

# Lot Quality Assurance Sampling to Monitor Supplemental Immunization Activity Quality: An Essential Tool for Improving Performance in Polio Endemic Countries

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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. 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.

**Keywords.** poliovirus; lot quality assurance sampling; mobile phones; independent monitoring.

The Global Polio Eradication Initiative (GPEI) relies on many tools to help interrupt wild poliovirus (WPV) transmission, one of which is good polio vaccination campaign monitoring. Until 2009, monitoring of national Supplementary Immunization Activities (SIA) was performed by independent monitoring (IM), an objective measure of SIA quality to help enable corrective action [1]. Concerns over discrepancies found between the high coverage levels reported by IM and the continued high number of confirmed WPV and circulating vaccine-derived poliovirus (cVDPV) cases in some areas, however, made the World Health Organization (WHO) look into additional monitoring

methods [2]. In November 2009, the WHO determined that additional evaluation methods should be used at the Local Government Area (LGA; geographic areas of administrative action) to monitor national vaccination campaigns in Nigeria. Clustered lot quality assurance sampling (LQAS) was then piloted in Northern Nigeria to evaluate the oral poliovirus vaccine (OPV) coverage of the November 2009 campaign [3].

At the time of the Nigeria pilot, LQAS was a relatively new sampling methodology for public health use. It is used to classify geographical areas (lots) as having “acceptable” or “not acceptable” vaccination coverage. This classification is based on whether the number of unvaccinated individuals in a sample (N) is greater than a decision value (d) [4]. Lots are classified as having vaccination coverage below an upper threshold (UT; usually target vaccination coverage) or above a lower threshold (LT; the minimum acceptable coverage level for the lot). As with any statistical test, there are associated classification errors of  $\alpha$  (the risk of accepting a lot with unacceptable coverage) and  $\beta$  (the risk

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of rejecting a lot with acceptable coverage). The area of vaccination coverage between the UT and the LT is an area of statistical uncertainty, the broadness of which impacts the sample size.

To tailor standard LQAS for the Nigeria pilot, the GPEI made 2 adjustments: (1) Clustering (dividing the sample into smaller clusters) to increase efficiency in the field [5] and (2) multiple classification thresholds to identify program strengths and weaknesses on a spectrum [3]. One lot (LGA in Nigeria) of 60 children is made of 6 clusters of 10 children each (Table 1).

In November 2009, this adjusted version of LQAS was piloted in 5 high-risk Northern states with the following methodology. A lot of  $N = 60$  children,  $\alpha = 12\%$ ,  $\beta = 22\%$ ,  $d$  values of 9, 21, and 33 unvaccinated children per lot, assessing coverage targets of 90%, 70%, and 50% respectively, were used. Using multiple decision values allowed WHO to highlight inter-lot variation in coverage and the sampling strategy included both high- and low-risk wards. Six wards per LGA, using probability proportional to size (PPS), and 1 settlement per ward, using target population estimates, were selected for sampling. Households were selected randomly using a spin-the-bottle method with different sampling intervals depending on village size. A standardized questionnaire was administered to each child's caregiver, and vaccination was determined by the presence of the indelible ink fingermark given after vaccination on the child's finger [3].

The outcome of this initial pilot showed that LQAS helps identify areas of particularly weak coverage quality, highlighting with statistical reliability where lots were failing to meet the target coverage required to eradicate polio. LQAS data demonstrated more variability in coverage levels than IM data and provided the GPEI with data that were more in line with continued circulation of poliovirus in Northern Nigeria [3]. The rigorous methodology of randomized cluster, house, and child selection, combined with a more stringent selection of surveyors to conduct the surveys are both factors that make LQAS more reliable.

**Table 1. Parameters for Multi-threshold LQAS Study, Northern Nigeria, November 2009**

Clusters	N	d	LT (%)	UT (%)	SD range	$\alpha$ range (%)	$\beta$ range (%)
6 × 10	60	9	75	90	0–0.1	5–9	8–14
6 × 10	60	21	55	70	0–0.1	8–12	17–22
6 × 10	60	33	33	50	0–0.1	7–12	18–21

Abbreviations:  $\alpha$ , probability of accepting lot with unacceptable proportion of defectives;  $\beta$ , probability of rejecting lot with acceptable proportion of defectives;  $d$ , decision value: number of unvaccinated children above which lot is rejected; LT, lower threshold: minimum acceptable vaccination coverage; N, sample size: number of individuals per lot; SD, standard deviation; UT, upper threshold: assess target vaccination coverage.

