

FURTHER OBSERVATIONS ON COMPARISON OF IMMUNIZATION COVERAGE BY LOT QUALITY ASSURANCE SAMPLING AND 30 CLUSTER SAMPLING

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Abstract. Lot Quality Assurance Sampling (LQAS) and standard EPI methodology (30 cluster sampling) were used to evaluate immunization coverage in a Primary Health Center (PHC) where coverage levels were reported to be more than 85%. Of 27 sub-centers (lots) evaluated by LQAS, only 2 were accepted for child coverage, whereas none was accepted for tetanus toxoid (TT) coverage in mothers. LQAS data were combined to obtain an estimate of coverage in the entire population; 41% (95% CI 36-46) infants were immunized appropriately for their ages, while 42% (95% CI 37-47) of their mothers had received a second/booster dose of TT. TT coverage in 149 contemporary mothers sampled in EPI survey was also 42% (95% CI 31-52). Although results by the two sampling methods were consistent with each other, a big gap was evident between reported coverage (in children as well as mothers) and survey results. LQAS was found to be operationally feasible, but it cost 40% more and required 2.5 times more time than the EPI survey. LQAS therefore, is not a good substitute for current EPI methodology to evaluate immunization coverage in a large administrative area. However, LQAS has potential as a method to monitor health programs on a routine basis in small population sub-units, especially in areas with high and heterogeneously distributed immunization coverage.

INTRODUCTION

Since its inception, the 30 cluster sampling technique (EPI methodology) has been considered adequate for its ability to estimate the immunization coverage within 10 percentage points of the coverage in the entire population (Henderson and Sundaresan, 1982; Lemeshow and Robinson, 1985). Since the overall coverage has increased, program managers are feeling the need to identify small health units with poor performance so that supervision could be focused on the units of greatest need (Lanata *et al*, 1988; Lemeshow and Robinson, 1985; Lemeshow and Stroh, 1988; 1989), which is vital to further increase the coverage. Unfortunately, EPI methodology can not identify small health units with poor performance (Lemeshow and Robinson, 1985; Lemeshow and Stroh, 1988). In contrast, the Lot Quality Assurance Sampling (LQAS), which was initially developed for use in industries (Dodge and Romig, 1959) may identify such units (Lanata *et al*, 1988; Lemeshow and Robinson, 1985;

Lemeshow and Stroh, 1988, 1989; Singh *et al*, 1995; Singh *et al*, 1996), but very limited experience is available on its applicability in the health sector (Lanata *et al*, 1988; Lemeshow and Stroh, 1989; Singh *et al*, 1995, 1996 in press). The authors field tested LQAS in 3 Primary Health Centers (PHCs) *ie*, Sadauli Kadeem in district Saharanpur (Uttar Pradesh) and Malakhera and Naugaon in district Alwar (Rajasthan). The results from Sadauli Kadeem (Singh *et al*, 1995) and Malakhera (Singh *et al*, 1996) have been published elsewhere; the results from Naugaon are presented in this communication.

MATERIALS AND METHODS

LQAS

LQAS is a stratified random sampling with small samples (n) from each stratum or lot. A lot is considered as having an acceptable level of immunization if the number of unimmunized children in the sample " n " is equal to or less than a critical value " d ". A lot with more than " d " children unimmunized is rejected. Since immunization cover-

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age in children as well as mothers was reported to be high, we chose a sampling plan of $n = 10$ and $d = 1$. With this plan, at least 95% of the lots with coverage equal or less than 62% will be rejected. Conversely 74% of the lots will be accepted at 90% coverage; the lots will be accepted with increasing probability as the percentage coverage in the area increases. Binomial distribution can be used to calculate the probabilities if the sample size (n) is less than 10% of the lot size (N) otherwise hypergeometric distribution will be used (Dodge and Romig, 1959). Because LQAS is a stratified random sampling, the results from lots can be combined to obtain a point estimate for the entire population. The details about LQAS can be found elsewhere (Dodge and Romig, 1959; Lanata *et al*, 1988; Lemeshow and Robinson, 1985; Lemeshow and Stroh, 1988, 1989; Singh *et al*, 1995).

