Enabling Pharmaceutical Traceability in The Nigerian Supply Chain using GS1 Global Standards: Lean Traceability Including In-Country Serialization of COVID-19 Vaccines

Prof. Mojisola Christianah Adeyeye[a.1] , Mr. John Olusola Kayode[a], Mr. Adekunle Adebola Adeniran[a], Mrs Folasade Monisola Osho[a], Mr Walter Udokwelu[a]

[a] National Agency for Food and Drug Administration and Control (NAFDAC)

Abstract

Traceability of the pharmaceutical products across a supply chain creates an environment that provides visibility of the product status from plant to patient. The supply chain is the trade journey products make to consumers or retail stores (e.g., pharmacy store, patented drug store, medical store etc.,) via a network of producers, manufacturers, distributors, transporters, and vendors taking that product from creation to delivery. Some of the key benefits of introducing traceability in the Nigerian pharmaceutical sector, besides securing the supply chain, include an increment in the quality of data to support pharmacovigilance, decrease in the presence of substandard and falsified (SF) medications and ultimately an increase in patient safety. The drug distribution system in Nigeria is largely undefined and there have been in-country efforts to define it. One such effort has produced a national policy document referred to as the Nigeria Pharmaceutical Traceability Strategy, which stipulates the plan to achieve supply chain visibility, prevent infiltration of the SFs and strengthen existing regulatory and legal frameworks in Nigeria using GS1 global standards. The National Agency for Food and Drug Administration and Control (NAFDAC) and other drug regulatory agencies in Africa jointly signed a Call to Action during the second GS1 African Healthcare Conference held in Lagos, Nigeria on September 16-20, 2019 to demonstrate commitment to pursue pharmaceutical traceability by adopting global supply chain standards. This article focuses on how NAFDAC in collaboration with GS1 Nigeria, National Primary Health Care Development Agency (NPHCDA) and other partners have implemented traceability as a public sector pilot for the COVID-19 vaccines received in Nigeria from March 2021 to December 2021. This included the serialization of COVID-19 vaccines that were received without serial numbers that uniquely identify the secondary packing of the COVID-19 vaccines. The lessons learned from the pilot would be used to support development and dissemination of traceability regulation, publish guidelines for traceability implementation, and engage stakeholders meaningfully as Nigeria implements full track and trace of pharmaceutical products.

Keywords: Traceability, Master Data, Event Data, Serialization, Supply chain, Substandard and Falsified medications, COVID-19 Vaccines.

[1] Corresponding Author: Prof. Mojisola Christianah Adeyeye[a] - **cm.adeyeye@nafdac.gov.ng**

1. Introduction

1.1 Combatting SF Medical products in Nigeria

The critical challenges affecting the pharmaceutical supply chain in Nigeria are the lack of visibility and monitoring of the commodities along the chain. This opens the network up for circulation of sub-standard and falsified (SF) products that could result in negative health outcomes and undermine huge investments targeted at tackling diseases of public health significance.

The National Agency for Food and Drug Administration and Control (NAFDAC) was established - by the Decree 15 of 1993 as amended by the Decree 19 of 1999 and now the NAFDAC ACT Cap N1 Laws of the Federation of Nigeria (LFN), 2004 - to regulate and control the importation, exportation, manufacturing, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, chemicals, and detergents (NAFDAC, 2004). The ACT places the burden of drug distribution, sale, use, and security on the Agency.

In fulfilling its mandate, NAFDAC has been at the forefront of leveraging cutting-edge technologies to fight SF medical products. In the past, NAFDAC deployed the Truscan, Mobile Authentication Service (MAS), GPHF Minilab, and other digital interventions to strengthen the regulation of SF drugs. The increasing complexities of the pharmaceutical supply chain, chaotic drug distribution system, porous borders, and large population exacerbate Nigeria's susceptibility to SF medical products. Furthermore, with the increasing globalization of trade, supply chain fragmentation, and a complicated supply chain, National regulatory authorities' oversight capacity has become overstretched (WHO, 2019). These challenges necessitate bold innovative approaches and complementary partnerships to tackle the indefiniteness of the supply chain.

1.2 Pharmaceutical Traceability; a tool for Combatting SF Medical Products

Traceability is the ability to identify and trace the following:

- history (a set of events about an entity/item of interest)
- distribution
- location and
- use of products along the supply chain.

Traceability provides visibility of product status and location within the supply chain. This offers immense benefits in protecting the supply chain against the proliferation of SF medical products by:

- detecting counterfeit or stolen products
- promoting more efficient reverse logistics
- addressing product recalls and unused products
- strengthening pharmacovigilance and post-market surveillance systems (USAID, 2018).

Additional benefits include inventory management simplification, improved logistics and stock management practices, increased and better data collection, overall improvement of cold chain management (IFPMA, 2021).

Global standards provide a foundational framework for organizations to implement pharmaceutical traceability. In recent times, drug regulatory authorities and the health sector are increasingly adopting these standards to enable pharmaceutical traceability (USAID, 2018). These standards encompass product identification by location, barcodes and EPC/RFD for automatic identification data capture (AIDC) and data exchange and are illustrated in Figure 1 below.

