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Full Length Research Paper

An Attempt to Validate Lots Quality Assurance Sampling Results using Vaccination Tracking System: an Overview of Supplementary Immunization Activities in Kano State

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Monitoring the quality of supplementary immunization activities (SIAs) is a key tool for polio eradication. Regular monitoring data, however, are often unreliable, showing high coverage levels in virtually all areas, including those with ongoing virus circulation. To address this challenge, lot quality assurance sampling (LQAS) was introduced in 2009 as an additional tool to monitor SIA quality. Also, vaccination team tracking system (VTS) was used to track teams through Global Positioning System (GPS) tracking using underlying geospatial data sets of wards, settlement points and satellite imagery. The aim of this research is to authenticate the association between Lot Quality Assurance Sampling (LQAS) and Vaccination Tracking System (VTS) so as to validate the results of the outcome of each of the immunization coverage measuring tools. The association between LQAS results and VTS-GIS tracking coverage were tested using Chi-square statistic. The LQAS bands were categorized into ≥90% and <90% on one hand and VTS-GIS coverage were categorized into ≥90% and <90% on the other. Each of the 44 LGAs was counted for each cross-tabulation of both measurement tools in a 2x2 contingency table. The results show that one of the assumptions for Chi Square test was violated, the need to use the significance of Fisher's Exact Test rather than Pearson Chi-Square becomes eminent to avoid loss of statistical power. The Fisher's Exact Test Significance for the one and two tailed test respectively thus: 0.393, 0.227; 1.000, 0.664; 1.000, 0.603; 0.236, 0.203; and 0.499 and 0.325. All of these values both for one and two tailed significance are greater than 5%, which is evidence that there is no significant association between LQAS results and VTS coverage. To this end, we conclude that since both immunization coverage quality assessment tools are independent at a lower threshold of 90%, it therefore suggests the need for upward review of the lower classification band.

Keywords: Lot Quality Assurance Survey, Vaccination Tracking System, Supplementary Immunization Activities, Fisher's Exact Test

INTRODUCTION

In 1988, when the Global Polio Eradication Initiative (GPEI) began, polio paralyzed more than 1000 children world-wide every day. Since then, more than 2.5 billion children have been immunized against polio thanks to the cooperation of more than 200 countries and 20 million volunteers, backed by an international investment of more than US$9 billion. There are now only 3 countries (Nigeria, Pakistan and Afghanistan) that have never stopped polio transmission and global incidence of polio cases has decreased by 99%- in 2013, 416 cases were reported for the entire year as opposed to over 350,000 in 1988 (GPEI,2012).

In 2006 Nigeria adopted an integrated strategy for Supplemental Immunization Activities (SIAs) known as the Immunization Plus Days (IPDs). The IPDs are a strategy used to deliver OPV together with other vaccines as well as other child survival health interventions such as ITNs, ORS, anti-helminthes etc. IPDs were introduced following an extensive consultative process and were aimed at increasing community confidence in the Polio Eradication effort while at the same time contributing to reducing high child mortality and morbidity in Nigeria. The IPDs were expected to contribute towards the achievement of the MDG 4 on child survival (NPHCDA, 2009; 2015).

In Nigeria, it is generally observed that the Program's successes since January 2014 was a feat that has never been attained in the history of polio eradication ever before. The elements of the program that made this possible have been articulated as a mix of carefully applied innovations. The bottom-line is; 2014 ended with only 6 World Polio Virus (WPV) on the statistics for Nigeria. This is an assurance that Nigeria will soon be declared polio free (Boniface, 2015).

As Nigeria progresses into 2015 and beyond, it is expected that the Nigeria program conduct full-fledged vaccination campaigns to boost population immunity in areas where Surveillance identifies WPV in environmental samples, an expanded use of IPV combined with OPV to stop the transmission of Circulating Vaccine Derived Polio Virus (cVDPV), an accelerated inclusion of IPV in Routine immunization schedules, broadened social mobilization activities through community structures, scaling-up on high-impact innovations like the supervised outside household immunization (Directly Observed Polio Vaccination) to further reduce the number of missed-children, introduction of local feeding centers in non-compliant settlements, deployment of substantial special vaccination teams in areas where DOPV and Health camps are not deployable due to security challenges, astute creativity in mobilizing communities to take advantage of SIAs in areas where mass media announcements may have security implications, and deepened ownership by Local governments in order to consolidate the milestone achieved (Boniface, 2015).

