

# Evaluation Of Immunization Coverage By Lot Quality Assurance Sampling In A Primary Health Center Area

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## Abstract

**Objective:** Application of the Lot quality assurance sampling (LQAS) technique to measure indicators of quality of immunization coverage; assess the vaccination status of the target population; identify areas of high and low coverage in the study area  
**Design:** LQAS was used with modifications. Fifteen program-in-built quality indicators of the Reproductive and Child health program were assessed for quality of immunization coverage. The adopted sampling plan involved a sample size of 19 in each sub center and a maximum of three un-immunized children that the random sample would tolerate. The binomial distribution was used. This 19–3 sampling plan sets the probability of concluding that an indicator is performing well for a lot or sub center that has coverage of 90% level at 0.88 while those for a sub center that has a 65% coverage is set at only 0.059  
**Setting:** All six sub centers of K Gollahalli Primary Health Center, Bangalore South Taluka, Karnataka, attached to the Department of Community Medicine, Kempegowda Institute of Medical Sciences, Bangalore  
**Subjects:** Mothers, of children aged 0-11 months, and children aged 12-23 months residing in the primary health center area, selected from a random sample of households.  
**Results:** 114 children and 114 mothers were surveyed. Overall coverage was 84% and the rest (16%) were partially immunized/un-immunized children. Overall, low performance was observed in four sub centers  
**Conclusion:** LQAS can be used as an effective tool to monitor routine immunization activity. The present study, with modification of LQAS method would decrease the time taken for evaluation of immunization coverage. Appropriate immunization of subjects in areas with high coverage should be the focus to improve the quality of Immunization.

## INTRODUCTION

Lot Quality Assurance Sampling (LQAS) is a sampling technique used in industrial quality management to accept or reject homogenous product lots based on previously established quality levels. This technique aims to facilitate the decision-making process regarding the quality of examined lots, rather than to obtain precise estimates<sup>1</sup>.

Traditionally, the Expanded Programme of Immunization (EPI)-30 cluster surveys require a minimum population of 30,000 and do not provide a formal method to identify smaller units where success and failure are likely to have occurred<sup>2</sup>. LQAS has found application in the field of health in areas relating to Immunization coverage. The LQAS method can identify individual supervisory areas where improvements in vaccine delivery need to be made. LQAS can be conducted using smaller sampling frames<sup>2</sup>. This capability may assume importance for programs where immunization infrastructure has already been developed<sup>2</sup> and efforts can be focused on identification of these individual

supervisory areas where services can be improved if extra supervision and support are provided<sup>2</sup>. This study was undertaken to identify those supervisory areas that need attention and to know the applicability of LQAS technique in our setting.

## MATERIALS AND METHODS

The present study was conducted in K. Gollahalli Primary Health Center (PHC) area, which is one of the rural practice areas of Kempegowda Institute of Medical Sciences (KIMS), Bangalore with a population of 31,457 (January 2004). The PHC has a total of 64 villages from its six sub centers.

## SUBJECTS

Mothers, of children aged 0-11 months, and children aged 12-23 months residing in the study area were selected from a random sample of households

## SAMPLING DESIGN

LQAS requires sampling lots, which contain homogenous sampling units within each lot to ensure good comparison

between the lots. To ensure homogeneity, a lot was defined as all children aged 12-23 months and all mothers of children aged 0-11 months residing in a sub center. Each lot was considered to contain homogenous sampling units since a sub center was served by a different Junior Health Assistant Female/Male.

### **SAMPLE SIZE/LOT SIZE**

Lot size: A lot size of 19 children and 19 mothers in each sub center was selected.

Decision rule: Decision rule means the level of acceptability or the cut-off for performance of an indicator. A decision rule of 3 non-compliers or un-immunized children was considered. This means a maximum of 3 un-immunised children or non-compliers is acceptable in a sub center. If there are more than 3 un-immunised children or non-compliers in a sample of 19, then the sub center is considered low performing otherwise it is considered a high performing sub center.

Overall performance of a sub center for a particular group of quality indicators depends on the performance of every single quality indicator in that group. If there are more than or equal to 50% of the quality indicators which are high performing then the sub center is considered a high performance sub center. Otherwise it is considered a low performance sub center.

Why lot size of 19 and a decision rule of 3?