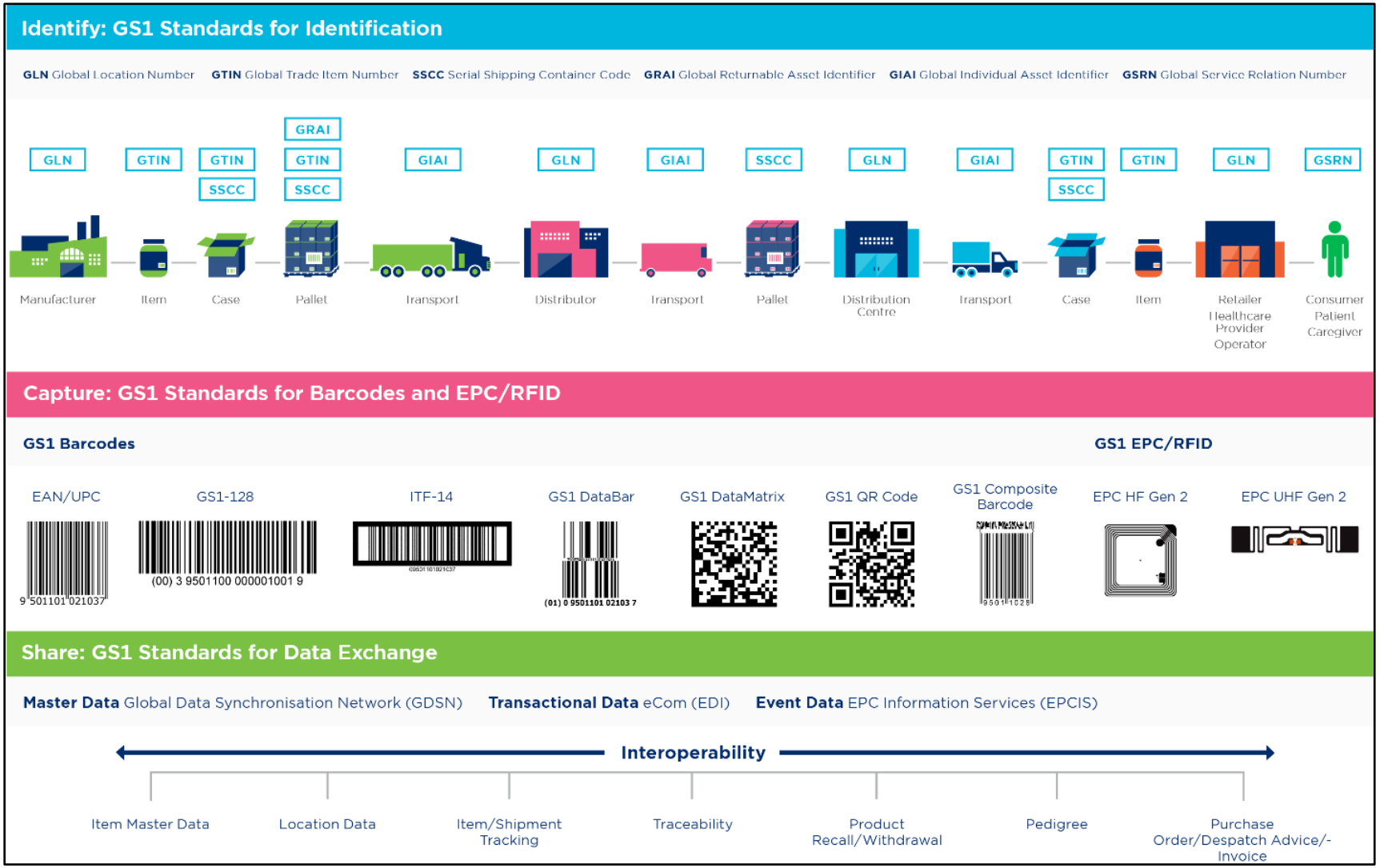

Figure 1: GS1 Standards for Supply Chain Management (GSI, 2021).

1.3 Traceability Journey in Nigeria

Globally, pharmaceutical traceability was first pioneered in Turkey, principally to prevent packaging and barcode scams implicated in huge national expenditure on medicines. Korea, the EU, India, and the USA are implementing several adaptations of this technology (Parmaksiz, Pisani, Kok, 2020).

The 1st African Conference organized by GS1 and conducted in Ethiopia, in May 2018 was very educational for the Nigerian delegates in attendance and led to the 2nd GS1 African Healthcare Conference to be held in Lagos, Nigeria. At this Conference, a Call to Action to pursue pharmaceutical traceability by adopting global supply chain standards was signed by 25 African Regulatory authorities and 6 health financing and donor organizations.

A core component of Nigeria's second National Strategic Health Development Plan (NSHDP II) is to "improve availability and functionality of health infrastructure required to optimize service delivery at all levels" as well as "ensure that quality medicines, vaccines, and other health commodities and technologies are available, affordable and accessible to all Nigerians" (FMOH, 2017). In line with this plan, the Federal Government of Nigeria and its development partners advocated for increased application of standards to strengthen stewardship and technical leadership in supply chain management and commodity security including the application of standards in strengthening pharmaceutical commodity management systems and data management. This goal was formalized with the development of the Nigeria National Pharmaceutical Traceability formally launched by the Honorable Minister for Health (HMH) on the 8th of October 2020 (FMOH, 2020). This plan is driven by five strategic objectives highlighted in Figure 2 below.

To implement traceability for all pharmaceutical products, NAFDAC established a five-year (2020-2024) roadmap which includes conducting both public and private sector pilot projects to better understand the current capabilities and implications of the implementation of traceability for all actors in the pharmaceutical supply chain. See major activities of the five-year plan in Figure 3.

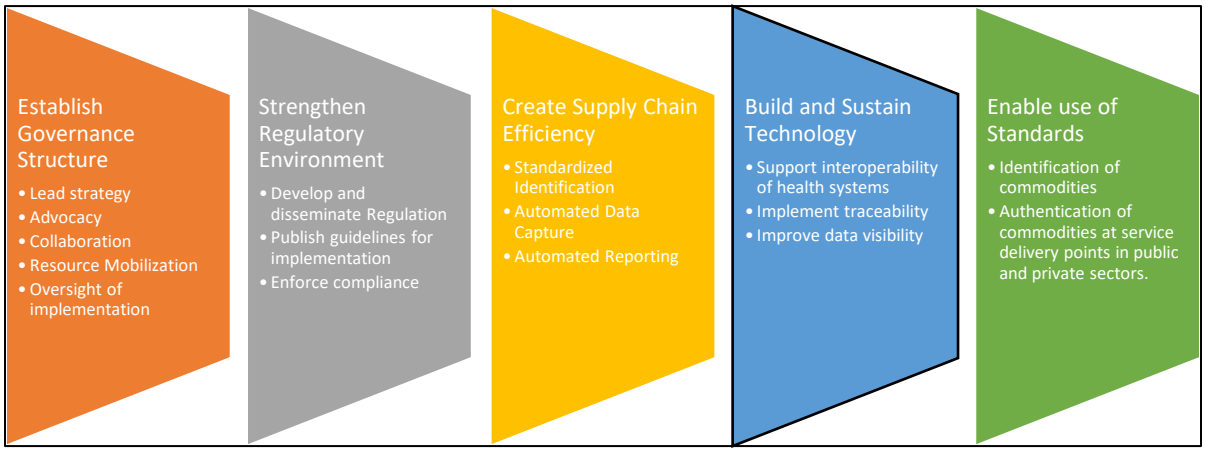

Figure 2: National Pharmaceutical Traceability Strategic Objectives (FMOH, 2020).