Monitoring the quality of supplementary immunization activities (SIAs) is a key tool for polio eradication. Regular monitoring data, however, are often unreliable, showing high coverage levels in virtually all areas, including those with ongoing virus circulation. To address this challenge, lot quality assurance sampling (LQAS) was introduced in 2009 as an additional tool to monitor SIA quality. To this effect, the World Health Organization has been adapting and testing the Lot Quality Assurance Sampling (LQAS) method, which classifies areas of interest corresponding to "lots" as accepted or unaccepted levels of vaccine coverage, to evaluate vaccination programmes in developing countries (Brown et al., 2014). Conducting LQAS surveys in the field is straightforward: if in a sample of individuals, the number of unvaccinated exceeds a pre-set decision value, then the area (lot) is classified as having an unsatisfactory level of vaccine coverage and mop-up activities are recommended. This ease of application makes the LQAS a very operational tool to detect pockets of low vaccine coverage and therefore direct focused vaccination effort s (GPEI, 2012).

Now used in 8 countries, LQAS provides a number of programmatic benefits: identifying areas of weak coverage quality with statistical reliability, differentiating areas of varying coverage with greater precision, and allowing for trend analysis of campaign quality. LQAS also accommodates changes to survey format, interpretation thresholds, evaluations of sample size, and data collection through mobile phones to improve timeliness of reporting and allow for visualization of campaign quality. LQAS becomes increasingly important to address remaining gaps in SIA quality and help focus resources on high-risk areas to prevent the continued transmission of wild poliovirus (Brown et al., 2014).

The LQAS classification is based on a decision value (d), which is the maximum allowed number of unvaccinated individuals in the lot to classify it as having reached a certain vaccination coverage threshold. For programmatic reasons, with Global Polio Eradication Initiative (GPEI), two decision values (d) are used in order to classify lots according to three bands of vaccination coverage: High, Medium and Low.

In this sense LQAS can help to assess the quality of supplementary immunization activities (SIAs) in the polio-infected or high-risk areas to implement corrective action (e.g. mopping-up) in the areas of weak coverage identified.

Traditionally, LQAS has been proposed with simple random sample design. This means that, if the sample size required to perform the assessment is N=60, then 60 individuals need to be sampled completely randomly in the lot. However, if a lot is large geographical area sampling 60 individuals completely randomly would require considerable time and resources and make the assessment unpractical.

To increase the practicality and rapidity of the assessment, Cluster Lot Quality Assurance Sampling (Cluster-LQAS) has been developed which divides the sample (N) into smaller (k) of n individuals each (GPEI, 2010). For example, if N=60, k=6, n=10, six villages would be selected randomly in the health district, and in each village select ten individuals randomly, instead of conducting up to 60 trips in 60 different locations (UMPCPD,2010).

The recent GPEI informal consultation on monitoring (February 2012) recommended the following interpretation framework:

(a) 0-3 unvaccinated (out of 60): coverage is the Higher Band (i.e. above 90%) →PASS (Maintain the current coverage).

(b) 4-8 unvaccinated (out of 60): coverage is probably in

the Medium Band (i.e. between 80 and 90%) →WARNING (Review other indicators), for example in-process monitoring or administrative coverage in order to decide how to increase coverage levels above 90% in the lot.
(c) 9 or more unvaccinated (out of 60): coverage is in the Lower Band (i.e. lack of evidence that it is above 80%) →FAIL (Consider re-doing the SIA) (GPEI MANUAL, 2012).

Even though there are 3 bands as stipulated by WHO interpretation of LQAS results with respect to polio immunization, in Nigeria four bands are used to interpret the results as follows:

(a) 0-3 unvaccinated (out of 60): coverage is the Higher Band (i.e. above 90%) →PASS (Maintain the current coverage).
(b) 4-6 unvaccinated (out of 60): coverage is probably in the High Band (i.e. between 80 and 90%) →FAIR (Consider the current coverage).
(c) 7-8 unvaccinated (out of 60): coverage is in the Medium Band (i.e. between 60 and 80%) → WARNING (Review other indicators, for example in-process monitoring or administrative coverage in order to decide how to increase coverage levels above 80% in the lot.
(d) 9 or more unvaccinated (out of 60): coverage is in the Lower Band (i.e. lack of evidence that it is above 60%) →FAIL (Consider re-doing the SIA) (UMPCPD, 2010).