This study was undertaken in PHC Nugaon during the period from 8 December, 1992 to 1 February, 1993. This PHC had a population of 156,029 distributed in 27 sub-centers. In a pilot study in district Alwar, it was found that the child and mother immunization registers were grossly incomplete, whereas eligible couple (survey) registers were fairly accurate and complete (Singh *et al*, 1995). We therefore chose the latter as the sampling frame. A sub-center was considered a lot for LQAS. On the direction of the health chief in the district, health workers and Anganwadi workers accompanied the surveyors along with their immunization records.

Each sub-center consists of many villages; 10 households were selected at random from the combined list of all the villages. If there was no eligible child in the selected households, or the household was locked, or the mother was not available, the surveyors selected the next nearest household having an eligible child. All children 3-11 months of age residing in the sub-center area constituted the population (N) of the lot. Records and/or a history by the mother were used to assess the age and vaccination status of the children. Less than 15% of children and mothers had immunization cards. A typical scar was also accepted as evidence of BCG immunization. Children were considered appropriately immunized for their ages, if they had received the following immunizations at the time of survey:

Vaccine/Dose	Age
DPT1 OPV1 BCG	3 to 5 months
DPT3 OPV3 BCG	6 to 10 months
DPT3 OPV3 BCG measles	11 months

Mothers of sampled children were also assessed for TT immunization status prior to the delivery of the child. For a particular dose of vaccine to be valid, we used the same criteria which have been recommended by the EPI and described elsewhere (EPI, 1991; Singh *et al*, 1996).

30 cluster survey

The 30 cluster sampling survey was also carried out according to the methodology of EPI. Nevertheless, the first household in the chosen cluster was not selected at random, but was close to the village center. Mothers of infants (0-11 months) were sampled for TT coverage, whereas 12-23 months old children were sampled for child coverage, however, only vaccines administered in infancy were considered for analysis. The technique has been described elsewhere (EPI, 1991).

Resources required

A detailed record was kept of the money and time required for the two surveys. All personnel who worked on the surveys were government officials and they drew their salaries in addition to travel and daily allowances to cover expenses during the survey period. Salaries were not considered in the calculations of expenses.

RESULTS

Of 27 sub-centers evaluated by LQAS, only 2 were classified as having an acceptable level of immunization in children, whereas none had acceptable immunization coverage in mothers (Table 1). Using stratified sampling theory and weights proportional to the population in each lot (Karmel and Polasek, 1970), LQAS data for all the lots were combined to obtain estimates of immunization coverage in the entire population. As shown in Table 2, about 41% of the infants were immunized appropriately for their ages by the time they had

Table 1
Immunization coverage by LQAS in PHC Naugaon.

Child/ Mother	"n"	"d"	Threshold coverage %	No. of sub-centers surveyed	No. of sub-centers accepted
Child	10	1	62	27	2
Mother	10	1	62	27	0

Table 2
Combined immunization coverage for all the lots by LQAS.

Child/ Mother	Age group	No. surveyed	Up-to-date	% Coverage (95% CI)
Child	3-5 months	145	66	43.1 (36.3-49.9)
	6-10 months	95	35	40.8 (34.2-47.5)
	11 months	30	7	24.8 (15.9-33.7)@
	All ages	270	108	41.0 (35.9-46.2)
Mother		270	107	42.0 (36.6-47.4)

@ No child in this age group was selected from 13 sub-centers. The analysis pertains to 14 sub-centers comprising 77,569 population.

reached one year of age; coverage levels were 42% in mothers.

The coverage for individual doses of vaccines in 12-23 months old children sampled by EPI methodology are shown in Table 3; about 44, 44, 49 and 27% of the children had received appropriate doses of OPV, DPT, BCG and measles vaccines, respectively, before they reached one year of age. Overall, 27% of the children were fully protected with all the vaccines.