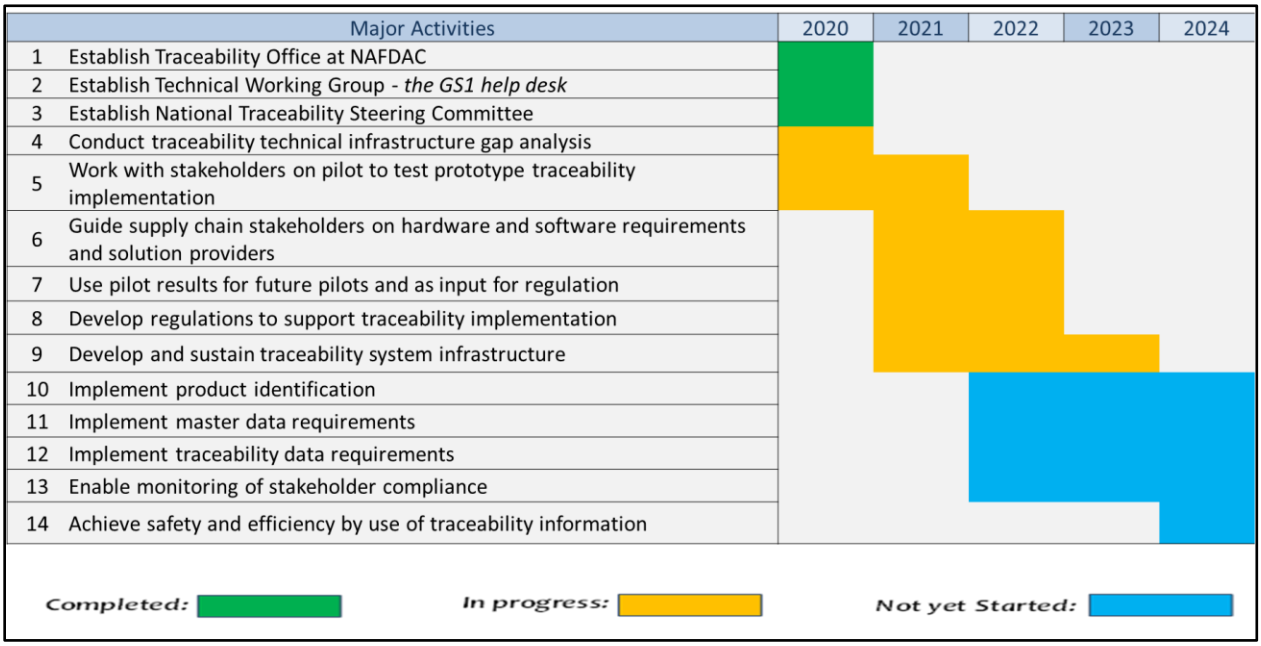

Figure 3: NAFDAC's Traceability Implementation (Five-Year Plan) (NAFDAC, 2021).

1.4 The COVID-19 Pandemic; an opportunity for Traceability Implementation in Nigeria

The COVID-19 Pandemic, which triggered an emergency global response including expedited vaccine productions and clinical trials by numerous manufacturers worldwide, presented a window to pilot traceability in the public sector. NAFDAC, in conjunction with the National Primary Health Care Development Agency (NPHCDA) and GS1 Nigeria, implemented a public sector traceability pilot for all the COVID-19 vaccines shipped into Nigeria as part of the regulatory strengthening and underscoring its mandate. NAFDAC also conducted the In-Country Serialization of non-serialized Moderna, and Pfizer brands of COVID-19 Vaccine received in Nigeria to enable the traceability of these vaccines through the supply chain. The success of the project will among other things:

i. Serve as a proof of concept and assure stakeholders that traceability is fully implementable in Nigeria for vaccines, medicines, and medical devices.

ii. Enable NAFDAC and stakeholders better understand the implications of implementing traceability and help to set realistic requirements and timelines for all.

iii. Provide reliable data on the movement of the vaccines through the supply chain to the end-user useful for detection of potential infiltration of the supply chain, reduction of incidences of wastage and expiration, shortages, and pilferage.

iv. Support the design and validation of a traceability model according to local country requirements and the development of a prototype system that can be tested in real-time.

v. Contribute to the development of NAFDAC guidelines on technical and functional requirements to build the necessary infrastructure for the implementation of traceability in Nigeria.

vi. Provide recommendations for

improvement to the existing road map for traceability implementation.

1.4.1 Objectives of Initiative

1.4.1.1 General Objective

The main objectives of the lean traceability pilot for COVID-19 Vaccines, with healthcare supply chain actors, using GS1 standards, include ensuring accountability and safety of medical products through mitigation of substandard and falsified medicines, prevention of infiltration, wastage, and diversion; use of the technology to accompany pharmacovigilance and safety; and post-marketing recall when needed.

1.4.1.2 Specific Objectives

With the above-mentioned objectives, NAFDAC seeks to implement traceability for COVID-19 vaccines using GS1 standards to:

i. Uniquely identify each unique secondary pack of the vaccine

ii. Uniquely identify locations in the supply chain through which the vaccine will be distributed.

iii. Identify personnel who have custody of the vaccine.

iv. Track the movement (events) of the vaccine as it moves through the supply chain at every point through the scanning of the DataMatrix barcodes on the vaccine.

v. Use the traceability data to support the pharmacovigilance activities for the vaccine.

