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# Clustered lot quality assurance sampling to assess immunisation coverage: increasing rapidity and maintaining precision

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**Summary**

OBJECTIVE Vaccination programmes targeting disease elimination aim to achieve very high coverage levels (e.g. 95%). We calculated the precision of different clustered lot quality assurance sampling (LQAS) designs in computer-simulated surveys to provide local health officers in the field with preset LQAS plans to simply and rapidly assess programmes with high coverage targets.

METHODS We calculated sample size ($N$), decision value ($d$) and misclassification errors (alpha and beta) of several LQAS plans by running 10 000 simulations. We kept the upper coverage threshold (UT) at 90% or 95% and decreased the lower threshold (LT) progressively by 5%. We measured the proportion of simulations with $\leq d$ individuals unvaccinated or lower if the coverage was set at the UT (pUT) to calculate beta (1-pUT) and the proportion of simulations with $>d$ unvaccinated individuals if the coverage was LT% (pLT) to calculate alpha (1-pLT). We divided $N$ in clusters (between 5 and 10) and recalculated the errors hypothesising that the coverage would vary in the clusters according to a binomial distribution with preset standard deviations of 0.05 and 0.1 from the mean lot coverage. We selected the plans fulfilling these criteria: alpha ≤ 5% beta ≤ 20% in the unclustered design; alpha ≤ 10% beta ≤ 25% when the lots were divided in five clusters.

RESULT When the interval between UT and LT was larger than 10% (e.g. 15%), we were able to select precise LQAS plans dividing the lot in five clusters with $N = 50$ ($5 \times 10$) and $d = 4$ to evaluate programmes with 95% coverage target and d = 7 to evaluate programmes with 90% target.

CONCLUSION These plans will considerably increase the feasibility and the rapidity of conducting the LQAS in the field.

**keywords** lot quality assurance sampling, evaluation, immunization, vaccine coverage, survey, methodology

## Introduction

Vaccination campaigns targeting disease elimination aim to achieve very high levels of coverage, up to 95% in every district (Dietz *et al.* 2004). In many countries, high routine coverage levels are also targeted for most antigens (Robertson *et al.* 2003; Lim *et al.* 2008). The Expanded Program for Immunization (EPI) Cluster Survey to estimate vaccination coverage was designed by the World Health Organization (WHO) (Henderson & Sundaresan 1982) and has been used widely. The survey uses a two-stage stratified sampling technique: in the first stage, the population is divided into a set of non-overlapping clusters, then a determined number of clusters is sampled with probability proportionate to the size (PPS); in the second stage, a determined number of subjects are selected within each cluster (Bennett *et al.* 1991). This method provides a coverage estimate for the entire territory under study, but it is not intended for decision-making at cluster level (Hoshaw-Woodard 2001). WHO initially recommended a 30 clusters × 7 individuals design, but this sample size was revised to allow for ad hoc calculations according to specific estimate needs (WHO 2005).The lot quality assurance sampling (LQAS) was used by industry to classify batches of products as either acceptable or unacceptable for sale according to the proportion of defective units present by inspecting a sample of them (Sandiford 1993). LQAS has been proposed in the health sector to assess immunisation coverage or disease prevalence in areas of interest (Cotter *et al.* 2003; Robertson & Valadez 2006). When used to assess immunisation coverage, the LQAS is essentially a test of the null hypothesis that an area (lot) has an unacceptable proportion of unvaccinated individuals. Two coverage thresholds need to be defined to

test this hypothesis, an upper threshold (UT) and a lower threshold (LT). The UT is generally the coverage target of the vaccination campaign, and the LT is the minimum level to consider the lot as having acceptable coverage. Based on these thresholds, it is possible to calculate a decision value or maximum number of defectives allowed (*d*) to classify, according to determined statistical probabilities, the lot as having acceptable or unacceptable levels of vaccine coverage by examining a sample (*N*) of the population. The probability to reject the lot is that the coverage is below the UT, while the probability to accept the lot is that the coverage is above the LT. Hence, with the LQAS, we are able to assess whether immunization coverage in the lot is below the top or above the bottom of the 'grey area' delimited by the UT and the LT (Lemeshow & Taber 1991).