Assuming an acceptable coverage level of 90% and an unacceptable coverage level of 65%, the sampling plan of 19-3 was selected. Here 19 is the sample size and 3 is the decision rule. This sampling plan is considered optimal for the coverage levels 90 and 65%. This is because a sample size of 19 and a decision rule of 3 will have a  $\beta$ -error of 0.015 and a  $\alpha$ -error of 0.059<sup>10</sup>. A sample size less than 19 will have  $\alpha$  or  $\beta$ -errors more than 10%. Sample sizes more than 19 will not yield better  $\alpha$  or  $\beta$ -errors for the assumed coverage values<sup>10</sup>.

### **SAMPLING UNIT**

A household containing eligible child and / or an eligible mother was considered a sampling unit in this study. This is different from other LQAS surveys for immunization, where the children were selected randomly using the voters' list or the eligible couple (EC) registers as sampling frame. In our study area we found that neither the EC register nor the

voters' list was complete or updated. The most complete and updated sampling frame available was the number of households in each village from the latest pulse polio immunization program. A household containing eligible subjects was considered a sampling unit.

### **SELECTION OF HOUSEHOLDS**

Selection of the household was according to the National Universal Immunization Programme (UIP) coverage evaluation survey guidelines<sup>12</sup>. From the center of the village, the number of streets leading from the center of the village was counted and a street was selected randomly using a currency note. Again the side of the street was selected randomly using a coin. The number of houses on the selected side of the street was counted and a random number was chosen between 01 and the number of houses counted, using a currency note. The house representing the random number was selected as the first house. The next nearest door to the first house was chosen as the second house and so on. This method was followed until the required number of households containing children in the age group of 12 – 23 months and mothers who have delivered in the past one-year were found.

To ensure representation of every village in the sample, the number of households to be surveyed in a particular village was selected based on the proportion of the number of households in the village. The total number of households in a particular village was obtained from the latest pulse polio immunization program data in the PHC. Medical interns collected relevant data for the study. They were given half-day training regarding the study and method of data collection. Half-day field training on selection of households and administering the questionnaire was conducted prior to the start of the activity. Data was collected using standard coverage evaluation forms of the Universal Immunization Programme. The authors supervised the data collection activity in the field. The definitions used for various quality indicators were according to UIP coverage evaluation guidelines. Working definitions for indicators of appropriate immunization were developed and used in this study. These definitions are provided in table1. Data collection in each sub center/lot took a day each. The total period of data collection was 6 days.

### **REASONS FOR PARTIAL / NON-IMMUNIZATION**

Apart from asking for reasons for partial / non-immunization from the questionnaires, the opinion of the Primary health

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center staff was also collected regarding the reasons for partial or non-immunization. The results of the survey were presented to the PHC staff. All the PHC staff, including the medical officer and the health workers, who actually perform the immunization activity, in the field was present during the meeting. A focus group discussion was held to collect opinions on the results of the survey. Audio recording of the proceedings were also collected.

### RESULTS

A total of 15 Reproductive and Child Health (RCH) program-in-built quality indicators were considered for assessment of quality of immunization coverage, under 3 different headings. Of these 15 quality indicators, 4 indicators for immunization coverage, 7 indicators for appropriate immunization and 4 indicators for ANC coverage were assessed. Table 2 differs from other conventional tables. The numbers provided are those of non-compliers/ Un-immunized children. A non-complier is one who does not possess a valid Immunization card or ANC card, those who haven't had a safe delivery and/ or institutional delivery. The performance of each sub center depends on the number of non-compliers/ un-immunized children. If there are more than 3 (decision rule) non-compliers/ un-immunized children then the sub center is a low performance sub center for that individual quality indicator. It was observed that all the sub centers have high performance for immunization and low performance for appropriate immunization (table 3). Three sub centers (III, IV & V) have high performance for ANC quality indicators.

When all quality indicators were considered (table 4), overall, two sub centers (III and IV) were high performance sub centers compared to the other four (I, II, V & VI) in the primary health center.

During the focus group discussion with the PHC staff the main inferences which emerged were

Poor performance in measles Immunization (table 2) in sub center II and V was due to operational reasons. Measles vaccine was not administered when the number of children was inadequate (at least five), as the vial should be used within 4 hours of reconstitution

Inappropriate measles immunization was due to the exact date not being known as a result of the card being left at mothers' residence while coming back to the husbands' residence as expressed by the health care staff.

The PHC staff agreed that the absence of BCG (Bacilli Calmette Guarine) vaccine scar was probably due to improper technique.

ANC cards were also left in the mothers' place after delivery while moving to husbands' residence.