2.1 Scope

The Scope of the Traceability Project is as follows:

i. To scan the Data Matrix barcodes on the secondary packaging of the COVID-19 vaccines expected to be used within Nigeria using specified data capturing devices, a mobile application TRACKGENIC® developed for the pilot and the NAFDAC Ports Clearance Application PIDCARMS.

ii. To maintain a data repository for reference and traceability of each secondary pack.

iii. Locations through which the Vaccine will be tracked will be from the NPHCDA National Strategic Cold Store at Abuja to 37 State Cold stores including the FCT and at least one (1) selected Local Government Cold Store in each State and One (1) Healthcare Facility in each selected Local Government.

iv. The COVID-19 vaccines will also be tracked from the FCT and Lagos Cold Stores to Two (2) Pharmacovigilance Sentinel Healthcare Facilities, which include the University of Abuja Teaching Hospital Gwagwalada and the Lagos University Teaching Hospital.

v. This paper will focus on traceability implementation from its inception in March 2021 till December 2021.

2.2 Out of Scope

The paper will not consider:

- Primary Packaging Traceability at point of administration
- Traceability to locations not specified in the scope.

2.3 Phase of Activities for COVID-19 Vaccine Traceability in Nigeria

To ensure the successful deployment of the traceability project, a phased approach was adopted, detailing the technical requirements, resources, and infrastructure needed. Activities are captured in Figure 4 below. Key activities are highlighted below:

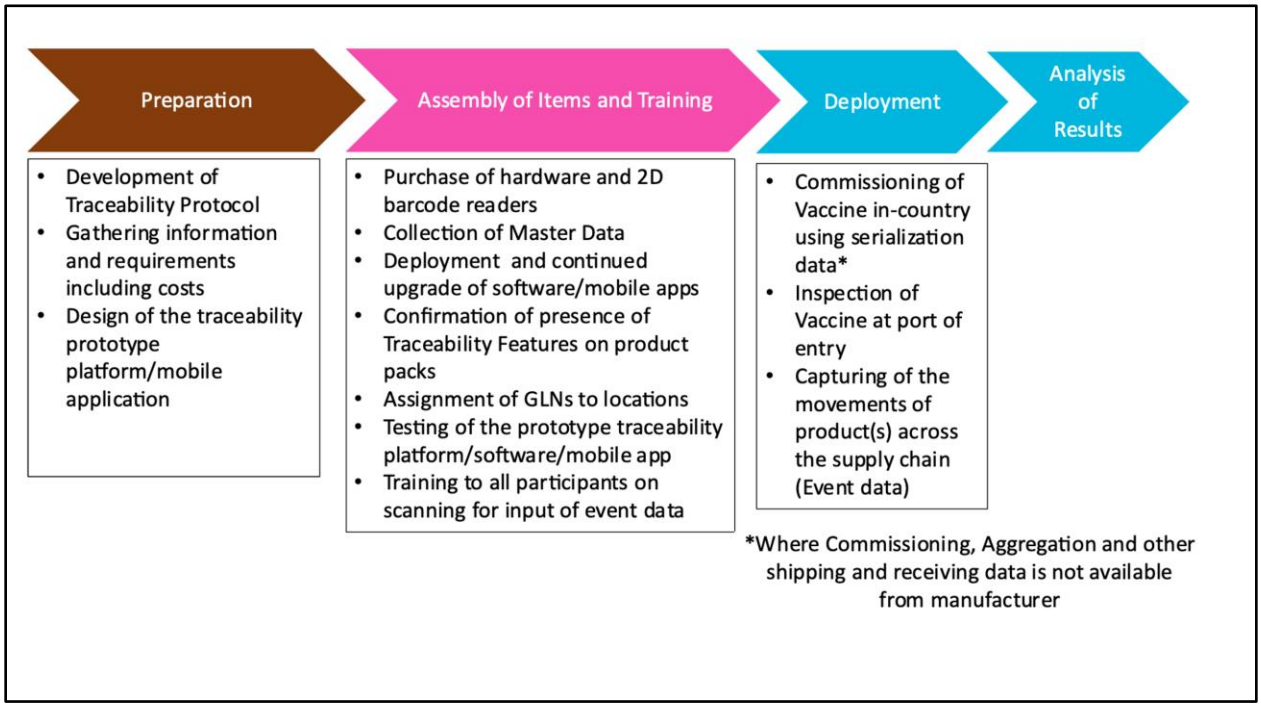

Figure 4: Phase of Activities for COVID-19 Vaccines in Nigeria

2.3.1 Packaging and Location Features

Identification of the vaccine was at the level of the Secondary Package Figure 5 describes the levels of packaging material) with Global Trade Item Number (GTIN) + batch/lot number + expiry date + serial number where this combination uniquely identifies every product pack.

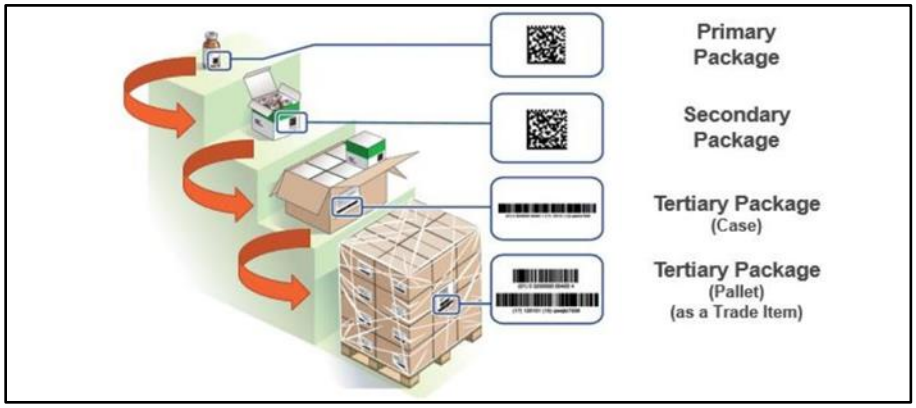

Figure 5: Levels of Packing

Global Location Number (GLN) uniquely identified each supply chain location and the DataMatrix barcode was used to embed traceability data + Human Readable Interpretation as seen in Figure 6 below.

