LETTER TO EDITOR

Traceability for strengthening supply chain systems and enhancing real-time visibility: Focus of NAFDAC on advancing vaccine traceability in Nigeria

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ABSTRACT

This study explores the successful implementation of activities aimed at scaling traceability for COVID-19 and routine immunization (RI) vaccines to the local government area and selected healthcare facilities in Nigeria, funded by the Bill and Melinda Gates Foundation. The study was executed by the National Agency for Food and Drug Administration and Control (NAFDAC) and sought to enhance supply chain systems by deploying advanced traceability mechanisms and ensuring real-time stock visibility. The article discusses the accomplishments, challenges, and regulatory framework of NAFDAC, emphasizing GS1 technology-driven traceability, and presents the results of the field scanning activities conducted in July 2023. The approach involved a phased public sector pilot, showcasing the feasibility and challenges of tracking vaccine movement through the supply chain. The result shows the detection of 43 unique products across 1022 facilities from a total of 110,113 scans, offering valuable insights into vaccine distributions. The strategic goals of the project aligned with developing safety surveillance systems in low- and middle-income countries (LMICs) to facilitate patient access to global health products. Similarly, significant improvement in traceability through automated data capture (barcode scanning) and expanded coverage for COVID-19 and selected RI vaccines in Nigeria was found. Against this background, the information derived from this report will build confidence in patients regarding vaccine authenticity, establish a transparent and robust supply chain, and foster pharmacovigilance capability through integration with the track-and-trace systems. Thus, the study provides invaluable insights and opportunities for global health practitioners, policymakers, and researchers to incorporate track-and-trace into regulatory systems by other national regulatory authorities.

KEYWORDS

NAFDAC, traceability, COVID-19, vaccines, visibility

INTRODUCTION

Traceability is an indispensable system for ensuring quality, compliance, and accountability. Traceability can be defined as the ability to trace all processes from the procurement of raw materials to production, consumption, and disposal to determine when and where the product was produced and by whom [1]. Through traceability, information on the manufacturers, suppliers, and distributors is recorded and tracked from the point of manufacturing, procurement, distribution, and sales to ensure that their histories are tracked and traced [2].

According to the World Health Organization (WHO), traceability technologies are described as the technical possibility to trace medical products (such as drugs, vaccines, and medical devices) along the supply chain – from the point of manufacture to the point of dispensing, or the final place where the medical product is administered to a patient – to strengthen the visibility and real-time monitoring of the integrity of the products [3].

In a like manner, vaccine traceability is characterized by the ability to monitor the entire product lifecycle of a vaccine – from production to distribution and then administration. This has emerged as a crucial aspect of ensuring the safety, efficacy, and accessibility of vaccines globally [4]. Scaling the traceability for COVID-19 and routine immunization (RI) vaccines to the local government area (LGA) and selected healthcare facilities in Nigeria led by National Agency for Food and Drug Administration and Control (NAFDAC), signifies a concerted effort to elevate supply chain systems by deploying advanced traceability mechanisms in the country. By emphasizing product monitoring and real-time stock visibility, this initiative not only aligns with the strategic goals of developing safety surveillance systems in low- and middle-income countries (LMICs), but also contributes to global collaborative endeavours in promoting transparency in supply chain systems.

In recent years, the global landscape of healthcare has witnessed a paradigm shift towards the development and implementation of innovative solutions to bolster the efficiency and transparency of vaccine supply chains. This evolution is particularly evident in the strategic initiatives undertaken by the NAFDAC in Nigeria [4]. Funded by the Bill and Melinda Gates Foundation, NAFDAC embarked on a ground-breaking project to scale the implementation of a track-and-trace system for COVID-19 and RI vaccines.

This article provides a comprehensive exploration of the successful implementation of the track-and-trace system, elucidating the achievements, challenges faced, and the reinforced regulatory framework of NAFDAC. Likewise, the utilization of GS1 standards to uniquely identify products, locations, and personnel within the supply chain underscores a commitment to international best practices. Conversely, by delving into the intricacies of the phased public sector pilot, this work illustrates the feasibility and challenges associated with tracking vaccine movement through the supply chain in the country.