**Figure 1**

Table 1: Definition for indicators for appropriate immunization

Antigen	Duration
BCG	Within 3 months of the date of birth and presence of BCG scar
DPT1	After 6 weeks of birth
DPT3	Within 6 months of birth with at least 4 weeks interval between the three doses
Measles	After 270 days from the date of birth and within one year
Full Immunization	All vaccines immunized appropriately along with presence of Immunization card and BCG scar

**Figure 2**

Table 2: Distribution of subjects among different quality indicators

ANC Quality Indicators (n=19)							
1	Safe Delivery	7	5	1	1	2	4
2	ANC Card	11	14	14	13	11	9
3	Institutional Delivery	10	5	2	1	8	8
4	TT2/ Booster	3	6	4	3	0	7

**Figure 3**

Table 3: Performance of Sub centers among different groups of Quality indicators

Performance	Sub Center					
	I	II	III	IV	V	VI
<b>Immunization (n=4)</b>						
High	3	2	4	4	2	4
Low	1	2	0	0	2	0
Overall	High	High	High	High	High	High
<b>Appropriate Immunization (n=7)</b>						
High	2	2	3	2	2	2
Low	5	5	4	5	5	5
Overall	Low	Low	Low	Low	Low	Low
<b>ANC (n=4)</b>						
High	1	0	2	3	2	0
Low	3	4	2	1	2	4
Overall	Low	Low	High	High	High	Low

n = number of indicators in the group

**Figure 4**

Table 4: Overall Performance of Sub Centers for All Quality Indicators

Sub Center	Performance			Total (n=15)*	Overall performance
	Immunization Coverage	Appropriate Immunization	ANC		
I	3	2	1	6(40.0)	Low
II	2	2	0	4(26.6)	Low
III	4	3	2	9(60.0)	High
IV	4	2	3	9(60.0)	High
V	2	2	2	6(40.0)	Low
VI	4	2	0	6(40.0)	Low

n= total number of indicators

Figures in parenthesis indicate percentages

**DISCUSSION**

The study area had an overall immunization coverage of 84.21% (table not shown). The reasons for partial or non-Immunization were also collected. Details regarding this can

be made available by the corresponding author on request.

The non-retention of ANC and Immunization cards (table 2) was probably due to mothers leaving their cards at their mother’s place while returning to their husband’s place and not because the cards were not given. Focus of this study was mainly on coverage and lack of knowledge regarding appropriate Immunization among the health staff were the reasons for inappropriate Immunization.

LQAS in this study has been adopted with some modifications. The households serving as the sampling unit, every village being visited, proportionate number of households visited in each village and use of UIP guidelines for selection of households are the modifications. This modification will reduce the time in conducting the survey, which is cited as a drawback for LQAS in other studies<sup>3</sup>. However, this may be time consuming, since all the villages in the sub center need to be visited. But this modification definitely reduces the time taken by using simple random sampling. This modification also helps to conduct an independent evaluation of immunization coverage and to monitor routine immunization by the PHC staff, as most of them are aware of UIP methodology. LQAS helps the medical officer and his supervisory staff to focus on low performing areas, focus on individual indicators and even allocation of resources with equity. Other advantages of LQAS method as applicable to Immunization services are the use of small sample sizes, ability to detect deficiencies in small areas (sub centers) and simplicity of applying the technique with appropriate modifications using readymade tables.

**HIGH OR LOW PERFORMANCE SUB CENTER?**

All sub centers have high performance for Immunization and low performance for appropriate Immunization (table 3) quality indicators. These make it necessary to focus on quality of appropriate Immunization when the quality of Immunization coverage is high and hence provide better Immunization services in the study area.

LQAS uses only dichotomous variables. Using a binomial distribution, the probability of finding 16 or more immunised children or compliers when the coverage is 90% is 0.88, whilst the probability of finding 16 or more immunised children or compliers when the coverage is 65% is only 0.059.

Since the study area has an overall coverage of 84.21%

(table not shown), EPI cluster surveys cannot be used to monitor significant change in coverage since the confidence interval becomes narrower as coverage becomes greater or smaller than 50%<sup>4</sup>. Thus, the LQAS method incorporating a sampling plan used in our study would be useful in monitoring changes in subsequent surveys. Though the LQAS method cannot provide a precise estimate of coverage for individual sub centers due to a small sample size, it will be helpful in providing precise estimates for overall coverage in the PHC.

In conclusion, only program in built quality indicators were assessed. Technical quality of services and degree of satisfaction of clients were not assessed for quality of immunization services. Focus should shift towards improvement of quality of appropriate Immunization where quality of coverage is high. The modification in the methodology applies to most primary health center areas especially in a setting like India where updated complete list of individuals is not available. However, the utility of LQAS as a method to assess immunization coverage and to monitor significant change in performance of supervisory areas is re-emphasized in this study.

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