

Assessment of the Quality of the Reverse Cold Chain Management in the Acute Flaccid Paralysis (AFP) Surveillance System for Polio Eradication; South-south Zone, Nigeria 2015

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Abstract Background: The Global Polio Eradication Initiative (GPEI) uses the reverse cold chain system to measure the integrity and quality of stool specimen collected and transported to the laboratory. This paper aims to determine the quality of the reverse cold chain system during stool specimen collection and transportation to the polio laboratory. **Methods:** A cross-sectional survey was conducted between November-December 2015 using structured questionnaires uploaded on an open data kit-collect mobile software (ODK-collect) in 56 LGAs and 332 sites in Akwa Ibom, Bayelsa, Cross River, Delta, Edo and Rivers States. The information collected from all identified respondent covered knowledge on stool sample collection, packaging, storage and transportation. The data collected using the ODK-collect mobile software was submitted to WHO server in real-time. The EPIINFO software was used to run queries on the database and to obtain the specific data sets used in this study from the WHO server. **Results:** A total of 165 AFP cases were reported between November and December 2015. The mothers and the DSNOs collected 77% and 15% off the stool specimens respectively. Almost all cases (98.2%) had 2 stool specimens collected 24-48hours apart (98.1%) into dry, leak proof containers (98.2%). Between January-October 2015, 1955 AFP stool specimen were sent to the polio laboratory from the 6 states in the zone. Though 80.4% of the icepacks used were frozen, power shortages still affected the production of 55.3% of these icepacks. This was coupled with the long distances travelled by the DSNOs to their respective state capitals (WHO office) for travel clearance and specimen inspection. 63% of the stool specimens were placed in the Vehicle's trunk during transport to the laboratory. **Conclusions:** This study identifies gaps in the reverse cold chain system; we recommend that the gaps observed in this survey be addressed systematically. This would enhance the reverse cold-chain system and the AFP surveillance system by extension as we proceed towards polio-free certification.

Keywords: reverse-cold-chain, AFP-surveillance, non-polio-enterovirus

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1. Introduction

The Global Polio Eradication Initiative (GPEI) has made giant strides since its inception by the World Health Assembly's Resolution 41.28 of 1988. [1,2]. This resolution stated the commitment of the World Health Organization (WHO) to eradicate poliomyelitis in all countries. Currently, Nigeria is on the verge of attaining this goal haven successfully deployed the strategies of high routine immunization (RI) coverage with at least 3 doses of oral polio vaccine (OPV), supplemental

immunization activities (SIAs), effective surveillance system and mopping-up immunization campaigns to stop transmission of the wild poliovirus in the country in July 2015. [3,4]

It has however become imperative to review the quality of the data used to determine a country's polio-free status in line with the GPEI's framework for polio-free certification as Nigeria approaches this feat. These entails close monitoring of the reverse cold chain system for stool specimen transportation and subsequent feedback from the polio laboratory. The low internal temperature of the carrier boxes used in transporting stool specimens from acute flaccid paralysis (AFP) cases remains important for

the preservation of the poliovirus and other non-polio enteroviruses (NPEVs) [5]. A recent study reported that the poliovirus titer depended to a large extent on the temperature regime of the reverse cold chain transport system. [6]. This means that undue delays and prolonged exposure to heat on the way to the laboratory could result in the breakdown of the reverse cold chain system.

In the absence of poliovirus, NPEV isolation rates from stool samples collected from AFP cases serves as one of the global indicators for polio eradication. WHO requires that, at least 10% of stool samples submitted to the laboratory must have NPEVs isolated [7]. One of the key factors that could adversely affect NPEV isolation is the reverse cold chain management from the point of stool sample collection until it gets to the laboratory. This indicator therefore describes the condition of the stool specimen at arrival in the laboratory and determines the ability of the accredited laboratory to isolate poliovirus from that specimen if it was present.

This operational research seeks to determine the quality of the reverse cold chain system during stool specimen collection and transportation to the polio laboratory, determine the level of involvement of the Local Government Area (LGA) Disease Surveillance and Notification Officers (DSNOs) in stool specimen collection, to find out how these stool samples were collected from AFP cases and by whom and finally, to make recommendations on how to bridge identified gaps in stool collection and transportation while sustaining the good practices observed.

2. Methods

2.1. Study Design

A cross-sectional survey was conducted between November-December 2015 using structured questionnaires uploaded onto an open data kit-collect mobile software in 56 LGAs and 332 sites in Akwa Ibom, Bayelsa, Cross River, Delta, Edo and Rivers States while assessing previous data collected between January-October 2105.