Figure 6: 2D Data Matrix + Human Readable Interpretation

2.3.2 Supply Chain Map

For this traceability project, the movement of the COVID-19 vaccines was tracked forward through the supply chain to the recipients and the origin of the vaccines is traced back to the manufacturer. The vaccines were scanned at different points from the port of entry to the recipient as shown in Figure 7 below.

2.3.3 In-Country serialization Activities

2.3.3.1 First In-Country Serialization of Moderna COVID-19 Vaccines Received in Nigeria

The arrival of the Moderna brand of the COVID-19 vaccine in August 2021 at the NPHCDA Strategic Cold Store, FCT – Abuja triggered the first in-country vaccines serialization event for Nigeria, which was done collaboratively by designated teams of experts from NAFDAC, and GS1 Nigeria.

The GTIN (Global Trade Item Number), Lot Number/Batch Number, and Expiry Date were already assigned by the manufacturer to the vaccines received. However, the Serial Number that creates the uniqueness among the item instances in a batch was not assigned to the vaccines received but was generated in-country after the vaccines arrived in Nigeria.

The GS1 Element String including the GS1 Application Identifiers was used to encode and generate the GS1 DataMatrix barcode for unique identification of each secondary pack of the Moderna vaccines. The GS1 Element String comprised segments of GTIN, Lot Number, Expiry Date, and Serial Number. The segments were delimited with Application Identifiers. The GS1 Element String was used as the Unique Identifier for each secondary pack of the vaccine.

The Serial Number Pattern was Alphanumeric and for the barcode encoding, the Serial Number Character Length was between 8 and 10. The volume of serial numbers generated was based on the expected number of secondary packs in the shipment. Unused barcodes were destroyed while commissioned barcodes that were not used to label any pack were decommissioned and then destroyed.

The in-country serialization of Moderna vaccines was conducted between the 10^{th} – 15^{th} of August 2021 (6 days). The activities included the following:

i. Generation of serialized unique identifiers (UID) corresponding to the quantities received for each of the batches.
ii. Encoding the GTIN, Batch Number, Expiry Date, and Serial Numbers in a GS1 standard DataMatrix followed by printing of the barcode on label stickers.
iii. Commissioning the printed barcode stickers by scanning and arranged by batches.
iv. Labelling the vaccines stored in Ultra-Cold Chain (UCC) freezers with the already commissioned barcode stickers.

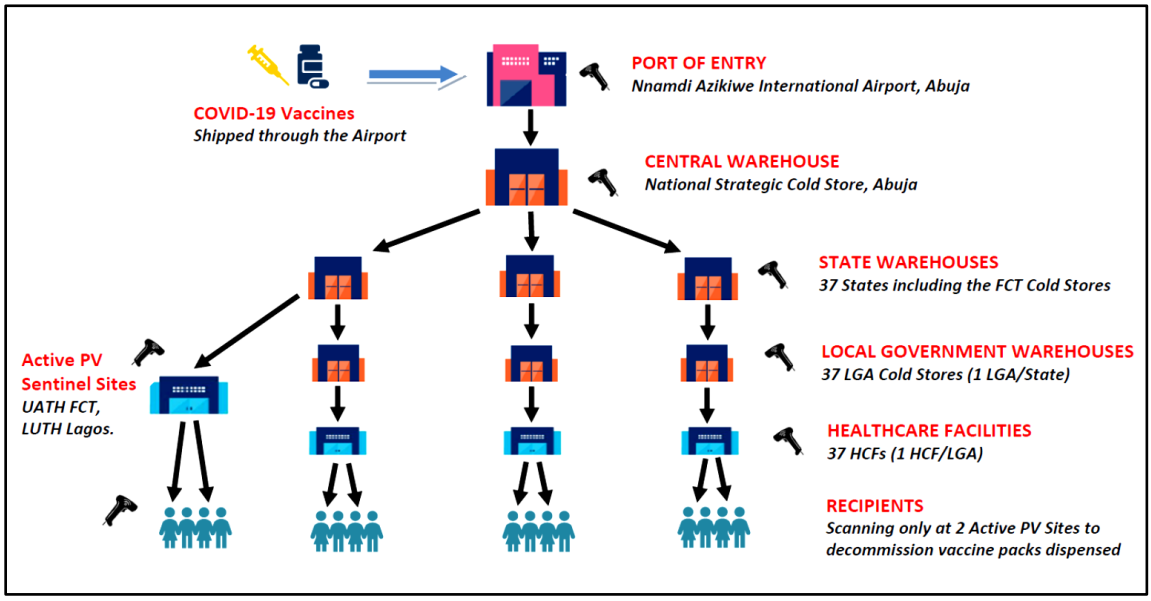

Figure 7: Traceability of COVID-19 Vaccines Supply Chain Map

2.3.3.2 Second in-Country Serialization of Pfizer BioNTech COVID-19 Vaccines Received in Nigeria

Pfizer BioNTech vaccines arrived in Nigeria on the 14th and 15th of October 2021. It was discovered that while the diluents were serialized, the trays carrying the vials were not. A meeting was scheduled on the 19th of October 2021 with a representative from Pfizer to discuss the need for the serialization of the vaccines or perhaps a request for the serialization data if possible, especially for the track and trace efforts already started in the country for COVID-19 vaccines. The outcome of the meeting was that Nigeria could go ahead to serialize in-country and then share the data with Pfizer USA.

The in-country serialization of Pfizer BioNTech vaccines was conducted between the 28th – 31st of October 2021 (4 days). The activities also proceeded as was done for the Moderna vaccines detailed in section 2.3.3.1 above. In addition to the aforementioned activities, the barcodes that should not be scanned were obscured.[2] A third and fourth in-country serialization was also conducted for Pfizer BioNTech and Moderna COVID-19 vaccine received into the country in November 2021, in the same manner as the first and second in-country serialization were conducted. For both Pfizer and Moderna vaccines, the serialization was done for in-country monitoring knowing that many manufacturers could not include this in the process because of the pandemic. Based on the global traceability initiatives, manufacturers are now sensitized to make the GS1 technology-driven bar-coding in their manufacturing.