## BENEFITS OF LQAS AND EXPANSION OF THE PROGRAM

After the successful 2009 pilot in Northern Nigeria, the LQAS initiative was scaled up and implemented nationwide where early results demonstrated continued low-quality vaccination coverage during national and sub-national rounds.

The 2010–2012 strategic plan recommended the expansion of LQAS to provide reliable data on campaign quality [6], and in 2011, the LQAS initiative was introduced in Pakistan as a standard monitoring tool. The Polio Eradication and Endgame Strategic Plan 2013–2018 reiterated the need for LQAS, particularly in endemic countries, because the LQAS methodology strikes the best balance between ease of field implementation and statistically-reliable results to track trends over time in the most high-risk areas [7]. LQAS was most recently piloted in Afghanistan in April 2013. In addition, it has been used in 6 other countries with active eradication programs: India, Angola, and Chad in 2011, and Niger and the Democratic Republic of Congo in 2012. (Figure 1)

## LQAS AND IM COMPARISONS

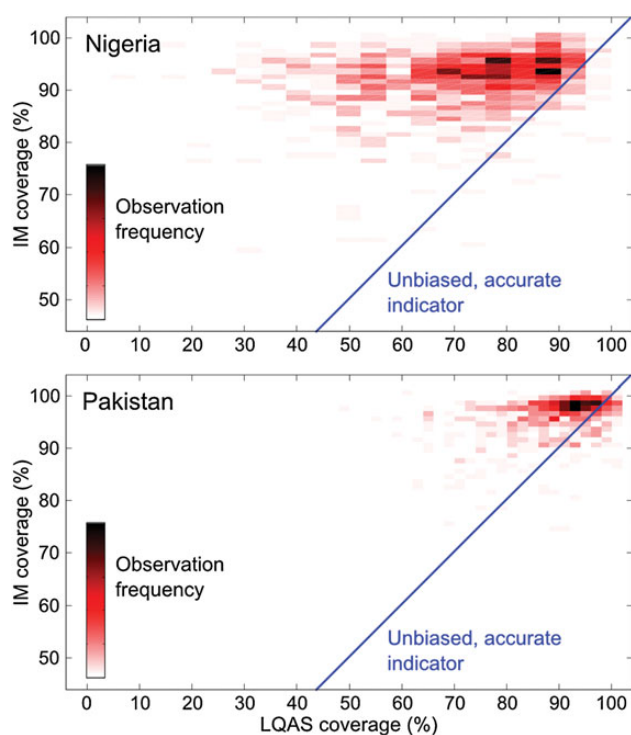
The major programmatic benefit of LQAS is its ability to identify areas with weak coverage. Analyses by the Institute for Disease Modeling (Global Good) fund (IDM) illustrated this unique advantage by studying the concordance between IM and LQAS. Analysis of LQAS and IM data in Nigeria between 2010 and 2012, in which 865 of the 894 LQAS lots collected were



**Figure 1.** Map of countries in which LQAS has been implemented by GPEI, 2009–2013. Geographic distribution of countries in which LQAS has been implemented during the period 2009–2013. Nigeria (2009); Pakistan (2011); India (2011); Angola (2011); Chad (2011); Democratic Republic of Congo (2012); Niger (2012); Afghanistan (2013). Shaded countries have used LQAS. Abbreviations: GPEI, Global Polio Eradication Initiative; LQAS, lot quality assurance sampling.

matched with IM data, shows that IM only captures 5.3% of the LQAS variance. IDM determined that IM is biased upward as compared to LQAS and that LQAS has a better capacity to differentiate areas with low vs high quality. The analysis showed that if IM reports coverage above 90%, there is a 48% chance that LQAS will report a covered fraction below 80%, and a 15% chance of a covered fraction below 60% [8] (Figure 2).

A similar characteristic was observed in Pakistan for the period of January 2011 to July 2012. IDM matched 850 of the 869 LQAS lots to corresponding IM coverage at the district-aggregated level. IM captured only 12% of the LQAS variance in the 850 matched lots. For instance, if IM reported coverage above 95%, there was a 29% chance that LQAS would report a covered fraction below 90%, and 7% chance of a covered fraction below 80% (Figure 2). In Pakistan, like in Nigeria, IDM found that IM systematically underestimates the fraction of missed children during vaccination campaigns. In total, 85% of the matched LQAS lots showed a lower covered fraction than the corresponding IM coverage (unbiased would show 50%) [9]. Most recently, a March 2013 pilot initiative of LQAS was