The focus of this study was to collect quantitative data on the status of reverse cold chain including stool sample collection, packaging, storage and transportation to the polio laboratory. It was meant to provide a general view about some of the issues that could be addressed to enhance the quality of reverse cold chain in the zone. Structured questionnaire and in-depth interview were used. The questionnaire was developed for all identified respondents, namely, the LGA Director of Primary Health Care, Disease Surveillance and Notification Officers and Parents/Caregivers of recent AFP cases, and covered

knowledge of recommended procedures for stool sample collection, packaging, storage and transportation.

2.2. Data Collection

This study used a convenient-sampling method. A desk review was conducted to select LGAs with low or decreasing non-polio enterovirus isolation trend, evidence of poor reverse cold chain, high population density and good AFP surveillance core indicator performance. Study participants were recruited after informed consent was obtained. Interviewers identified the respondents and administered a questionnaire.

The data collected using ODK-collect mobile software were submitted to the WHO server in real-time. EPIINFO-a customized software built by the United States Centers for Disease Control and Prevention in partnership with WHO was used to run queries on the Access database and obtain the specific data sets used in this study.

Specifically we ran several analyses using EPIINFO and Microsoft Excel version 2010 to obtain the required data sets and produce the study results. Select-Statements command in EPIINFO was used to select the particular variable and place constraints on the time interval for the data sets needed for the study.

3. Results

Section 1- Procedure of stool specimen collection at the Household (family) level: November-December 2015.

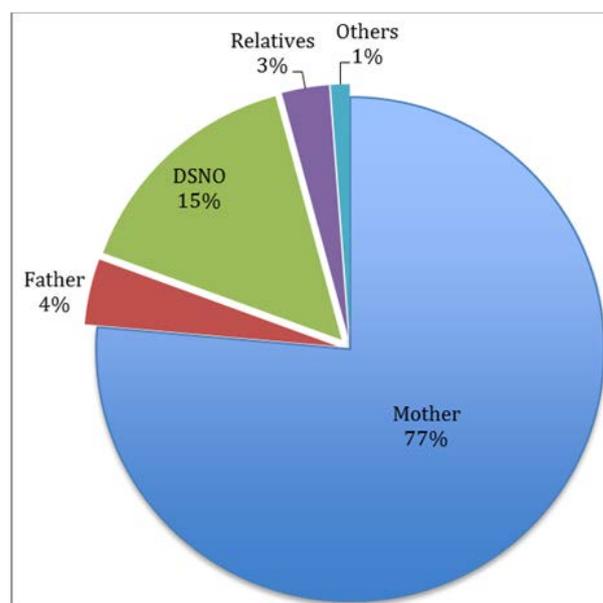


Figure 1. Individual contribution to AFP stool specimen collection at the family level: November-December 2015

Table 1. Assessment of the AFP stool specimen procedure at the family level: November-December 2015.

Parameters	Yes (%)	No (%)
Were 2 stool specimen collected from all AFP cases	163 (98.2)	2 (1.8)
Did stool samples collected weigh about 8grams (thumb size)?	164 (99.4)	1 (0.6)
Was stool sample collected immediately the child passed stool into a dry, leak proof container?	163 (98.2)	2 (1.8)
Was stool sample collected immediately and stored in a Geostyle specimen carrier and properly sealed?	160 (96.9)	5 (3.1)
Were the two stool samples collected 24-48 hours apart in all cases of AFP investigated?	162 (98.1)	3 (1.7)
Any issue with stool specimen collection process at the house hold level?	25 (15.2)	140 (84.8)
Is there history of visiting different health care giver/sites before the case was notified/reported?	48 (29.1)	117 (70.9)
Is the parent/caregiver aware of other AFP case(s) around the neighbourhood or anywhere apart from this case?	2 (1.8)	163 (98.2)

Adequate stool specimen collection remains paramount to the AFP surveillance system as without which; case detection would amount to mere speculations. **Figure 1** highlights individual contributions to AFP stool specimen collection at the family level, November-December 2015.

A total of 165 AFP cases were reported between November and December 2015. The mothers collected 77% of the stool specimens with the DSNOs only participating minimally (15%).