Table 4 compares the TT coverage estimated by the different methods; the coverage levels were 41 and 42% in mothers of all children sampled by EPI methodology and LQAS respectively. In contrast, the routine system reported that 85% of the targets for a second/booster dose of TT allotted for 1992-93 (a proxy for coverage) have been achieved.

The coverage levels estimated (of course, by different methods) in children of different age groups are illustrated in Table 5. Of all the children

Table 3
Immunization coverage (child) by 30 cluster sampling.

Vaccine/dose	% Coverage (95% CI)
DPT1/OPV1	57.1 (46.1-68.1)
DPT2/OPV2	48.6 (36.7-60.5)
DPT3/OPV3	43.8 (31.6-56)
BCG	49.0 (37.6-60.4)
Measles	27.1 (16-38.1)
Fully immunized	27.1 (16-38.1)

under 6 months of age who should have received all the three doses of OPV/DPT, only 14% had received these doses; however, coverage increased to 47% by one year of age. Conversely, 91% of the allotted targets for the third dose of DPT/OPV (a proxy for coverage) were reported to be achieved in 1992-93.

Table 4

Tetanus toxoid (TT2/booster) coverage in mothers; a comparison by LQAS, cluster sampling and routine reporting.

Method	Age in months	No. surveyed	% Coverage (95% CI)
30 cluster sampling	0-11	210	40.9 (31.9-50.8)
30 cluster sampling	3-11	149	41.6 (30.8-52.4)*
LQAS	3-11	270	42.0 (36.6-47.4)*
Routine reporting	0-11		85.1**

* No statistically significant difference.

** Achievement of allotted targets in 1992-1993; a proxy for coverage at the time of survey.

Table 5

Child age and immunization coverage @.

Child age in months	Method	OPV3/DPT3	BCG (No. surveyed)	Measles
3-5	LQAS	13.9 (115)*	46.9 (145)	-
6-10	LQAS	40.0 (95)	53.7 (95)	15.0 (40)**
11	LQAS	46.7 (30)	46.7 (30)	23.3 (30)
12-23	Cluster sampling	43.8 (210)	49 (210)	27.1 (210)
0-11	Routine reporting	90.7#	97.3#	85.6#

@ not weighted coverage

* Children more than 3.5 months of age

** Children more than 9 months of age

Achievement of allotted targets in 1992-1993; a proxy for coverage at the time of survey

Note: There is no difference between coverage in 11 months old (LQAS) and 12-23 months old children (cluster sampling).

The amount of time needed and the expenses incurred in the two surveys have been described in Table 6. LQAS was found to be 40% more costly and 2.5 times more time consuming than the EPI survey. On an average, two and half and six and half hours were needed to complete the survey in a cluster and lot, respectively; this includes the travel time to a cluster or lot. Around 11,500 and 15,900

Rupees were spent for the cluster and LQAS surveys respectively.

DISCUSSION

The results are in agreement with our earlier observation that homogeneous and low level of

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Table 6

Time and money used for the surveys in PHC Naugaon.

	LQAS	30 cluster
Unit used in the survey	Sub-center	Cluster
No. of sub-centers or clusters	27	30
No. of children/mothers per unit	10	7
Number of the villages visited	125	30
No. of the villages visited per sub-center or cluster	4.6	1
Total households visited	1,228	848
No. of households visited for one child and one mother	4.5*	4**
No. of households visited per sub-center or cluster	46	28
Total man days required for the survey	122	85
Officer days	25	25
Driver days	27	30
Surveyor days	70	30
Time spent (hours) for the actual survey (excluding traveling and training time)	121	38
Average time spent for survey per sub-center or cluster (hours/minutes)	4.30	1.15
Average time spent for traveling per sub-center/cluster in hours/minutes (not exact, only guess)	2	1.15
Money spent (Rupees)		
Daily allowances		
Officers	1,400	1,400
Driver	900	1,000
Surveyors	2,600	1,100
Petrol/oil/lubricant	10,000	7,000
Contingency/minor vehicle repairs	1,000	1,000
Total	15,900	11,500

* Mother of the same child which was eligible for coverage survey.