2.3.4 Activities performed to Support Surveillance Activities

2.3.4.1 Training and Capacity Building on Data Capture;

[2] There were about three barcodes on each Pfizer BioNTech vaccine tray besides the stickers we had printed and which would be affixed on it, this was a challenge and would create confusion for those we would be scanning when the vaccine is eventually released for distribution. On top of each tray were QR and 2D data matrix barcodes and another 2D data matrix by the side. And then the labels we had printed which were to be affixed on each tray. This challenge was resolved by sticking blank labels on the barcodes on top of each tray to obscure them and then the serialized labels we had generated were affixed directly on the 2D data matrix by the side. This way, designated officers for scanning during distribution are not confused. The measures we took were necessary to reduce error margins for wrongful scanning.

Each focal officer was trained on the use of the Trackgenic app; an android application, a tool developed by GS1 Nigeria, and empowered to scan and collate unique data from the DataMatrix barcodes. This application uses the camera modules of android smartphones and tablets to emulate handheld scanners and pick valid barcodes.

2.3.4.2 Monitoring and Supervisory Visits; Each state's focal officer(s) visited (and continues to visit) the state's central store each time COVID-19 vaccines are received from the NPHCDA Store in Abuja, to scan appropriately (record receipt events) before products are distributed to dispense sites for vaccination. Scanning is also done at these dispense sites to yield dispense events and mark such products as dispensed.

Many of the Local Immunization Officers (LIOs) and Cold Chain Officers (CCOs) were also trained on the use of the Trackgenic mobile app.

2.4 Data Analysis

Data received from the pilot were analyzed using the R and Python language and environment for statistical computing. Preliminary data management involved data cleaning to identify and handle scan data capture errors. Exploratory analysis was performed to show the data structure distribution of the data attributes. Results of the analyzed data are presented in tables and figures.

2.5 Inclusion Criteria

Only scan data that captures the correct Electronic Product Code (EPC) format of the GS1 standard 2D data matrix as well as the correct GLN format for Locations/Read Points was VALID and included in the analysis. Scans with incorrect EPC format or GLN Read Point were excluded from the analysis.

3.0 RESULTS

3.1 AstraZeneca/Oxford Vaccines

This project commenced in March 2021 with the arrival of 3,924,000 (about four million) doses of the COVAX AstraZeneca/Oxford vaccines (Covishield) manufactured by the Serum Institute of India.

For the scanning undertaken upon entry at the airport and across 425 registered locations across 34 states and the FCT state cold stores, Figure 8 displays the distribution of valid and invalid scans for Astrazeneca COVID-19 Vaccines across the country.

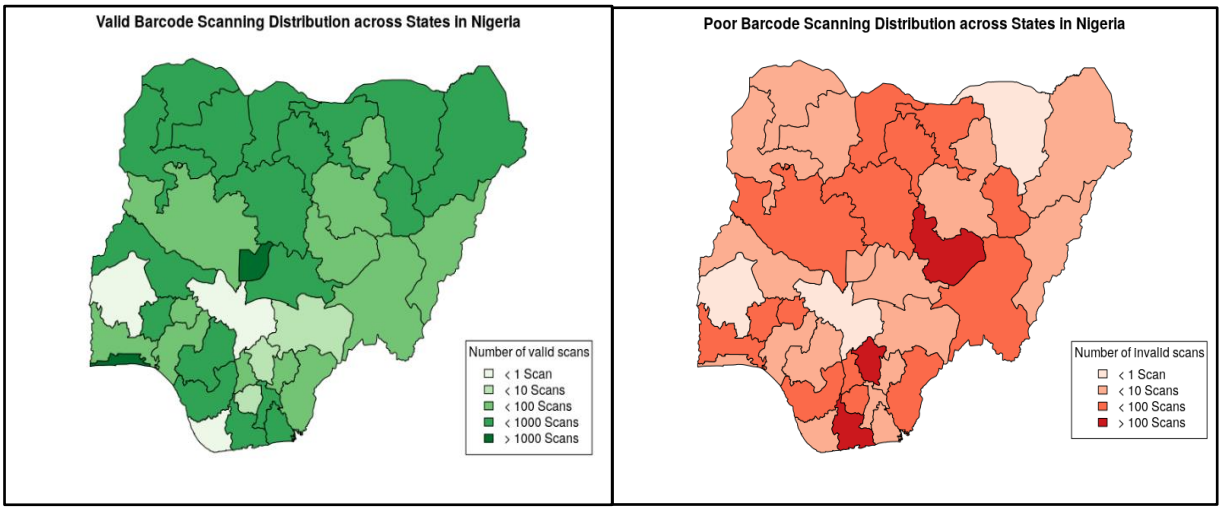

Figure 8: Distribution of Valid and Invalid Scans for AstraZeneca COVID-19 vaccines across the States of Nigeria.