**Figure 2.** Institute for Disease Modeling analysis: IM vs LQAS concordance in Nigeria (*above*) and Pakistan (*below*). Two-dimensional histogram of IM-LQAS coverage pairs, collected in 2011 and 2012. The frequency of observations is presented on a color scale: the more frequent a specific IM-LQAS pair, the darker the shaded region. If IM was an unbiased indicator of coverage, it would lie along the line. Dark Gray, more frequently observed pair; Light Gray, less frequently observed pair; line, IM as unbiased, accurate indicator. Abbreviations: IM, independent monitoring; LQAS, lot quality assurance sampling.

conducted in Afghanistan with results displaying a similar discordance between previous monitoring data and LQAS data. When comparing post-campaign coverage assessment (PCA) in-house surveys with LQAS, 79% (19/24) of the lots showed higher coverage in PCA results than LQAS. And when comparing out-of-house surveys to LQAS results, 67% (13/19) of lots showed higher coverage in out-of-house surveys than LQAS.

## LQAS SHOWING TRENDS IN COVERAGE

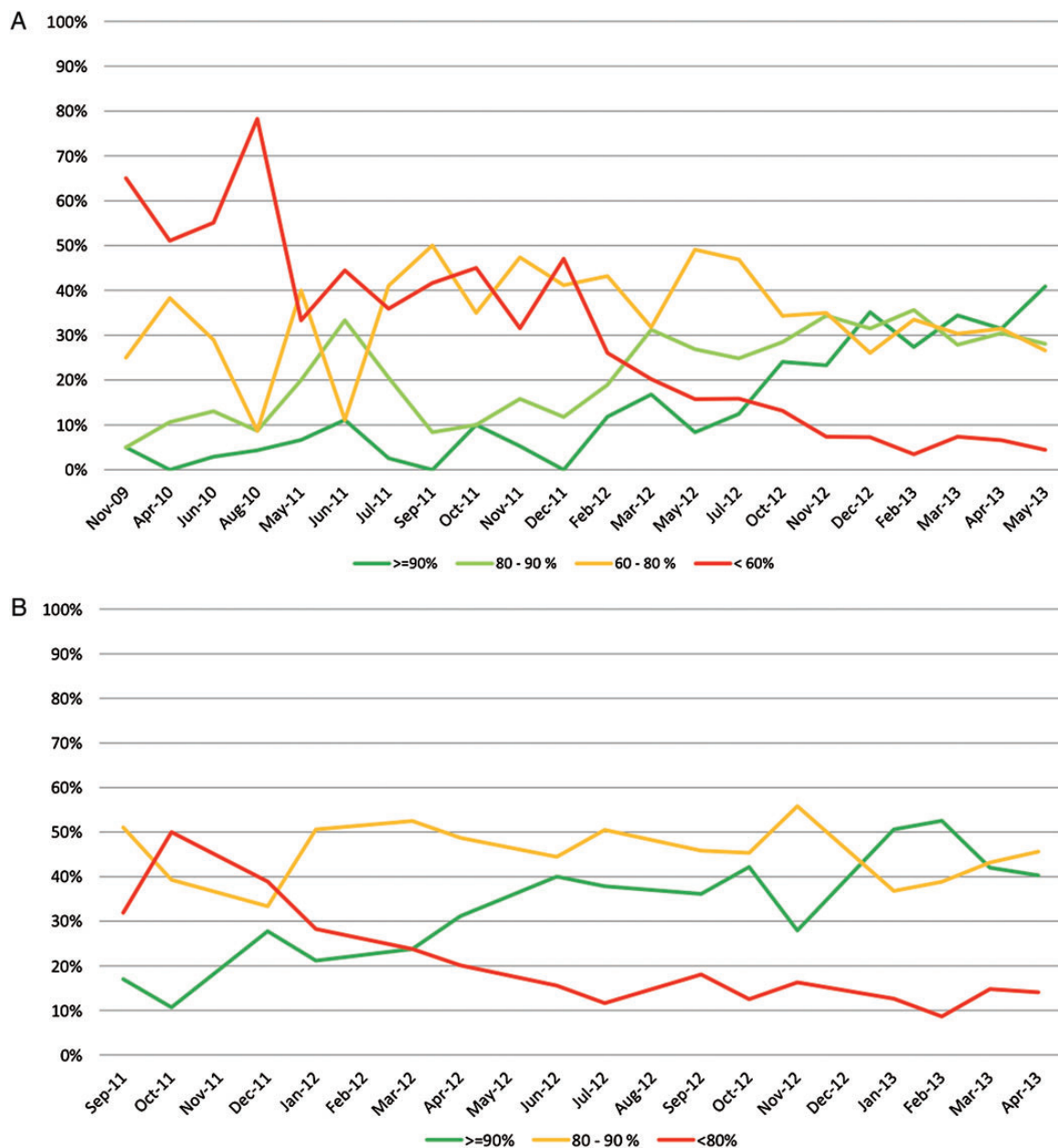
LQAS data also allow the GPEI to monitor trends of SIA quality. Although early LQAS results demonstrated the continued need for campaign quality improvement and stringent monitoring in both Nigeria and Pakistan, over time, an upward trend in coverage quality has been noticeable in both countries. In Nigeria, for example, the percentages of LGAs classified as “accepted at 90%” increased steadily from 5% (1/20) in November 2009 to 41% (83/171) in May 2013. Moreover, the percentages of LGAs surveyed classified as “not accepted at 60%” decreased steadily from 65% (13/20) in November 2009 to 4% (9/203) in May 2013, reaching its lowest level of 3% (8/230) in February 2013. This trend of improvement is particularly noticeable in 2012, during which several operational and programmatic changes—including increasing vaccination teams, revision of microplans, and the development of an Emergency Operation Center—were implemented (Figure 3A).