The achievement in 2014 have been largely due to the improved quality of SIAs, with the proportion of LGAs achieving an estimated coverage of at least 80% coverage as verified by LQAS increasing from 70% in December 2013, to 97% in December 2014 (4.2_12IMB.pdf-NPHCDA NPEEP, 2015). One of the challenges of missing children was that some settlements were not included in the settlement master-list and hence were not part of the daily implementation micro plans and therefore not visited by teams. Most of the areas not captured were small settlements and hamlets in the outskirts of the major settlements.

Additionally, even when the settlements were on the daily implementation plan, some settlements and hamlets were not visited by vaccination teams due to poor team performance. In 2013, GIS/GPS technology was used to improve the quality of micro-planning by incorporating settlements in the GIS ward maps onto the hand-drawn maps done during walk-through macro-planning and enumeration exercise. Also, vaccination team tracking system (VTS) was used to track teams through Global Positioning System (GPS) tracking using underlying geospatial data sets of wards, settlement points and satellite imagery. The VTS process includes several components and focuses primarily on the vaccination days of the polio campaign to visualize in real time if the settlements-urban areas, small settlements and hamlets were covered. Team tracks are uploaded each day from the tracking phones to laptop at the Local Government Area (LGA) level and then transferred to the Emergency Operations Center (EOC) dashboard through MiFi and shared with the LGA team, State EOC, State Technical Teams and National EOC (NPHCDA 2014 NPEEP). Where the teams did not cover all settlements], feedback was provided to the LGA/ward team to ensure that the vaccination teams are re-deployed to vaccinate children in the missed or poorly covered settlements (NPHCDA 2014 NPEEP). VTS expanded to 50 very very High Risk (VVHR) and Very High Risk (VHR) LGAs by February 2014, 60 LGAs in March 2014 70 LGAs in May 2014 (NPHCDA 2014 NPEEP) and 80 LGAs as at August 2015 (www.vts.eocng.org). Each sub-national campaign (SIA or SIPD) targets LGAs in selected States, primarily in northern-most States where GIS maps are available. Each round, the EO selects up to 80 high-risk LGAs in these States to be tracked (vts.eocng.org)

In line with polio eradication activities, NPHCDA in collaboration with other partners enhanced use of new technologies to compliment the current tools and processes for mapping, micro-planning and tracking vaccinators during polio National Immunization Days (NIDs) and analyzes data for the generation of geospatial products such as maps and charts relevant for taking informed decisions for effective program implementation.

To ensure the quality of the underlying geospatial data sets used in the generation of these products, extensive field data collection and map correction was done which enable the expansion of the number of tracking LGAs to 40 by July 2013 (NPHCDA 2014 NPEEP).The aim of this research is to authenticate the association between Lot Quality Assurance Sampling (LQAS) and Vaccination Tracking System (VTS) so as to validate the results of the outcome of each of the immunization coverage measuring tools to avert acceptable misclassification risk.

METHODOLOGY

Area of study

The study was carried out in Kano, state, northern Nigeria. It was formed in 1968 from Kano province, and in 1991 its northeastern portion was split off to form Jigawa state. It is bordered by the states of Jigawa to the north and east, Bauchi to the southeast, Kaduna to the southwest, and Katsina to the northwest. It has 44 Local Government Areas. It has latitude and longitude in decimal degrees of 12.1°, 8.5° and altitude/ elevation of 473 m (1550 ft). Kano consists of wooded savanna in the south and scrub vegetation in the north and is drained by the Kano-Chalawa-Hadejia river system. The state's light sandy soils are excellent for growing peanuts (groundnuts), a major export. Other crops include cotton, onions, indigo, tobacco, wheat, and gum arabic; millet, sorghum, beans, cowpeas, and corn (maize) are subsistence crops. Cattle, horses, goats, and sheep are grazed, and hides and skins are exported. Tin and columbite are mined. Kano State is the most populous state in Nigeria with a population of 9,383,682 people with 5% growth according to 2006 census (http://www.population.gov.ng/) with huge daily population movement due to its nature of commercial and industrial center (https://www.britannica.com/place/Kano-Nigeria). It could be recalled that the State was hitherto the epicenter of polio circulation with large number of vulnerable children persistently missed due to non-compliance to polio vaccines. With waning political commitment and accountability at all levels, there has been growing concerns among stakeholders on the need to increase political oversight towards achieving polio interruption in northern Nigeria (http://www.afro.who.int/en/nigeria/press-materials/item/9418-kano-state-governor-restates-commitment-to-polio-eradication-and-other-child-survival-interventions.html).