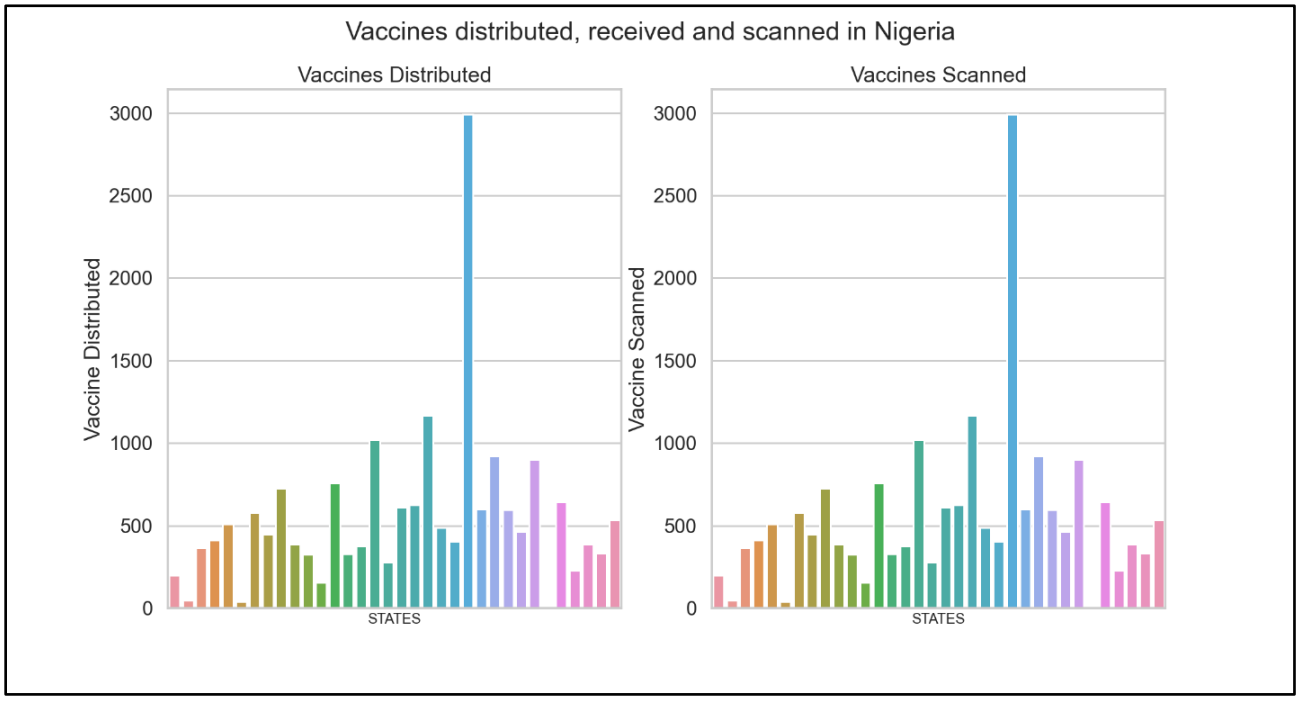

Figure 9: Chart showing the pattern of the first tranche of Moderna vaccines distributed vs Moderna vaccines scanned across the states in Nigeria

3.2 Moderna Vaccines

A total of 28,600 packs of the Moderna COVID-19 vaccines were serialized and scanned (about 4 million doses of the vaccine). Data shows that the number of Moderna Vaccines shipped to the states is equal to the number of vaccines received in the states. From Figure 9 above, the quantity of vaccines distributed is similar to the quantity scanned across the states in Nigeria.

3.3 Johnson and Johnson Vaccines

On 11 August 2021, 177,600 doses of Johnson and Johnson COVID-19 vaccine shipment were received in the country. These packets had serial numbers; thus scanning was done on the secondary packaging by scanning into the NAFDAC PIDCARMS portal for appropriate tracking and tracing when the vaccine is deployed for use. A shipment of the AstraZeneca vaccine (699,760 doses) donated by the UK Government was also received in the country on 16 August 2021. These were also scanned accordingly before distribution to the states.

3.4 Detailed summary of Vaccines received in-Country

The various shipments of vaccines received in Nigeria including the aforementioned ones are displayed in Figure 10 below. N.B. The Oxford-AstraZeneca COVID-19 are sold under the brand names Covishield and Vaxzevria (previously COVID-19 Vaccine AstraZeneca.

4.0 DISCUSSION

The availability of commissioning and aggregation event data prior to the shipping of the product is crucial to traceability. Event data was not available before the arrival of the AstraZeneca vaccines, and this occasioned the scanning and commissioning of every secondary pack shipped to Nigeria during the port inspection of the vaccines. . A total of 7,672 packs of 50 multi-dose vials which accounted for 97.76% of the expected vaccines were successfully commissioned. The omitted packs could be due to scan errors or the omission of some packs during the scanning.

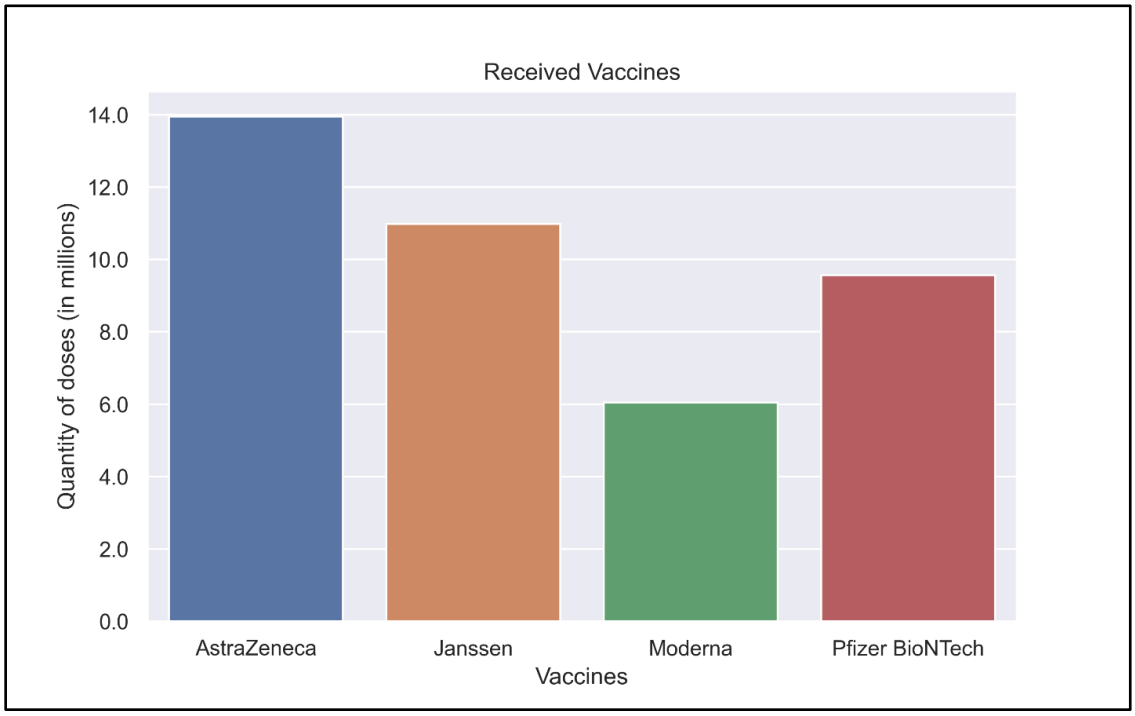

Figure 10: Quantity of Vaccines and brands received in-Country (March – December 2021)