Thus, this study aims to present the outcomes of field scanning activities conducted in July 2023, revealing insights into the detection of unique products across a myriad of facilities in Nigeria. It also discusses the collaborative efforts with global entities such as WHO-HQ, PAHO, ASEAN, and MHRA, emphasizing the project's role in reinforcing safety systems across regions. Furthermore, the synopsis addresses the broader implications of success – instilling confidence in patients, establishing a transparent supply chain, and fostering pharmacovigilance capabilities through seamless integration with the track-and-trace system.

Against this background, it is envisaged that the insights gleaned from the NAFDAC initiative and innovative approach will serve as eye-openers and opportunities for global health practitioners, policymakers, and researchers to emulate. Similarly, it serves as a beacon, showcasing a successful model for incorporating track-and-trace into regulatory systems, with a particular focus on its applicability in LMICs. The strides made in Nigeria stand as a testament to the transformative potential of technology-driven solutions in advancing public health on a global scale.

NAFDAC strategies for enhancing vaccine traceability in Nigeria

Some of the strategic steps that facilitate vaccine traceability in the country include:

I. Global supports

Vaccine traceability has become a focal point in global health initiatives, with various organizations emphasizing the importance of secure and transparent supply chains. Collaborative efforts and support involving entities like the WHO, Pan American Health Organization (PAHO), Association of Southeast Asian Nations (ASEAN), and the Medicines and Healthcare products Regulatory Agency (MHRA), underscore the commitment to ensuring the safety and efficacy of vaccines on a global scale [5].

II. Embracing technological advancements

The successful implementation of the track-and-trace system in Nigeria, utilizing advanced traceability mechanisms and GS1 standards, aligns with the broader trend of leveraging technology for enhanced traceability. The importance of technologies such as barcoding, RFID (radio-frequency identification), and blockchain in providing real-time visibility and

accountability in vaccine supply chains were included in the discussion below.

III. Safety surveillance systems

The strategic goals of the project, focusing on safety surveillance systems in LMICs, resonate with the global efforts to bridge healthcare disparities. Studies emphasize the importance of establishing robust surveillance systems in resource-constrained settings to monitor vaccine safety, track adverse events, and facilitate timely responses.

IV. Regulatory framework and GS1 technology-driven traceability

The strengthened regulatory framework of NAFDAC, with an emphasis on GS1 technology-driven traceability, reflects a broader trend in regulatory bodies globally. The role of regulatory agencies in setting standards, ensuring compliance, and fostering innovation in traceability technologies to safeguard public health are highlighted in this paper.

Opportunities in vaccine traceability

Patient confidence and activities promoting pharmacovigilance

The success of the project is defined by its impact on instilling confidence in patients regarding vaccine authenticity and establishing a transparent supply chain. This synopsis emphasizes the interconnectedness of traceability systems with pharmacovigilance efforts, contributing to a proactive approach to monitoring vaccine safety and efficacy.

Strengthening supply chain systems

The global significance of vaccine traceability is to strengthen supply chain systems, with a focus on the challenges, technological advancements, and regulatory frameworks shaping this initiative. The success story of the Nigerian pilot project adds a valuable perspective to the existing body of knowledge, contributing insights that can inform future initiatives in LMICs and beyond.

Challenges in vaccine traceability

Nonetheless, the phased public sector pilot approach in tracking vaccine movement through the supply chain acknowledges the challenges inherent in implementing traceability systems. Existing literature explores challenges such as infrastructure limitations, data security concerns, and the need for stakeholder collaboration in successfully deploying traceability solutions.

Aim and objectives of vaccine traceability project by NAFDAC

The project aimed to improve the scanning of COVID-19 and other RI vaccines at the level of the LGA and healthcare facilities to demonstrate the feasibility and possible challenges of tracking the movement of these vaccines through the supply chain while providing real-time event data as a prelude to the implementation of full track-and-trace in Nigeria.