** Mother of different child.

immunization coverage is an impractical situation to apply LQAS (Singh *et al*, 1996). Almost all the sub-centers were classified as having an unacceptable level of immunization coverage (Table 1). Therefore, the results did not allow interventions to be focused on sub-centers in need of assistance to reach higher level of coverage. However, the data allowed the combination of results from all the lots to obtain an estimate of immunization coverage in the entire population; about 41% of the infants were immunized appropriately for their ages and 42% of their mothers had received a second/booster dose of TT (Table 2). Nevertheless, we might have drawn the same inference by using a cheaper and less time consuming technique (EPI methodology)

if we had sampled the children of same age group in two surveys.

Even if children sampled by LQAS and 30 cluster sampling were not contemporary, all the mothers included in LQAS survey and 149 mothers sampled in EPI survey were contemporary (Table 4); the TT coverage was remarkably similar, 42% (95% CI 37-47) and 41.6% (95% CI 31-52), respectively. As was observed in the previous study (Singh *et al*, 1996), the results indicated the ability of EPI methodology to estimate the immunization coverage in a large administrative area with reasonable efficacy.

Although the results obtained by two samplings

were consistent with each other, there was a big gap between the reported coverage and survey results (Tables 4, 5). The reported coverage were more than 85% for all the vaccines, whereas the estimated coverage did not reach even 50% with any of the vaccines. In fact, Naugaon was selected because of high reported immunization coverage; LQAS is supposed to be more useful in areas with high immunization coverage (Singh *et al*, 1996). Further analysis of the data revealed that obstacles, especially absence of vaccinator, were responsible for about 40% of the immunization failures in the child coverage survey (data not presented). It seems that the health system not only failed to deliver the vaccines to the beneficiaries but also inflated the achievements. This is an area of great concern which needs to be addressed if the goal of eradication of poliomyelitis by 2000 and mid-term goals for measles and tetanus neonatorum are to become a reality.

The results also suggest that LQAS is operationally feasible in our country (Singh *et al*, 1995, 1996). Contrary to apprehensions (Lemeshow and Robinson, 1985), fairly accurate sampling frames were available in the study area in the form of eligible couple (survey) registers. Moreover, fairly accurate lists of households are also available in non-health sector, for example, economic registers and voter lists. Furthermore, the decision to issue identity cards to all the voters in the country may further provide an excellent sampling frame throughout the country. However, conduction of LQAS by external personnel (as was in this study) is not a practical situation. Instead, medical officers and health supervisors who make regular and frequent visits to the sub-centers may use LQAS technique to monitor/evaluate the immunization program while carrying out other routine duties. LQAS required minimal training and the problem of prolonged time period required for survey can be solved by completing the job in several visits (Lemeshow and Stroh, 1988; Singh *et al*, 1995).

A slight modification in the LQAS methodology also reduced the survey time as compared to the previous study (Singh *et al*, 1996), *ie* from six to four and half hours despite being similar situations in two study areas. In the previous study, when a household was not found having an eligible child, a replacement was randomly selected from the same village (Singh *et al*, 1996), whereas in this study, the surveyors visited the next nearest house-

hold as is done in the EPI survey. This made the job simpler and less time consuming.

Nevertheless, being costier (40%) and more time consuming (2.5 times), LAQS is not a good substitute for current EPI methodology to evaluate immunization coverage in a large administrative area. However, LQAS merits serious consideration as a supplementary method for the routine monitoring of health programs on a small area basis, especially in areas with high overall coverage when the characteristics to be measured are heterogeneously and disparately distributed.

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