Children under the age of 5 for which Supplementary Immunization Activities are mostly designed for, constitute 20% of the population. Over the past couple of years, the number of confirmed WPV cases in Nigeria has declined substantially, from a total of 122 cases in 2012, down to 53 cases in 2013. The goal of the 2014 National Polio Eradication Emergency Plan was to stop transmission of wild poliovirus. Nigeria made significant progress toward meeting that target reporting 6 cases in 2 states (as at 12 January 2015), with the last case reported on 24 July, 2014. It is also important to highlight that no WPV type 3 cases have been reported in Nigeria since November 2012. In 2014, there was continued geographical restriction of polioviruses to 5 LGAs in 2 States-Kano and Yobe, compare to 29 LGAs in 9 States in 2013. Kano remained as the last sanctuary with active transmission in to 3rd quarter of 2014 and with 19 out of 41 VVHR LGAs in the preliminary list of 5 HR states for 2015 (NPEEP, 2015) hence the focus of the study on Kano State.

Source of data collection

Secondary data were collected of monthly LQAS results for Kano State from January to December 2015 were sourced from the Kano Polio Emergency Center and the Geographic Information System tracked coverage was collected from the Vaccination Tracking System website for the same frame of time.

Vaccination Tracking System takes the vaccination teams' Global Positioning System coordinates during campaign days and calculates the several types of figures which are included in a number of reports. The most useful reports which are available at the website (www.vts.eocng.org) are as follows:

(i) The geographic coverage by geographical level, from State to Wars, displays the cumulative percentage visited by zone. On this report one can drill from State to LGA to Ward to Settlement, and check reliability of the data according to the percentage of teams that have already reported compared to the number of teams deployed.
(ii) The missed or partially covered settlements reports show all settlements with a cumulative percentage visited below a certain threshold for partial geo-coverage (70% for Urban Areas, 50% for Hamlets Areas and 100% foe small settlements) and for missed settlements (50% for Urban Areas, 1% for Hamlets Areas or 40% for large Hamlet Areas and 1% for small settlements. It is used every day by all actors in the campaign to adjust next day activities.

From the foregoing, it implies that by aggregating the cumulative of Urban Areas, Hamlet Areas and Settlements, each LGA would have two thresholds of classification since the minimum coverage is 90%. This means that there are above 90% and below 90% across LGA coverage. In 2015 Supplementary Immunization Activities for polio eradication were conducted in January, March, April, June, July, September, October and December. LQAS was conducted in all the 44 LGAs of Kano State after each Supplementary Immunization Activities but Vaccination Tracking was carried out in selected LGAs in the months of March, October and December while in the remaining months, it was conducted in all the LGAs. Therefore, we focused on LQAS-VTS data for months that have all the LGAs covered by LQAS and VTS for all encompassing analysis and these are: January, April, June, July and September.

Method of data analysis

The association between LQAS results and VTS-GIS tracking coverage were tested using Chi-square statistic. Chi Square statistic is commonly used for testing relationships between categorical variables. The LQAS bands were categorized into ≥90% and <90% on one hand and VTS-GIS coverages were categorized into ≥90% and <90% on the other. Each of the 44 LGAs was counted for each cross-tabulation of both measurement tools. The null hypothesis states that there is no significant difference between LQAS results and VTS-GIS tracking coverage while the alternative hypothesis states that there is significant difference between the two surveys. The confidence level is 95% and the significant level is 5%. The VTS-GIS tracking coverage could be used as external validation tool to ascertain the authenticity of LQAS results. Chi square assumptions as outlined by Field, (2005) stipulate that:

(i) Each person, item or entity contributes to only one cell of the contingency table.
(ii) The expected frequencies should be greater than 5.

Table 1. Results of LQAS and VTS Coverage in 44 LGAs of Kano State.

Date	LQAS	VTS		
		≥90	<90	Total
January 2015	≥90	23	14	37
	<90	6	1	7
	Total	29	15	44
April 2015	≥90	26	11	37
	<90	5	2	7
	Total	31	13	44
June 2015	≥90	24	11	35
	<90	6	3	9
	Total	30	14	44
July 2015	≥90	25	12	37
	<90	3	4	7
	Total	28	16	44
September 2015	≥90	25	9	34
	<90	6	4	10
	Total	31	13	44

Source: vts.eocng.org and Kano State Emergency Operations Center.