The probability of accepting a lot with an unacceptable proportion of defectives is known as the alpha error (or consumer risk), while the beta error (or provider risk) is the probability that a lot with acceptable coverage is rejected by the LQAS plan. LQAS can be seen as a screening test to identify poor performance, and the alpha and beta errors can be linked to specificity and sensitivity. We can define sensitivity (1-alpha) as the proportion of truly positive (lots with unacceptable levels of coverage correctly rejected) among the screened population, and specificity (1-beta) as the proportion of truly negative (lots with acceptable levels of coverage correctly accepted) in the population, although it is worth mentioning that this is somewhat imprecise, because the LQAS test is used in a way that does not take into account lots classified as having mediocre coverage (above the LT but below the UT) (Sandiford 1993). The decision rule of the LQAS test is straightforward: if the number of unvaccinated individuals found is bigger than *d*, then we reject the area as not having reached adequate immunisation coverage; if the number of unvaccinated individuals is equal or less than *d,* then we accept the area as having reached adequate immunisation coverage. This has the advantage that as soon as the number of unvaccinated exceeds *d,* we can stop sampling and reject the lot without having to complete the whole sample. Compared with the EPI cluster survey, LQAS has the advantage of allowing to classify a lot in terms of coverage using a smaller sample size (Hoshaw-Woodard 2001).

Rapid house-to-house monitoring (RHHM) has been proposed to assess rapidly areas that are possibly below 95% vaccination coverage. Based on LQAS, the RHHM has the advantage to be practical and fast, because it relies on a sample of 20 individuals and on decision values of 0–1, 2 or 3+, but its statistical value may be questioned because the sample is not randomly selected (it uses rather a convenient sample approach) and the probabilities of rejecting or accepting the area in terms of coverage are not specified (Dietz *et al.* 2004).

The objective of this study was to provide the scientific basis for a straightforward approach of the LQAS for assessing immunization coverage at the district level and propose a clustered design for the lot sample size while maintaining statistical rigour. We calculated the precision of different clustered LQAS designs in computer-simulated surveys to provide local health officers in the field with preset LQAS plans to simply and rapidly assess the vaccine coverage in their area. In addition, we describe the probabilities of misclassification, which are helpful in justifying scientifically appropriate corrective actions.

## Methods

### Accept/reject probabilities of clustered LQAS

We calculated *N*, *d* and related classification probabilities of several LQAS plans with different coverage thresholds using SampleLQ (Myatt 2001). We then assumed that the individuals (*N*) were not sampled randomly in the lots but in smaller clusters. We hypothesised that coverage in each cluster would vary from the mean lot coverage according to a binomial distribution with preset standard deviations (SD) of 0.05 and 0.1. We then ran 10 000 computer simulations keeping the same *N* and *d* but with different clustered designs (from a maximum of ten clusters per lot to a minimum of five) to assess how clustering would have affected the precision of the LQAS test.

For each simulated scenario, we calculated the number of vaccinated that we were expecting to find if each individual had a probability of being vaccinated as the UT. According to the cumulative binomial principle, on which LQAS is based, *d* can theoretically go from 0 to *N* (Staff of the Computation Laboratory 1954). For each of the values of *d,* we counted how many of the 10 000 simulated scenarios had that number of unvaccinated individuals or lower. We then divided the count by 10 000 to obtain the proportion of simulations that had *d* individuals unvaccinated or lower, if the coverage was UT%. The proportion obtained expressed how likely it was that the number of unvaccinated found was *d* or less if the population true coverage was at UT (i.e. the probability of acceptance or pUT). To calculate the probability of rejection (pLT), we set the coverage in our simulations to the LT and performed the same calculations as above with the difference that we wanted to see how many of the simulated lots had coverage above the LT if the number of unvaccinated was more than *d*. We calculated this proportion as the

complement of the proportion of lots with *d* or lower unvaccinated individuals; hence the proportion of lots with more than *d* unvaccinated individuals if the coverage was LT%. The proportion obtained expressed how likely it was that the number of unvaccinated individuals found was more than *d* if the true population coverage was at the LT. We then calculated the alpha error as 1-pLT and the beta error as 1-pHT.

### Selection of the clustered LQAS plans

We kept the UT fixed at 90 and 95%, which are two coverage targets typically used during vaccination campaigns (Sutter & Maher 2006; Pezzoli *et al.* 2009) or routine immunisation activities (CDC 2009; Zhao *et al.* 2009). To select the most convenient LQAS plans for use in the field, we adopted the following criteria for precision: alpha should have been ≤5% and beta ≤20% in the simple random design (unclustered); alpha ≤ 10% and beta ≤ 25% in the clustered design hypothesising a SD of up to 0.1 from the mean lot coverage. We first calculated the smallest sample size allowing satisfactory precision to assess the shortest 'grey areas' (e.g. UT95%–LT90%). To find the best balance between precision and manageable sample size, we progressively decreased the LT by 5% in the following plans and assessed which smaller sample sizes were adequate to conduct LQAS tests with the same or better precision criteria.