Similarly, in Pakistan, LQAS results reflect an overall improvement in campaign quality from September 2011 through April 2013. For example, early LQAS results in October 2011 showed only 11% (8/47) of surveyed Union Councils (UCs) classified as “accepted at 90%,” whereas 40% (83/206) were so classified in April 2013. Additionally, the number of UCs classified as “not accepted at 80%” decreased in the same time period, from a high of 50% (28/56) to 14% (29/206; Figure 3B). In Afghanistan, where LQAS was recently piloted, subsequent rounds will allow us to similarly monitor trends of coverage quality.

## CONTINUED EVALUATION OF AND IMPROVEMENTS TO LQAS

### New Guidelines and Protocol Adaptations

Since the Nigeria 2009 pilot, improvements to the LQAS protocols have been adopted in different countries. Primarily, in February 2012, the GPEI informal consultation on monitoring determined that new survey interpretation and guidelines would prevent unacceptably large  $\alpha$  errors and new language would clarify classification. Therefore, the new framework for lots of 60 children is as follows: 0–3 unvaccinated: “accepted at 90%”; 4–8 unvaccinated: “accepted at 80%”; 9+ = “not accepted at 80%” (Table 2). An additional threshold of “accepted at 60%” and “not accepted at 60%,” with an associated  $d$  value of 20+



**Figure 3.** Trends of campaign coverage quality as measured by LQAS data. *A*, Nigeria LQAS trends: November 2009–May 2013. This figure represents a retrospective analysis of LQAS data in Nigeria from the initial November 2009 pilot to the most recent campaign in May 2013. In Nigeria, 1 lot is 1LGA. For each month that LQAS was conducted, LGAs were classified according to current thresholds, and the total percentage of LGAs classified under each category was plotted to demonstrate trends of vaccination campaign quality. Dark green, “Accepted at 90%”; Light green, “Accepted at 80%”; Yellow, “Accepted at 60%”; Red, “Not accepted at 60%”. *B*, Pakistan LQAS trends: September 2011–April 2013. This figure represents a retrospective analysis of LQAS data in Pakistan from its initial implementation in 2011 to the April 2013 campaign. In Pakistan, 1 lot is 1UC. For each month that LQAS was conducted, UCs were classified according to current thresholds and the total percentage of UCs classified under each category was plotted to demonstrate trends of vaccination campaign quality. Dark green, “Accepted at 90%”; Yellow, “Accepted at 80%”; Red, “Not accepted at 80%.” Abbreviations: GPEI, Global Polio Eradication Initiative; LGA, local government area; LQAS, lot quality assurance sampling; UC, union council.

unvaccinated children out of 60, was adapted to differentiate between areas of particularly weak coverage [1]. Additionally, in Nigeria, the selection of random settlements is now performed using a master list of settlements, rather than wards, so all settlements in an LGA stand an equal chance of being selected.