Table 2. Chi-Square tests for January 2015 LQAS-VTS

	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.453	0.228	0.393	0.227	
Continuity Correction[b]	0.594	0.441			
Likelihood Ratio	1.641	0.200	0.393	0.227	
Fisher's Exact Test			0.393	0.227	
Linear-by-Linear Association	1.420	0.233	0.393	0.227	0.186
N of Valid Cases	44				

Table 3. Chi-Square Tests for April 2015 LQAS-VTS.

	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	0.004	0.951	1.000	0.664	
Continuity Correction[b]	0.000	1.000			
Likelihood Ratio	0.004	0.951	1.000	0.664	
Fisher's Exact Test			1.000	0.664	
Linear-by-Linear Association	0.004	0.951	1.000	0.664	0.346
N of Valid Cases	44				

Although it is acceptable in higher contingency tables to have up to 20% of expected frequencies below 5, the result is a loss of statistical power (so the test may fail to detect a genuine effect).

In January, April, June and September of 2015, the cell where <90% VTS coverage intercept <90% LQAS results shows a count of less 5 whereas in April 2015, cells <90% on LQAS result intercept both ≥90% and <90% on the VTS coverage are less than 5. Table 1 shows vividly that assumption has been violated. To avoid loss of statistical power so that the test may not fail to detect a genuine effect, Fisher's Exact Test was considered for interpretation of the results instead of the Pearson Chi Square. Fisher's exact test is a statistical significance test used in the analysis of contingency tables. Although in practice it is employed when sample sizes are small.

RESULTS AND DISCUSSION

Tables 2-4 are Chi Square test results for months of January, April, June, July and September 2015 as displayed in (Tables 2-6) also show the Fisher's Exact Test Significance for the 2 and 1 tailed test respectively thus: 0.393, 0.227; 1.000, 0.664; 1.000, 0.603; 0.236, 0.203; and 0.499 and 0.325. All of these values both for 1 and 2 tailed significance are greater

Table 4. Chi-Square Tests for June 2015 LQAS-VTS

	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	0.012	0.913	1.000	0.603	
Continuity Correction[b]	0.000	1.000			
Likelihood Ratio	0.012	0.913	1.000	0.603	
Fisher's Exact Test			1.000	0.603	
Linear-by-Linear	0.012	0.914	1.000	0.603	0.305
Association N of Valid Cases	44				

Table 5. Chi-Square Tests for July 2015 LQAS-VTS

	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.553	0.213	0.393	0.205	
Continuity Correction[b]	0.669	0.413			
Likelihood Ratio	1.495	0.221	0.393	0.205	
Fisher's Exact Test			0.236	0.205	
Linear-by-Linear Association	1.518	0.218	0.393	0.205	0.156
N of Valid Cases	44				

Table 6. Chi-Square Tests for September 2015 LQAS-VTS.

	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	0.679	0.410	0.449	0.325	
Continuity Correction[b]	0.185	0.667			
Likelihood Ratio	0.654	0.419	0.449	0.325	
Fisher's Exact Test			0.449	0.325	
Linear-by-Linear Association	0.664	0.415	0.449	0.325	0.212
N of Valid Cases	44				

than 5%. This is evidence that there is no significant association between LQAS results and VTS coverage. Since in all of the Contingency tables, one of the assumptions for Chi Square test is violated, the need to use the significance of Fisher's Exact Test rather than Pearson Chi-Square becomes eminent to avoid loss of statistical power. Looking at all the value of Fisher's Exact Significance of greater than P-Value of 5% in table II-VI, we do not reject the null hypothesis and conclude that the twin Quality control tools of Statistical Process control (VTS) and Quality Assurance Survey (LQAS) are not dependent on each other. Therefore, LQAS cannot be used as a validating tool to VTS and vice versa.

Conclusion

To this end, we conclude that since both immunization coverage quality assessment tools are independent at a lower threshold of 90%, it therefore suggests the need for upward review of the lower classification band. This work would allay the presumption that the LQAS and VTS coverages are in congruent. The reason for their independence is not ascertained in this work. We however recommend that further study on factors responsible for the lack of significant difference can looked at.

Authors` declaration

We declare that this study is an original research by our research team and we agree to publish i
t in the journal.

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