### Statistical calculations

We used Stata v10 for the statistical calculations (StataCorp 2008). The customized STATA program is available from the authors.

## Results

As an example of how we constructed the LQAS plans, we present the results of the calculations used to determine the best precision when the UT = 95%, LT = 85% and $N = 50$.

When the coverage in the simulated lots was set to 95%, each lot could have theoretically presented a number of unvaccinated individuals (*d*) from 0 to 50, but mostly between 2 and 3 (5% of 50). Similarly, if the real coverage in the lot was 85%, the number of unvaccinated in the lots would most likely have been around seven or eight individuals (15% of 50). The proportion of simulated lots that had up to three unvaccinated individuals, when coverage was 95%, was 76% (7594/10 000), this number was the pUT. The proportion number of simulated lots that had four or more unvaccinated over the total number of lots, when real coverage was 85%, was 95% (9531/10 000), this number was the pLT. Table 1 shows the different levels of error if the design was divided in 5 × 10 clusters or 10 × 5 clusters with SD at 0.05 or 0.1. Figure 1 is the operating characteristic curve for the LQAS plan-rejecting programmes with more than three defectives (*d*) with the two different clustered designs (5 × 10 or 10 × 5) and an assumed SD of 0.05.

**Table 1** Probabilities of error for lot quality assurance sampling (LQAS) plan rejecting with more than 3/50 unvaccinated with different clustered designs, hypothesising a SD of 0.1 and 0.05 from the mean coverage in the clusters

| Clusters (*K*n*) | *d* | LT | UT | SD | Alpha | Beta | OE |
|---|---|---|---|---|---|---|---|
| – | 3 | 0.85 | 0.95 | – | 0.047 | 0.241 | 0.288 |
| 10 × 5 | 3 | 0.85 | 0.95 | 0.05 | 0.048 | 0.242 | 0.290 |
| 10 × 5 | 3 | 0.85 | 0.95 | 0.1 | 0.074 | 0.269 | 0.343 |
| 5 × 10 | 3 | 0.85 | 0.95 | 0.05 | 0.062 | 0.260 | 0.322 |
| 5 × 10 | 3 | 0.85 | 0.95 | 0.1 | 0.102 | 0.300 | 0.402 |

*K*, number of clusters; *n*, number of individuals per cluster; *d*, decision value; LT, lower threshold; UT, upper threshold; SD, standard deviation; OE, observer error (alpha+beta).

For the 'grey area' of 5%, the precision criteria were not met especially in the clustered designs. For the plan with UT = 95% and LT = 90%, the smallest sample size fulfilling the criteria (alpha ≤ 5% and beta ≤ 20%) in the unclustered design was $N = 210$ and $d = 13$ with alpha = 4% and beta = 16%, but in the clustered design, only the design with 10 × 21 clusters and SD = 0.05 allowed for errors below the criteria (alpha ≤ 10% and beta ≤ 25%) with alpha = 7% and beta = 24%. For the plan with UT = 90% and LT = 85%, the smallest sample size fulfilling the criteria in the unclustered design was $N = 300$ and $d = 34$ with alpha = 5% and beta = 19%; again the precision criteria in

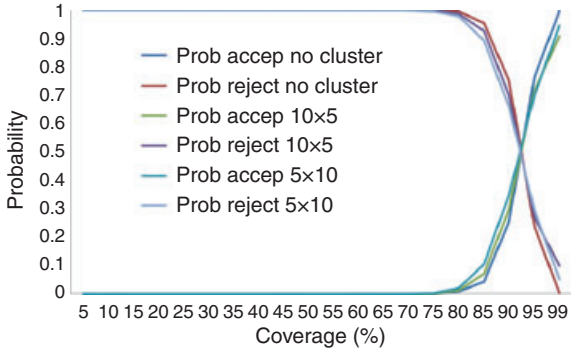


**Figure 1** Operating characteristic curves for lot quality assurance sampling (LQAS) plan-rejecting programmes with more than three defectives assuming no division in clusters, and a 10 × 5 and 5 × 10 clustered design hypothesising in the clusters a SD of 10% from the mean lot coverage.

the clustered design were fulfilled only when the plan was divided in 10 clusters of 30 hypothesising a SD of 0.05, with alpha = 8% and beta = 25%.