#### Introduction of Mobile Phones for Data Collection

The process of collecting, collating, and analyzing LQAS data on paper forms is important, but time-consuming, and can take 2–3 weeks to complete. To provide faster results, WHO turned to mobile phones and the *Magpi* (formerly *Episurveyor*)

**Table 2. Parameters for Multi-threshold LQAS New Guidelines, GPEI February 2012**

Clusters	N	d	LT (%)	UT (%)	SD range	$\alpha$ range (%)	$\beta$ range (%)
6 × 10	60	3	90	98	0–0.1	14–24	3–13
6 × 10	60	8	80	90	0–0.1	13–19	14–21
6 × 10	60	19	60	80	0–0.1	12–16	33–35

Abbreviations:  $\alpha$ , probability of accepting lot with unacceptable proportion of defectives;  $\beta$ , probability of rejecting lot with acceptable proportion of defectives; d, decision value: number of unvaccinated children above which lot is rejected; LT, lower threshold: minimum acceptable vaccination coverage; N, sample size: number of individuals per lot; SD, standard deviation; UT, upper threshold: assess target vaccination coverage.

application for the collection and transmission of data in real-time from the field.

*Magpi* consists of 2 elements: (1) a web-based platform to create digital forms, store data on a secure server, and export data to a computer; and (2) a mobile phone-based application to complete surveys and send data directly from the field to the server. In August 2010, WHO headquarters evaluated *Magpi* for LQAS in one of the polio infected countries. In January 2011, 37 WHO country office staff and the data manager were trained on the use of *Magpi* for LQAS form creation and data collection using *Nokia C5* mobile phones. Pilot results showed that no data were lost, the error rate was under 1%, and the transmission cost of 0.7 USD per lot was negligible compared to the gains in timeliness. Following this success, WHO proposed a pilot study to assess the feasibility of using *Magpi* for LQAS data collection in Nigeria.

In March 2012, WHO conducted a technical training and field test of *Magpi* for 7 staff in Abuja, Nigeria. Results showed that data transmission took place in real-time; data export from the server to the local computer was immediate; data collation was rapid (transfer from *Magpi* export format to final LQAS analysis format required under three minutes per cluster); and data errors were minimal due to built-in skip logic and value constraints. 24 *Samsung Mini Galaxy Android* phones were then preloaded with the *Magpi* application and trained supervisors conducted cascade trainings for 29 surveyors in 4 high-risk states (Kaduna, Zamfara, FCT, Kano). Following surveyor trainings, a pilot was conducted using mobile phones in 27 LGAs in these 4 states after the March 2012 SIA. In total, 90% (24/27) of the LGAs surveyed reported their LQAS data to the server by the end of the survey and all mobile phone data were available for analysis before paper forms were submitted. The country subsequently requested a scale-up in September 2012.

Since the initial mobile phone pilot in March 2012, the WHO Nigeria country office has collected an average of over 600 reports (clusters) of LQAS data per month with <1% error rate. Currently, data collected on the mobile phones are

uploaded, exported, and ready for analysis within 2 days, whereas the paper forms require 4–5 days for processing. The LQAS form is designed to be 1 cluster of 10 individuals. The digital form has evolved to include questions on dosage histories and caretaker awareness.

### Visualizing Campaign Quality

GPEI uses *ESRI ArcGIS* software to visualize campaign performance in 2 main ways: (1) coverage at cluster level using 5 classification levels: 0, 1–3, 4–7, 8–9, and 10 children unvaccinated out of 10 children surveyed (Figure 4A); and (2) coverage at LGA level using standard GPEI LQAS thresholds to view overall coverage quality at the administrative/programmatic action level (Figure 4B).