The traceability implementation was limited by the non-availability of mobile Android-enabled scanners at the level of the States, LGAs, and Healthcare Facilities, which led to issues with several invalid scans. This high rate of commissioning lends credence to the possibility and capacity to undertake pharmaceutical traceability in Nigeria. Also, the occurrence of invalid scans provides an investment case for providing the needed infrastructure such as hand-held barcode scanners, which are critical to a successful implementation of the traceability project in Nigeria.

For the period under review, the scanning activities for traceability of AstraZeneca vaccines showed valid scans from 34 States and the FCT. Only in Kogi and Oyo States were no scanning done while all the scans from Bayelsa State were poorly captured. Although some discrepancies were observed, the batch distribution detected by scanning for the AstraZeneca vaccines across the States was largely, as expected. A total of 425 locations were assigned GLNs across the different States and the FCT during the implementation. Despite the short timeline for deploying this pilot, the uptake of this project by 35 out of 37 federating units in Nigeria is a win and must be sustained. Whereas, states, where no scanning was done, would require investigation and necessary advocacy to ensure uptake.

The in-country serialization and commissioning of a total of 27,116 secondary packs of the Moderna 10 multi-dose COVID-19 vaccines accounted for 94.9% of the expected packs successfully labelled. Scanning for the commissioning of the barcode label stickers was done just before labelling the packs to ensure the timely return of vaccines to ultra-cold storage due to the temperature-sensitive nature of the vaccines. It took less than 2 minutes to label each tertiary pack of 12 secondary packs. The ultra-cold chain freezers were set to store the vaccines at approx. -45^0C and the labelling activity did not increase the temperature of the UCC above the -15^0C limit for storage. Multiple teams worked concurrently to ensure that the serialization was completed as scheduled. Similarly, the capacity to undertake the in-

country serialization reveals NAFDAC's readiness to deploy traceability.

The scanning done at dispense sites is carried out mainly in Abuja and Lagos for now (there are the two Active Sentinel Sites, other locations would be trained accordingly to carry out dispense activity. The dispense events mark the product (vaccine vial) as already utilized and any attempt to infiltrate the supply chain with a vial that has been dispensed on the PIDCARMS portal would be detected.

About 27,207 secondary packs (an estimated 3,796,240 doses) of 10 multidose vials of the Moderna vaccines were serialized and commissioned and seven (7) batches were detected.

As of 5 November 2021, valid scans (receive events) have successfully been recorded across the thirty-six (36) states of the Federation plus the FCT. The Lagos State recorded the highest number of scans (2, 993 valid scans across 4 batches) and Oyo state recorded the lowest (9 valid scans across 2 batches) for the Moderna vaccines.

The number of scanning sites/facilities is 310 with Niger state having 91, the highest, and about 13 other states including Kebbi, Ebonyi, Borno, Bayelsa, Anambra, and 8 other states having one each. For the period under review, there were no records of events for Kwara, Kogi, and Rivers State.

From collated "dispense events" for Moderna, FCT- Abuja recorded valid scans of 719 secondary packs while Lagos yielded valid scans for 893 packs. A total of 20,403 valid scans were recorded nationwide for "receipt events" and 1,612 scans for "dispense events" of the Moderna vaccines.

5.0 CONCLUSIONS

NAFDAC in collaboration with partners has initiated traceability protocols using hand-held portable scanners to collate data from affixed 3D barcodes on secondary packaging of these COVID-19 vaccines recorded over twenty-three million successful scans by the NAFDAC traceability office and ad-hoc staff at the National Strategic Cold Store (NSCS), Abuja. The vaccines are further scanned by the various PV officers in collaboration with Cold Chain Officers and Local Government LIOs using the Trackgenic App (a mobile app developed by the IT section of GS1 Nigeria) when the vaccines are distributed to States and eventually to the healthcare sites or facilities where vaccination occurs. Collated data were analyzed, cleaned, and employed to monitor real-time events relating to the dispatch, receiving and dispensing of vaccines.

The traceability of COVID-19 vaccines, which is still ongoing, has so far provided visibility of the movement of the vaccines across the supply chain in Nigeria. The in-country serialization of the Moderna and Pfizer BioNTech for the visibility of the vaccines across states during distribution has been largely successful, especially for the Moderna and the Pfizer BioNTech vaccines. Furthermore, implementing this pilot will be immensely beneficial in:

- consolidating existing regulations,
- publishing guidelines for traceability implementation,
- conducting private sector pilots,
- identifying technical and infrastructure gaps
- engaging stakeholders meaningfully; and
- establishing a fully scalable tracking and tracing system for pharmaceutical products..

Despite recorded success for in-country serialization and improved barcode scans, there is still a need for continual improvement especially in areas of training for human resources, peer communication, providing android-enabled scanners and related logistics.

Generally, Nigeria's successful traceability pilot distils valuable lessons for other countries, implementing similar interventions, especially within resource-constrained settings. First, the Agency leveraged its experience and the historical knowledge of its personnel in the area of deploying innovative cutting-edge digital technologies. Secondly, human resource requirements that enabled rapid deployment and

geographic spread of the traceability project were made possible by the Agency's regulatory presence in Nigeria's federating units. However, the gains from this project can only be sustained by strong collaboration and coordination with other relevant stakeholders. Finally, NAFDAC's ongoing efforts at implementing several institutional strengthening programs, such as the ISO 9001 Quality Management systems, and WHO Global Benchmarking Project, will increase its capacity to prevent, detect and respond to the challenge of SF medical products.

6.0 ACKNOWLEDGEMENTS

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7.0 CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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