When we increased the 'grey area' to 10%, we were able to find sampling plans with smaller sizes of $N = 105$ if UT = 95% and $N = 150$ if UT = 90%, fulfilling the criteria even when five clusters with 0.1 SD were simulated (Tables 2 and 3). When the 'grey area' was ≥15%, the LQAS plans fulfilling the criteria had all very manageable sample sizes of $N \leq 50$ even when they were divided in five clusters with SD = 0.1.

**Table 2** Sampling plans allowing for the classification of lots with UT = 95% and different LTs

| *n* | Clusters (*K***n*) | *d* | LT (%) | UT (%) | SD | Alpha | Beta | OE |
|---|---|---|---|---|---|---|---|---|
| 105 | – | 8 | 85 | 95 | – | 0.019 | 0.083 | 0.102 |
| 105 | 5 × 21 | 8 | 85 | 95 | 0.05 | 0.036 | 0.163 | 0.199 |
| 105 | 5 × 21 | 8 | 85 | 95 | 0.1 | 0.091 | 0.231 | 0.322 |
| 50 | – | 4 | 80 | 95 | – | 0.020 | 0.104 | 0.124 |
| 50 | 5 × 10 | 4 | 80 | 95 | 0.05 | 0.032 | 0.139 | 0.171 |
| 50 | 5 × 10 | 4 | 80 | 95 | 0.1 | 0.053 | 0.193 | 0.246 |
| 30 | – | 3 | 75 | 95 | – | 0.034 | 0.066 | 0.100 |
| 30 | 5 × 6 | 3 | 75 | 95 | 0.05 | 0.038 | 0.082 | 0.119 |
| 30 | 5 × 6 | 3 | 75 | 95 | 0.1 | 0.052 | 0.125 | 0.177 |
| 20 | – | 2 | 70 | 95 | – | 0.038 | 0.074 | 0.112 |
| 20 | 5 × 4 | 2 | 70 | 95 | 0.05 | 0.036 | 0.091 | 0.127 |
| 20 | 5 × 4 | 2 | 70 | 95 | 0.1 | 0.046 | 0.126 | 0.172 |

*K*, number of clusters; *n*, number of individuals per cluster; *d*, decision value; LT, lower threshold; UT, upper threshold; SD, standard deviation; OE, observer error (alpha+beta).

**Table 3** Sampling plans allowing for the classification of lots with UT = 90% and different LTs

| *n* | Clusters (*K***n*) | *d* | LT (%) | UT (%) | SD | Alpha | Beta | OE |
|---|---|---|---|---|---|---|---|---|
| 150 | – | 19 | 80 | 90 | – | 0.012 | 0.102 | 0.114 |
| 150 | 5 × 30 | 19 | 80 | 90 | 0.05 | 0.029 | 0.174 | 0.203 |
| 150 | 5 × 30 | 19 | 80 | 90 | 0.1 | 0.096 | 0.252 | 0.348 |
| 50 | – | 7 | 75 | 90 | – | 0.032 | 0.114 | 0.146 |
| 50 | 5 × 10 | 7 | 75 | 90 | 0.05 | 0.054 | 0.140 | 0.194 |
| 50 | 5 × 10 | 7 | 75 | 90 | 0.1 | 0.080 | 0.197 | 0.276 |
| 30 | – | 4 | 70 | 90 | – | 0.029 | 0.174 | 0.203 |
| 30 | 5 × 6 | 4 | 70 | 90 | 0.05 | 0.038 | 0.201 | 0.240 |
| 30 | 5 × 6 | 4 | 70 | 90 | 0.1 | 0.051 | 0.226 | 0.276 |
| 20 | – | 3 | 65 | 90 | – | 0.043 | 0.128 | 0.171 |
| 20 | 5 × 4 | 3 | 65 | 90 | 0.05 | 0.044 | 0.142 | 0.186 |
| 20 | 5 × 4 | 3 | 65 | 90 | 0.1 | 0.053 | 0.159 | 0.212 |

*K*, number of clusters; *n*, number of individuals per cluster; *d*, decision value; LT, lower threshold; UT, upper threshold; SD, standard deviation; OE, observer error (alpha+beta).