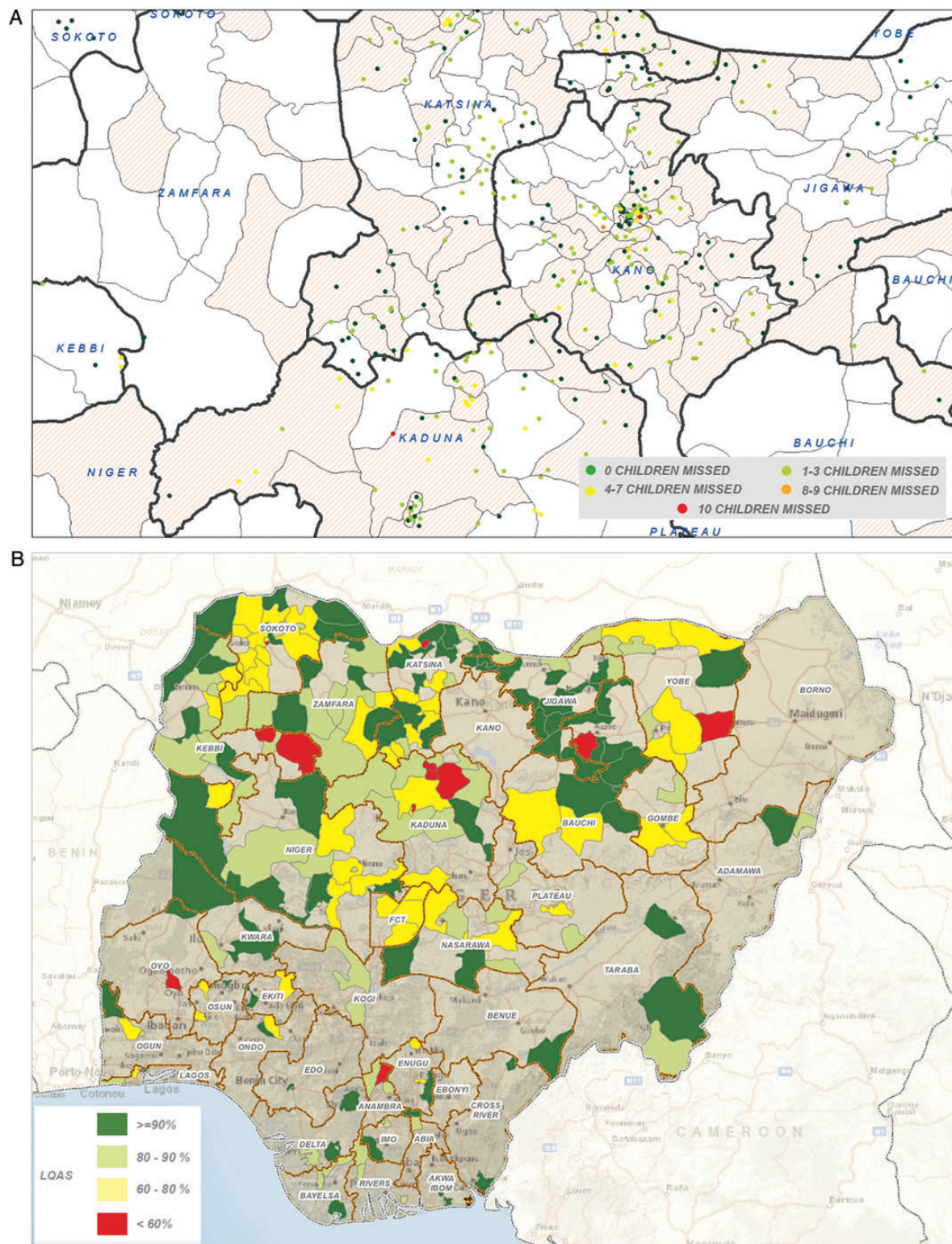
Visualizing LQAS data allow the GPEI to differentiate between areas that are completely missed by vaccination teams and areas in which the settlement is poorly covered. Cluster level maps easily identify both areas that have been reached but poorly covered (4–7 or 8–9 children unvaccinated), as well as areas that have probably not been reached at all (all 10 children unvaccinated) using points that are color-coded in yellow, orange, and red, respectively. These images indicate that the majority of clusters are reached, but not completely covered, with 1–3 children unvaccinated in 49.6% (303/610) of visualizable clusters in November 2012 and 47.7% (274/574) in April 2013.

Additionally, magnified versions of national maps can be used to instantly identify the areas of greatest need. Figure 5A and B demonstrates how certain geographic areas change over time, with clusters of 8, 9, or 10 unvaccinated children either disappearing or popping up from month to month. Missed settlements are clearly differentiated from those where intra-cluster vaccination performance remains weak. State-specific, cluster-level maps are also provided to state coordinators so that they can act immediately in a local context.