Table 1 shows that 98.2% of the AFP cases had 2 stool specimens collected 24-48 hours apart (98.1%) into dry, leak-proof containers (98.2%). Also, 96.9% of these stool

samples were stored immediately after collection into geostyles specimen carriers with frozen ice packs. There were mostly no problem (84.8%) with the stool specimen collection from the AFP cases and 70.9% of the children had not visited any healthcare centres before the cases were notified. Also, 98.2% of the parents in general were unaware of any other AFP cases around their neighbourhood.

Section 2- AFP stool specimen handling and the reverse cold-chain system involved in stool specimen transport: January-October 2015.

Table 2. Visitation to designated surveillance focal sites by state-level surveillance personnel and DSNOs across the states in the south-south zone, January- October 2015

States	No. Of surveillance focal sites	No. Of surveillance focal sites visited (%)	No. Of stool sample sent to the lab (%)	Distance travelled by DSNO to state capital for sample inspection (hours)
Akwa Ibom	184	16 (8.7)	48 (2.5)	0.3
Bayelsa	102	101 (99)	278 (14.2)	1.8
Cross River	102	51 (50)	217 (11.1)	2.9
Delta	104	81 (77.9)	578 (29.5)	2.4
Edo	150	68 (45.3)	488 (25)	1.8
Rivers	91	15 (16.4)	346 (17.7)	4.6

Table 3. AFP stool specimen handling and transport via the reverse cold-chain system at the LGA level, January-October 2015

Parameters	Yes (%)	No (%)
Was there existing stock of frozen ice pack? Observe and inspect the frozen ice pack available (n=56)	45 (80.4)	11 (19.6)
Does DSNO have source of constant power supply to produce ice packs? (n=56)	25 (44.5)	31 (55.3)
Are their Geostyle specimen carriers and ice packs used strictly for stool sample collection in all cases of AFP investigated?	48 (85.7)	8 (14.3)
Are the Geostyle specimen carriers and ice packs cleaned after use for collection and transport of stool samples?	47 (83.9)	9 (16.7)
Did all stool samples collected arrive the laboratory within 72 hours of collection in all cases of AFP investigated? (n=1,955)	1838 (94)	117 (6)
Did DSNO observe or collect stool samples personally? (n=1955)	645 (33)	1310(67)
Was there any delay on the road either by accident or mechanical fault of vehicle in all cases of AFP investigated? (n=56)	42 (75)	14 (25)
Was official documentation/clearance required for DSNOs to transport stool sample to the laboratory for security reasons? (n=56)	21 (37.5)	35 (62.5)
Was there any delay in submission of stool sample in the polio laboratory? (n=56)	9 (16.1)	47 (83.9)
Was the sample inspected for adequacy before receipt at the laboratory?	56 (100)	0 (0)
Were the personnel of the State cold store given prior notice for change of ice packs before DSNO leaves the LGA with stool sample? (n=56)	30 (53.6)	26 (46.4)
At the state level does the DSNO change icepacks before travel to Ibadan (n=56)	44 (78.6)	12 (21.4)
Are all the ice packs available from State (irrespective of source) well frozen to sustain temperature of <8°C for at least 48 hours at all times? (n=56)	53 (94.6)	3 (5.4)
Are there dedicated freezers and ice packs at the State-level (where icepacks are sourced) used strictly for AFP investigation? (n=56)	48 (85.7)	8 (14.3)
Prior to travel to the polio laboratory was the stool sample (last three samples) inspected by any WHO staff? (n=56)	42 (75)	14 (25)
Are DSNOs cleared before departure to the polio laboratory? (n=56)	51 (91.1)	5 (8.9)

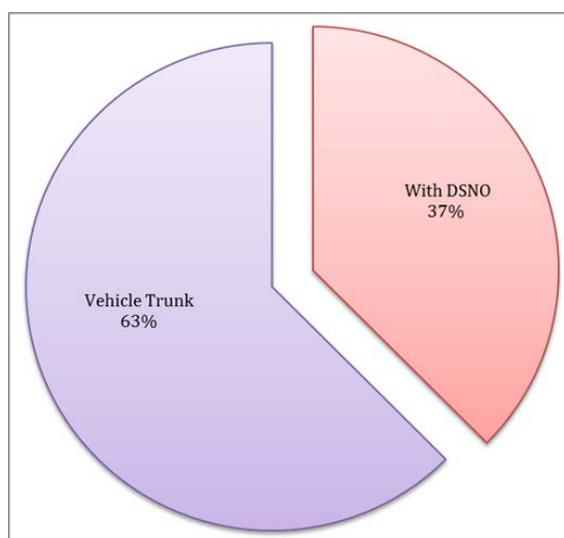


Figure 2. Vehicle position of Geostyles during transport to the polio reference laboratory

The LGA DSNOs and the surveillance focal person at the designated focal sites also play an important role in AFP case detection, investigation and transportation of stool specimen, using the reverse cold-chain system, to the polio laboratory for analysis.