## Discussion

Using the statistical simulation approach, we were able to determine the best precision achieved by different LQAS plans to evaluate immunization programmes with two different coverage targets: 90 and 95%. To increase feasibility, we divided the LQAS plans in smaller clusters. We then recalculated the precision of the clustered LQAS plans hypothesising that the mean coverage in the clusters would vary according to preset SDs from the mean coverage in the whole lot, adjusting in this way for inter-cluster variability. The precision of the LQAS test increased as the 'grey area' increased, allowing smaller sample sizes to be used.

LQAS plans with 'grey areas' shorter than 10% presented very low precision with errors above the established criteria, especially when clustering was considered, even when the sample size was very large (i.e. $N > 200$). We discarded such plans as unfeasible in the field. When we kept the 'grey area' at 15% or larger, the precision improved considerably, even using small sample sizes (≤50) and considering the possibility of clustering with a hypothesised a SD of 0.1 from the mean lot coverage. Furthermore, the precision did not seem to decrease considerably if a design of five clusters rather than 10 was used (Figure 1). To evaluate coverage rapidly, we recommend using the plans divided in five clusters of 10 with 15% grey area (i.e. UT = 95% and LT = 80% or UT = 90% and LT = 75%). The advantage of such plans is the small sample size meeting the precision criteria, with the disadvantage intrinsic to the LQAS methodology that rejected lots are likely to have real coverage <UT (95 or 90%) and accepted ones coverage >LT (80 or 75%).

Intuitively the smaller *N*, the faster a lot can be assessed. Very small sample sizes of 20 and even as small as seven have been proposed for LQAS tests (Hoshaw-Woodard 2001; Brooker *et al.* 2005). To achieve good precision with such small sample sizes, the LQAS test relies on classifications based on very large 'grey areas' (≥30%), and this may not be what the investigators in the field need if they intend to assess programmes achieving very high levels of coverage. We have shown how, if the 'grey area' is too small, this may affect the precision of the LQAS test (Table 2).The plans with a 'grey area' ≤10% were the less precise even if we increased *N* to more than 100.

If both errors could not be kept low, we decided to give priority to having a low alpha rather than beta. In this case, we should emphasize that rejection by the LQAS test does not necessarily imply poor performance, because we are more likely to judge unacceptable a lot that has actually good coverage (beta error) than to judge acceptable a lot that has bad coverage (alpha error) (Sandiford 1993).

Ideally, we would want beta low too, because it is the risk of investing resources where they are not needed. As we were more concerned with being sure not to have districts with people possibly at risk, we decided that the alpha error was more important, our priority being to 'reject' programmes that are not meeting the target. This may imply that the proposed plans have a greater negative predictive value than a positive predictive value (i.e. they are good at identifying positives but a great percentage of this may be negative, or of acceptable coverage). In this case, an alternative would be to follow-up the binomial LQAS test (i.e. accept/reject decision) with additional investigations, for example using a double-sampling approach to separate the mediocre from the poor (Myatt & Bennett 2008).

To assess districts with small 'grey areas', instead of the LQAS, the EPI cluster sampling could be used, which can give an estimate of coverage with a precision of ±5% (WHO 2005). This estimate would not be much different from assessing if the lot is above or below a 'grey area' with a width of 10% or less.

Especially when the 'grey area' was 15% or larger, the clustered LQAS plans met the criteria for precision established. In that case, the number of clusters did not influence the errors heavily, suggesting that using a division in to five clusters instead of 10 may be enough to guarantee randomization in the field and maintaining a certain level of variability. We had already explored the possibility of dividing the LQAS into five clusters in the field (Pezzoli *et al.* 2009). The approach that we describe in this article is similar, with the only difference that we hypothesize that the coverage may vary in the lots according to a binomial distribution rather than normal. We believe that the current approach is more solid because it prevents the predicted coverage in the clusters to go above one (100%) for the scenarios with high simulated coverage. Graphically, the distribution of coverage is more skewed rather than having a normal distribution around the mean, modelling better what happens in the field where it is not possible to see more than 100% of the population vaccinated (Figure 2).

Dividing the lots in five clusters increases the rapidity and the feasibility of the LQAS test in the field. Especially if the health officers need to evaluate an immunisation programme rapidly, a division in five clusters would require the investigators to travel only to five locations in the lot.