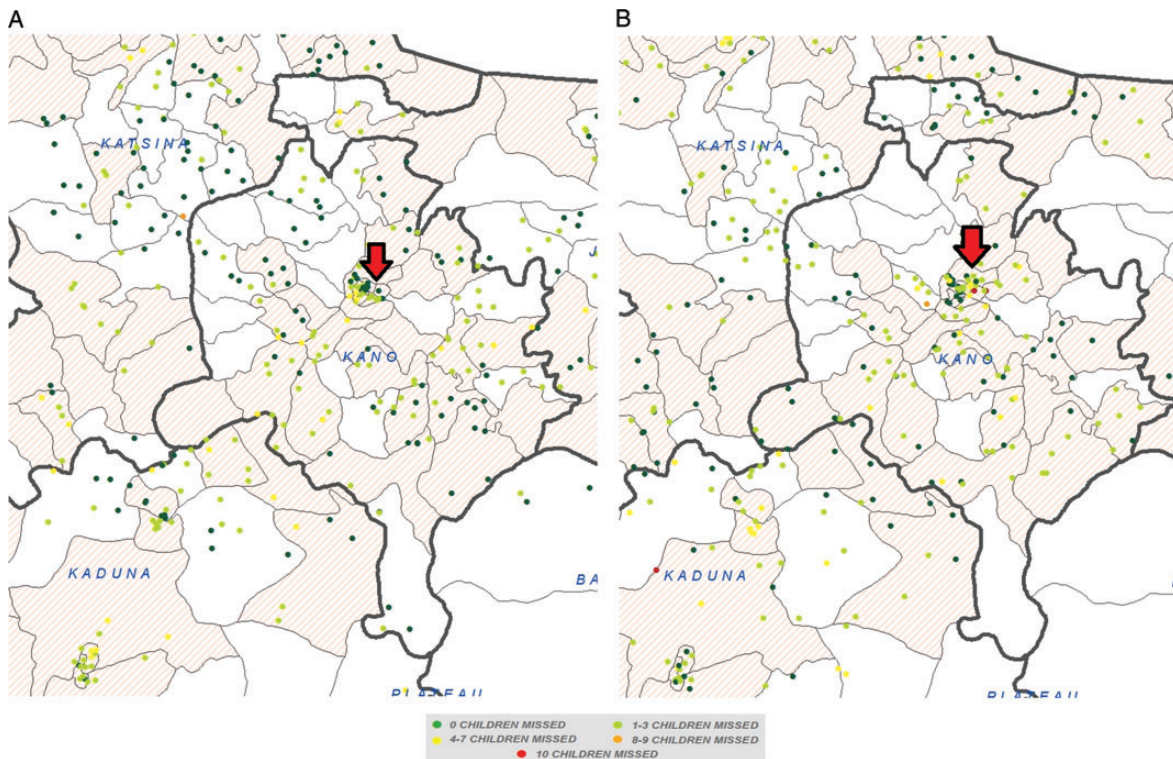
## CONCLUSIONS

Since its pilot implementation in November 2009 in Nigeria, LQAS has demonstrated its usefulness as a statistically reliable tool for monitoring polio vaccination campaign quality. The insight LQAS has provided into areas of strong vs weak coverage quality has helped to isolate the areas most in need of program intervention. Moreover, LQAS has allowed the GPEI to track trends in campaign quality over time, something that was not possible prior to its implementation. Using LQAS data, the GPEI has been able to see an overall improvement in campaign quality over time and to compare these trends with other program data and case information.

In addition, LQAS is a tool with the capacity to adapt to program needs. Since its inception, LQAS has accommodated changes to survey questions and formats, interpretation thresholds, and evaluations of sample size and statistical accuracy.



**Figure 4.** Two options for visualizing LQAS results collected on mobile phones. *A*, Coverage at the cluster level. This figure, for LQAS survey in April 2013, demonstrates the classification of clusters according to their number of unvaccinated individuals. Raw data from the maggi.com server are exported to the local computer and the number of unvaccinated children in each cluster is calculated and then uploaded to ESRI ArcGIS software for visualization. *B*, Coverage at the LGA level. This figure represents the overall lot-level (LGA-level) classification for all LGAs in which LQAS was conducted in Nigeria in March 2013. Worst performing areas (“not accepted at 60%”) are clearly visible on these maps. Color-coded national maps reflect the geographic distribution of the poorest lots in the country, clearly demarcating areas in need of continued vaccination campaign support. Abbreviations: LGA, local government area; LQAS, lot quality assurance sampling.



**Figure 5.** A and B, Geographic distribution and classification of cluster-level LQAS data collected on mobile phones in Nigeria. In this figure, map A reflects cluster-level coverage for the LQAS round in November 2012 and map B for April 2013. Each month, clusters are classified according to numbers of unvaccinated children and then visualized on maps using ESRI ArcGIS software. This figure shows how changes in cluster-level coverage quality are immediately visible. For instance, the red arrows pointing to Kano City area in both maps highlight how very poorly performing clusters stand out when they occur: a red dot represents a cluster where all 10 of the children surveyed were unvaccinated. These red dots are clearly visible in the April 2013 map. Abbreviation: LQAS, lot quality assurance sampling.