The aim of this project was achieved through the following objectives:

a. Deploy a minimum of two [2] Android-enabled mobile scanners for scanning to track and trace COVID-19 and RI vaccines at each of NAFDAC's 37 state offices (including the Federal Capital Territory (FCT)).

b. Increase scanning coverage for COVID-19 and RI vaccines to cover all 37 state cold stores in Nigeria (including the FCT).

c. Increase scanning coverage for COVID-19 and RI vaccines to cover all 774 LGA cold stores in Nigeria.

d. Increase scanning coverage for COVID-19 and RI vaccines to cover at least 15 healthcare facilities in each of the 37 states of Nigeria (including the FCT).

e. Reduce scan data errors observed from data collected from scanning COVID-19 vaccines and routine immunizations at the state cold stores to less than 5%.

METHODOLOGIES OF THE STUDY

I. Acquisition of Android-enabled mobile scanners

- Collaboration between the NAFDAC information communication technology (ICT) and procurement units facilitated the acquisition of 74 Android-enabled mobile scanners.
- The procurement aimed to provide comprehensive support for facilities nationwide, enabling the scanning of vaccines distributed across various locations in Nigeria.

II. Commissioning of vaccines at National Strategic Cold Store

- The commissioning of vaccines occurred at the National Strategic Cold Store in Abuja, FCT, serving as the primary reception point for all COVID-19 and RI vaccines in the country.
- This process involved scanning the 2D Data Matrix barcode on the secondary packaging of the vaccines into the NAFDAC Traceability Information System, establishing a reference point for the verification of subsequent scans within the supply chain.

III. Training and capacity building on data capture

- NAFDAC State Post Market Surveillance (PMS) Focal Officers received training on the use of the Trackgenic app, an Android application developed by GS1 Nigeria and NAFDAC for scanning and capturing traceability events as well as information from 2D Data Matrix barcodes.
- The Trackgenic app was installed on the Android-enabled scanners for efficient scanning and on Android smartphones for data capture from approved barcodes.
- The state PMS Focal Officers cascaded training to state and LGA Cold Store Officers and other stakeholders within the vaccine supply chain.

IV. Monitoring and supervisory visits

- The state PMS Focal Officers were mobilized to conducted monitoring and supervisory visits to state central stores where shipping events for distribution to LGA cold stores and healthcare facilities are usually initiated.
- Scanning was carried out at these dispense sites to record receipt events when COVID-19 and RI vaccines were received from the National Primary Health Care Development Agency (NPHCDA) Store in Abuja.
- Training on the use of the Trackgenic mobile app was extended to many Local Immunization Officers (LIOs) and Cold Chain Officers (CCOs) during these supervisory visits.

V. Data analysis

- Data obtained from the pilot was analyzed using the R and Python programming languages and corresponding environments designed for statistical computing. Microsoft Excel was employed for systematic compilation of the results into tables.
- Initial data management procedures included the identification and resolution of scan data capture errors through data cleaning. Exploratory analysis was conducted to illustrate the distribution of data attributes.
- The findings derived from the analyzed data are presented in tables and figures.

VI. Inclusion criteria

- Only scan data conforming to the accurate Electronic Product Code (EPC) format of the GS1 standard 2D Data Matrix and the correct Global Location Number (GLN) format for the locations/read points were considered valid and included in the analysis.
- Scans displaying an incorrect EPC format or GLN read point were excluded from the analysis.

RESULTS

The following tables and figures present the results of the scanning activities within the period of the field scanning activities.

Table I. Statistics of scanning activities during project period (1–31 July 2023)

Statistics	Value (*n*)
Total scans detected across all facilities	110,113
Total facilities (GLN) where scanning was detected	1,022
Total products tracked (GTIN)	43