Table 2 shows the visitation frequency to designated surveillance focal sites by state-level surveillance personnel and DSNOs across the states in the south-south zone, January- October 2015. During this period, a total of 1955 AFP stool specimen were sent to the laboratory with Akwa Ibom state accounting for the least stool sample sent (48). The state-level surveillance personnel/ DSNO visited only 8.7% of the 184 focal sites in Akwa Ibom state. In Bayelsa state, 99% of the focal sites were visited and 278 stool samples were sent to the laboratory, a feat only eclipsed by Delta state (578) even when only 77.9% of its focal sites were visited.

In **Table 3**, 80.4% of the 56 icepacks were frozen and maintained for stool specimen storage and transportation and 85.7% of the 56 geostyles were strictly used for stool sample collection.

The DSNOs only gave prior notice to the state cold store for icepack change for 53.6% of the total icepacks. However the state-level cold store still managed to change 78.6% of the icepacks for the DSNOs before they commenced travel to the laboratory. It should be noted that 94.6% of all icepacks available from the state-level irrespective of the source were well frozen to sustain internal temperature of the stool specimen carrier below 8°C for at least 48 hours. Also, 85.7% of the icepacks at the state level were produced in dedicated freezers strictly used for AFP case investigation. About 83.1% of both icepack and geostyles were cleaned after use for storage and transportation of stool specimen.

Prior to departure for the polio laboratory, a WHO staff inspected 75% of the stool specimens from the last 3 AFP cases from each state in the zone and 94% of all the specimens reached the laboratory within 72hrs of collection. The DSNOs were also given clearance for 91.1% of the stool specimens before transportation to the laboratory.

Figure 2 shows that 63% of the geostyles housing the stool specimens were kept in the vehicles' trunk. Delays were only experienced in 25% of the stool specimens being transported. Stool specimens were adequately inspected upon arrival at the laboratory for all cases reported (100%) with minimal delays experienced in the submission of the samples. (Table 2)

Table 2 also shows that it takes an average of 2.3 hours for the LGA DSNOs across all 6 states in the zone to get to their respective state capitals where the WHO office is located for stool samples inspection and travel clearance before proceeding to the polio laboratory.

4. Discussion

The quality of the AFP surveillance system depends entirely on the ability of the laboratory to isolate enteroviruses from stool samples and to provide result classification as to whether a case is polio-positive or NPEV related. But viral isolation isn't possible if the reverse cold-chain system used for the transportation of stool specimens is faulty or if the laboratories themselves are ill functioning. As such, a 10% NPEV isolation rate was set aside as the indicator that monitors the quality and management of the reverse cold-chain system. This is because the reverse cold-chain's ability to preserve NPEVs guarantees the preservation of polioviruses for isolation should there be any.

This operational research focused on the activities involved in maintaining the reverse cold-chain system from the point of stool sample collection to its transportation and arrival at the laboratory. This helped to identify lapses in the system and provide recommendations that would encourage improvement while sustaining the good practices observed.

A cross-sectional survey was done between November-December 2015 across all 6 states in the south-south zone. Results showed that the mothers at home were responsible for collection of 77% of the stool specimens from a total of 165 AFP cases recorded within the survey period. (Figure 1) The LGA DSNOs only collected 15% of such stool samples. (Figure 1) This is in disagreement with a study done in Ghana, which suggested that the healthcare

practitioners themselves were responsible for stool specimen collection [3]. An AFP notification form used for case investigation in Sosun Magun, Maldives agrees with the study done in Ghana. It suggested as a rule, that all stool specimens be collected at the health centre with guidance of a health worker [8].

The implication of this practice is that it ensures that the correct AFP stool specimen collection and preservation method is adhered to at all times. As such, we recommend continuous education of the DSNOs on the correct AFP stool specimen collection procedures and insist that the DSNO personally collects one of the two stool samples collected from each AFP case. This would boost confidence in the quality of stool specimen collected and add credibility to the collection process.