This methodological advantage gives rise to the main limitation of this study design. By dividing the sample into smaller clusters, we may introduce a degree of inter-cluster variability. To account for clustering, the Design Effect (DEFF) and the Intracluster Correlation (Rho) can be calculated using field data from cluster surveys (Pezzoli *et al.* 2009). The approach we described is based on statistical simulations and not on field data. We were unable to calculate DEFF and Rho with any reasonable precision using data from only five or 10 clusters per lot, instead we hypothesised that the coverage would vary in the clusters according to a maximum SD of 0.1 and demonstrated that the errors would be low if the 'grey area' was ≥15%. We recommend dividing the lots in to smaller clusters only if the territory of the lot is somewhat homogeneous in terms of coverage (i.e. there is indication that coverage in the lots does not vary more than 0.1 SD from the mean lot coverage). To gather this evidence, it may be possible to use the results of previous coverage surveys conducted on the same territory.

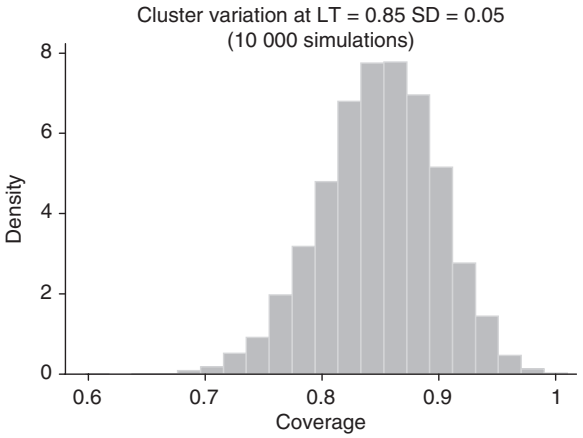


**Figure 2** Graph showing the variation around the hypothesised coverage of 85% if the standard deviation is set at 5% in the 10 000 simulations.

Our study suggests that to rapidly assess a lot, the interval between UT and the LT should be larger than 10% (e.g. 15%). If this condition is met, our findings suggest that it may be possible to divide the lots into five smaller clusters, to increase the feasibility and the rapidity on the field, making the clustered LQAS a very operational tool to monitor coverage in a lot (e.g. district) at the end or immediately after a vaccination campaign, when the logistic apparatus is still in place to take timely corrective actions to raise coverage in the areas of weakness identified. If the users in the field want to assess smaller 'grey areas', they should be aware that the likelihood of error increases. The investigators should in this case make a cost-benefit assessment and accept that they may be investing resources where they are not needed (because the beta error is higher than the alpha). If the costs of intervention are high (in terms of transport, travel allowances, training, vaccines and clinical needs), then it may not be justifiable to rely solely upon the LQAS tests to make decisions.

Selection of clusters in the lot should be performed according to PPS or with other methods if a list of the localities in the district with census information is not available (Bennett *et al.* 1991; Sadler *et al.* 2007).To select individuals in the clusters, we recommend following house-to-house sampling procedures to ensure random selection of households across the cluster avoiding convenience sampling. The first household in the cluster should be selected randomly preferably with a geographical method based on the map of the village (if the map is not available, the surveyors should draft one) and not using the spin the pen procedure (Grais *et al.* 2007). Once the first household is selected, surveyors should follow a procedure based on local census information to select subsequent households ensuring maximum spread of the survey. We recommend administering the survey to only one randomly selected individual per household. If the surveyors end up covering the entire locality without completing the cluster, they should move to the neighbouring one in the same lot to survey the remaining individuals.

Previous studies have discussed how the LQAS and the EPI cluster surveys serve different purposes even if they can sometimes achieve similar objectives (Singh *et al.* 1996; Hoshaw-Woodard 2001). In the context of a comprehensive evaluation of vaccination programmes, we recommend the use of clustered LQAS to monitor coverage quickly at the end of a vaccination campaign in selected geographical areas (lots) and EPI Cluster survey to estimate post-campaign coverage in the entire territory.

Immunization programme officers should use the clustered sample size of 50 ($5 \times 10$) with $d = 4$ to evaluate programmes with 95% coverage target and $d = 7$ to evaluate programmes with 90% target. These plans will facilitate considerably the execution of the LQAS in the field because the operators will not need to calculate the sample size to conduct the assessment of immunization coverage. However, users wanting a specific level of precision above that offered by the plans suggested here should use ad hoc calculations.

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