GLN – Global Location Number; GTIN – Global Trade Item Number
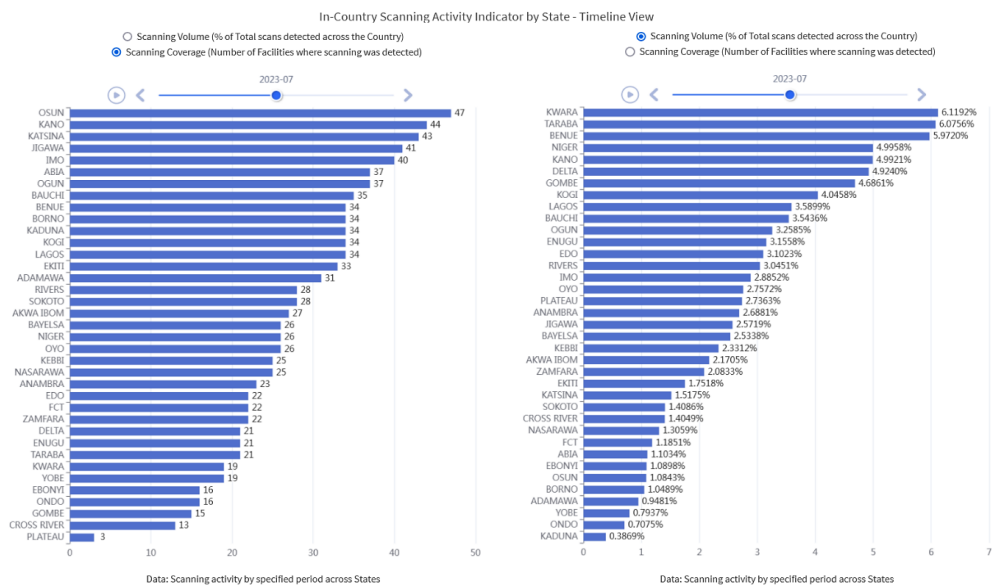

Fig. 1. Coverage and volume of scanning by states.

Table II. Statistics of scanning activities before and after project execution

Statistics	Before (2023 Jan-June)	After (2023 July-Dec)
Total scans detected across all facilities	97,278	188,191
Total facilities (GLN) where scanning was detected	162	1,153
Total products tracked (GTIN)	26	157

GLN – Global Location Number; GTIN – Global Trade Item Number

Distribution of Product Items across States

January - June 2023
(Before project implementation)

July - December 2023
(After project implementation)

● Items Last Scan Location
GLN: 162
GTIN: 26
Scans: 97,278

● Items Last Scan Location
GLN: 1,153
GTIN: 157
Scans: 188,191

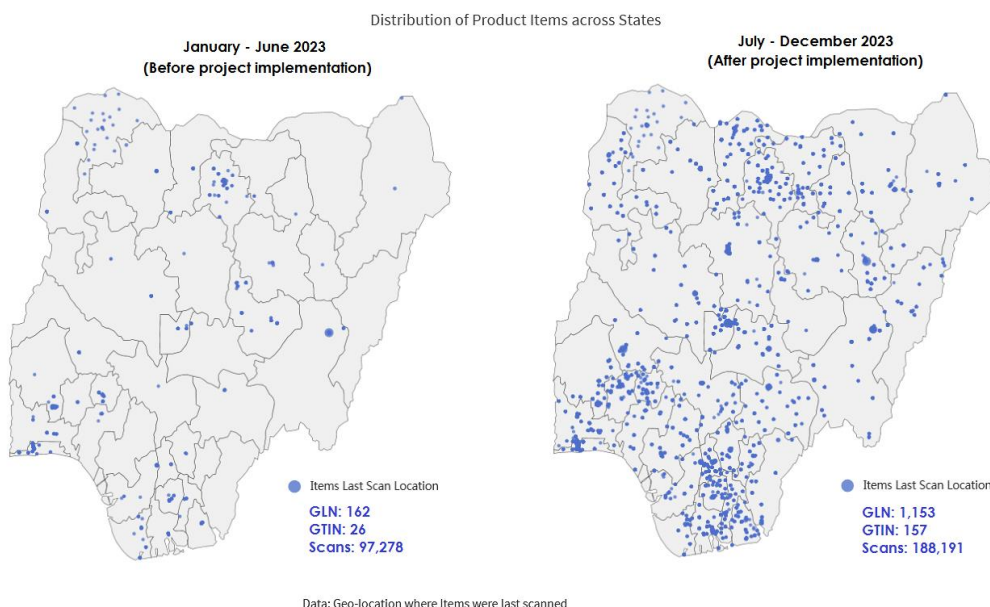Data: Geo-location where Items were last scanned

Fig. 2. Distribution of scanning activity detected across Nigeria.

