 – 40) from various professions such as supply chain, health/public health, information technology, financial/business, project management, regulatory and safety professionals. They were of various positions such as senior managers, middle managers, consultants as well as technical officers with work experiences ranging from 0 to above 20 years. The number of those who had experience of vaccine supply chain was significantly higher ( $p < 0.05$ ) among professionals than those who had no experience with the highest experienced being IT professionals, supply chain professionals and health-related supply chain professionals whereas approximately 38% of financial and business experts had no experience of vaccine supply chain. The same trend was observed among specialists but at least 25% of middle managers and regulatory/policymakers had no experience of vaccine supply chain. The number of those who had experience of vaccine supply chain was also found to be positively correlated with work experience ( $p < 0.05$ ). In contrast to a large number of those who had experience of vaccine supply chain among professionals with various years of experiences, poor awareness of thermostable vaccine was observed across all professions, specialties as well as year of experience. This might not be unconnected with the fact that thermostable vaccine is a form of new innovation to most LMICs like Nigeria. Only supply chain and health/public health/development professionals and regulatory & safety professionals had experience of vaccines supply chain as well as a good awareness of thermostable vaccine. The amazing discovery in our research was the poor awareness of thermostable vaccine seen among supply chain professionals, only (28.8%) had good level of thermostable vaccine awareness. Also, all IT

(100%) professionals were not aware of thermostable vaccine! The overall experience of vaccine supply chain was above 85% while the overall awareness of thermostable vaccine was just 41%. We discovered that the experience of professionals in vaccine supply chain increases with increase in number of years of experience ( $p < 0.05$ ) whereas the level of awareness of thermostable vaccine had no correlation with years of experience ( $p > 0.05$ ). Although research works on awareness of thermostable vaccines are rare, closely related research that assessed the knowledge of cold chain management among health workers in Nigeria was published by Ogboghodo *et al* [7] in April 2018. In Ogboghodo *et al* [7] study, 39.7% of participants had more than 5 years' experience in vaccine administration [7], similar to 43.0% seen in this study.

The general acceptability and feasibility of thermostable vaccines are generally high among Nigerian professionals regardless of specialization or year of experience. The least acceptability and feasibility were 93% and 87% respectively among professionals, 95% and 91% among specialist, 96% and 94% across years of working experience whereas 98% and 95% respectively overall. This result shows that professionals, business managers as well as the government need to pay more attention to thermostable vaccines. This will firstly improve vaccine logistics, delivery, coverage and efficiency. Ultimately, this has the potential to reduce infant mortality related to vaccine-preventable diseases, and subsequently/indirectly reduce mortality in elder people as infants and children constitute a bridge with them for some infections. Also, Ogboghodo *et al*. [7] found that 64.0% had poor knowledge while 93.2% had a positive attitude toward cold chain management. In this study, 41.0% had a good awareness of thermostable vaccines while acceptability and feasibility were 97.5% and 95.0% respectively. This is in contrast with results of a study done in Coastal South India in 2012 where the majority (76%) of respondents had an overall good knowledge of cold chain management [19]. This result indicates that more awareness/training on thermostable vaccines are needed among Nigerian vaccine supply chain professionals. Respondents rated Nigeria vaccine supply chain politically, private sector involvement and collaboration, regulatory and policy, workforce knowhow and technical/technological infrastructure ready to take up new innovation/technology such as thermostable vaccine.

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## Conclusion

This study found that the majority of participants had experience in vaccine supply chain but had poor knowledge/awareness of thermostable vaccines. The overall acceptability and feasibility of thermostable vaccines were generally high. This points to the fact that the professionals are aware of the challenges of vaccine supply chain and frantically seeking possible ways out. Preparedness of Nigeria vaccine supply chain to take up thermostable vaccines was rated for international political will, private sector involvement and collaboration, readiness in regulatory and policy, workforce know-how and national political will. It is therefore concluded that thermostable vaccines are paramount factors in the optimization of Nigeria vaccine supply chain. Further sets the agenda for Governments and other key players to consider investment in thermostable vaccines.

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