The 6 states in the zone had sent 1955 AFP stool specimen to the laboratory before the November-December survey period used in this study (i.e. from January-October 2015). This compares to the 2097 stool specimen recorded from 10 northern states in 2002 and 2003. [9] This shows that AFP case reporting in the AFP surveillance system in the zone is active. But, It could still do with some improvement. For example, surveillance officers only visited 8.7% of the 184 surveillance focal sites in Akwa Ibom state in comparison to other states in the zone. (Table 2) We recommend vigorous and continuous active surveillance visitation of the focal sites in all states to enhance AFP case reporting and boost the AFP surveillance system's ability to pick up such cases.

Results showed that the DSNOs only collected or observed the collection of 35.5% of the AFP stool specimen. (Table 3) This correlates with the data obtained from the survey used in this study. Other issues with logistics and the transportation of the stool specimen using the reverse cold-chain system also come in here. Though 80.4% of icepacks used during stool transport were frozen and ready to use at the time of this investigation, there was still the issue of constant power unavailability that affected the production of 55.3% of the total icepacks used. (Table 3) We advise that thermal generators (or other alternative means of power supply) be provided to the LGA cold store where the DSNOs reside to ensure icepack production with ease. It would eliminate shortages and erase doubts of inadequate icepacks (i.e. semi-frozen icepacks) for stool specimen transport via the reverse cold-chain.

Detergents were used regularly to clean 83.9% of the icepacks and geostyles. (Table 3) Precaution should be taken because these detergents could kill the enteroviruses if not thoroughly rinsed out. Alcohol, alkaline and other ingredients commonly found in detergents and soap are broad-spectrum antimicrobials [10,11]. This means that using detergents at 60-80% concentration (i.e. diluting a lot of detergent in a small amount of water) inactivates many hydrophilic viruses like adenoviruses, enteroviruses (poliovirus and other NPEVs are members of this family) and rhinoviruses [12]. However, their cidal activity drops sharply when diluted below a 50% concentration (i.e. more water than soap). We recommend proper use of detergents when cleaning icepacks and geostyles stool specimen carriers and advocate thorough rinsing with water to eliminate any residual detergent that may affect the viral integrity in the stool.

The DSNOs are mandated to report to the WHO office usually located in the state capitals for inspection and change of icepacks before stool specimen transport to the laboratory. Majority of the cases (91.1%) met this criterion but there is still the issue of travel distance from the LGAs to the State capital. For example, it takes about 4.6 hours for the LGAs in Rivers state to get to the state capital for sample inspection, packaging and clearance before transportation to the laboratory. Results already showed that unavailability of constant power supply affected the production of 46% of the icepacks even though 80.4% of them were found frozen at the time of this investigation. Hence, the possibility of reduced viral integrity due possibly to inadequate supply of frozen icepacks increases with the distance travelled to the state capital. Since 94.6% of the icepacks in the state level are well frozen to sustain temperature of 8°C inside the geostyle specimen carrier for at least 48 hours, we suggest that the DSNO changes the icepacks at the LGA level. This would cut down distance and long travel time to the State capital and help sustain the cold-chain system.

The states in the south-south zone transport their stool specimen to the polio reference laboratory in the University of Ibadan, south-western Nigeria. While 94% of the stool specimens arrived at the laboratory within the recommended 72 hours after collection, 25% of the geostyles housing the stool specimen experienced delays during transportation. (Table 3) Also, 63% of these geostyles were kept in the trunk of the vehicle during transport thereby exposing them to heat. (Figure 2) This isn't advisable as delays and prolonged exposure to heat on the way to the laboratory may destroy the virus. [13] Hence the provision of a private (official) means of transportation (as opposed to the public means currently used) fitted with air conditioners is recommended. This would eliminate delays caused by mechanical faults and undue stoppages by the Nigerian police during transportation. The geostyles should also be kept within the vehicle close to the DSNOs at all times during transport and not in the trunk.

However, some best practices were observed at the state level during the course this study. These included the provision of adequate frozen icepacks for reverse cold-chain transportation even at short notice from the DSNOs, the presence of dedicated freezers at the state cold stores for the sole purpose of supporting AFP stool specimen storage and transportation and the all time presence of adequately frozen icepacks for such transport. There was also the recent introduction of digital tracking devices attached to the geostyles. These track the activity of the stool specimen from the point of collection to its arrival at the laboratory. These may have contributed to the slight

improvement in the reverse cold-chain system in the zone as evidenced by the improved NPEV isolation rate

We commend the State Ministry of Health officials for the very positive findings observed. However, we still advice that the lapses observed in this survey be taken seriously and acted upon. This would enhance the reverse cold-chain system and the AFP surveillance system by extension as we proceed towards polio-free certification.

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