Table III. Scan errors detected and excluded from analysis of results by facility type and scanning device type

Facility type	Total valid scans (*n*)	Excluded poor scans (*n*)	% scan error	Scanning devices
State cold store	71,513	2,805	3.77%	Android-enabled scanners
LGA cold store	25,547	3,376	11.67%	Smartphones
Health facility	13,053	1,982	13.18%	Smartphones
Total	110,113	8,163	6.90%	–

LGA – local government area

DISCUSSION OF RESULTS

Table I shows the total number of scans made during the period of the project, which constitute all the scans from all traceability events within the project period. The table also displays the total number of facilities where the scans were detected, which represents the coverage of the scanning across the country. The total products tracked are identified by unique Global Trade Item Numbers (GTINs) of COVID-19 and RI vaccines detected from the scans received during the field scanning activities conducted during July 2023.

The facilities (in which scanning was performed in each state ranged from 3 to 43) are depicted in Figure 1. Osun State had the highest coverage in terms of the facilities that scanned vaccines for traceability, while Plateau State had the lowest number of facilities (3 in

total) that participated. Health workers in Plateau State were on strike at the time of the field scanning activity. This project considers the total number of scans received from scanning across facilities in Nigeria through the first half of the year 2023 (January – June) to represent the scanning activity before the project.

Table II presents the scanning activity for COVID-19 and RI vaccines before and after the project supervisory visits and scanning across the states, LGAs, and healthcare facilities. Similarly, Figure 2 displays the distribution of scanning activity detected by the GLN, which is associated with each scan captured during the project period across the facilities in the different states. There was increased activity as shown by the item's last scan location points on the map. There was an increase in the number of products scanned where each GTIN represents each unique product. The scans were generated from traceability event data capture

including receiving, shipping, and dispensing events. The procured scanners were deployed to augment the hardware for scanning at the state cold stores where the COVID-19 and RI vaccines are received and further distributed to LGA cold stores and healthcare facilities across the country. Likewise, Table III provides the scan errors detected and excluded from the analysis of results by the facility type and scanning device type. The results presented in Table III imply that there is improved data capture quality with the use of dedicated Android-enabled mobile scanners when compared to the use of smartphone cameras for scanning barcodes. This script delves into the broader implications of the project's success – instilling confidence in patients, establishing a transparent supply chain, and fostering pharmacovigilance capabilities. The phased public sector pilot outlined herein not only showcases the feasibility of tracking vaccine movement through the supply chain, but also provides critical insights into the challenges that were encountered and overcome.

CONCLUSIONS

The NAFDAC-led pilot track-and-trace project for COVID-19 and RI vaccines, generously funded by the Bill and Melinda Gates Foundation, stands as a transformative initiative that has significantly impacted the healthcare landscape in Nigeria. The implementation of a robust traceability system, marked by the utilization of GS1 standards, has not only enhanced the efficiency and transparency of vaccine supply chains, but has also positioned NAFDAC as a trailblazer in the adoption of innovative solutions.

The success of the project, as detailed in this article, is evident in the achievements of the field scanning activities conducted in July 2023. The detection of unique products across numerous facilities highlights the significant outcomes of the meticulous planning and execution of the track-and-trace system. Furthermore, the collaborative efforts with our esteemed partners both nationally and internationally underscore the project's contribution to reinforcing safety systems on a global scale.

As a beacon of success, the NAFDAC initiative offers valuable lessons for global health practitioners, policymakers, and researchers. It serves as a model for incorporating track-and-trace into regulatory systems, particularly emphasizing its applicability in LMICs. The strides made in Nigeria serve as a testament to the transformative potential of technology-driven solutions in advancing public health on a global scale. The accomplishments and lessons learned from this project contribute to the evolving discourse on strengthening healthcare systems worldwide.

Author's contribution

All the authors were involved in this project as well as in the drafting and editing of the manuscript. All the authors reviewed and agreed on the final version.

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