Moreover, the GPEI has made improvements to the LQAS program by beginning to collect data through mobile phones, to increase the timeliness and availability of data, and help to visualize clusters geographically so as to identify areas of weakness quickly and easily. LQAS remains a reliable and feasible tool for the monitoring of campaign quality, and it has been an essential and pragmatic tool for improving campaign performance for the GPEI.

There are, however, certain limitations to the implementation of LQAS campaigns that must be addressed. LQAS is a time-consuming enterprise, even with the use of mobile phones, and it requires surveyors of a high-caliber to maintain its reliability and credibility. For the highest quality LQAS, an effort should always be made to recruit university-educated surveyors, conduct and maintain high-quality trainings to ensure the surveyors' understanding of LQAS implementation (hiring outside consultants, if necessary), and be mindful of the time commitment required of the surveyors and supervisors to complete an LQAS questionnaire. The administrators of the program should focus on choosing the correct sample size, surveyor compensation, and location of the LQAS program. Surveyors should not be used more than 3 times, so as to maintain their independence, and the selection of

settlements should be performed from a central level utilizing a preorganized master list of settlements that will ensure that standard selection processes are used across the board. Additionally, LQAS measures coverage quality through fingermarking, and therefore the quality of fingermarking and good training of vaccination volunteers in this respect is essential. Although mobile phones improved the timeliness of reporting data, mobile telephone networks can pose challenges. The use of dual-SIM phones has helped overcome areas of poor network coverage, but when network is unavailable, surveyors or supervisors must have access to wireless internet or be able to complete a manual transfer of data from the phone's memory card.

Furthermore, access and security continue to physically limit LQAS. In polio-endemic countries, in particular, security has become an increasingly significant concern. In 2013, attacks on health workers and facilities in Nigeria and Pakistan led to brief campaign and LQAS suspension to ensure the safety of all health workers. Campaigns have since resumed, but LQAS remains suspended to safeguard surveyors. Similarly, in Afghanistan, certain districts are not accessible to surveyors due to the deteriorating security situation, an important factor, especially in Kandahar district, and Helmand and Kunar provinces,

which have previously reported polio cases regularly. Additionally, certain districts and villages will not welcome non-local surveyors collecting data on mobile phones, so LQAS must remain adaptable.

These issues require the GPEI to explore innovative methods of conducting surveillance and monitoring. The growing field of computer and mobile-based technologies may provide useful tools for program monitoring initiatives, and these innovations can be particularly useful in difficult to access areas.

## ADDITIONAL INNOVATIVE MONITORING TECHNOLOGIES

One technology that the GPEI plans to utilize is mobile phone Short Message Service (SMS). One example of how SMS has been used for the GPEI is an Aga Khan University study monitoring coverage during polio SIAs in Karachi. In this study, households with children under 5 years of age were surveyed and selected to be contacted during the vaccination campaign to find out if a vaccinator had visited their house and administered the vaccine. Results from this study have shown that coverage data obtained through SMS and phone calls matches the data collected through ground team monitoring and LQAS [10]. Moreover, at times when LQAS and monitoring teams were unable to access the same areas, the SMS and phone call study continued, demonstrating the benefit of utilizing personal mobile phones for program monitoring and surveillance.

The possibilities for technological innovations in the field of monitoring are expansive. In addition to the use of SMS to personal phones, the field of biometrics is expanding to help identify individuals for the delivery of services. For example, the Unique Identification Authority of India (UIDAI) program is currently generating a random identification number, matched with fingerprints, iris scans, and a photograph, for all Indian residents, with the intention of acting as a tool for effective monitoring of government schemes and programs [11]. UIDAI claims that the lack of identity documentation prevents the neediest Indians from accessing welfare programs, and UIDAI will help bridge that gap [12]. Public health initiatives, such as the GPEI, could potentially utilize initiatives like this to ensure that the entire target population in high-risk areas is vaccinated. Reaching those most in need is crucial for the eradication of polio; therefore, the adoption of mobile-phone and tablet-based applications that can digitally register aid-receiving individuals, collect data remotely, and track vaccine delivery and distribution could prove very useful [13].

As we get closer to the eradication of polio, LQAS and other innovations become increasingly important to address remaining gaps in SIA quality. Being able to identify areas with continuing weak coverage will help the GPEI focus resources on these high-risk areas and make corrective actions that can prevent the continued transmission of WPV. Particularly in hard-to-access

areas, new technologies can help staff reach the most at-risk populations consistently and without delay. The usefulness of LQAS demonstrated the benefits of exploring new tools for monitoring and surveillance, and the GPEI will continue to improve operations in order to interrupt WPV transmission globally.

## Notes

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