Research Article

Primary immunization coverage among children using lot quality assurance sampling technique in rural field practice area of a Medical College and Hospital, Bengaluru, Karnataka, India

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ABSTRACT

Background: In India, immunization has been a central goal of the health-care system from the 1970's, but universality is yet to be achieved. **Objectives:** The objective of the study was to assess the primary immunization status of children aged 12–23 months using lot quality assurance sampling (LQAS) technique in three primary health center (PHC) areas and estimate the dropout rates. **Materials and Methods:** A community-based cross-sectional study was carried out in three PHC areas of a Medical College Hospital, Bengaluru. LQAS technique was applied in 10 lots and 190 children aged 12–23 months were included. Lots are judged as acceptable or unacceptable based on the decision value, and dropout rates are estimated. **Results:** By 1 year of age, 92.6% of children were fully immunized, 7.4% were partially immunized, and no child was found to be unimmunized. One lot was found to be low performing. Dropout rate was 0.5%, 2.1%, and 3.2% between DPT1-DPT2, DPT2-DPT3, and DPT3-Measles, respectively. **Conclusion:** LQAS technique could be used to identify areas needing resource assignment to improve immunization coverage.

KEY WORDS: Children; Karnataka; Lot Quality Assurance Sampling; Primary Immunization Coverage

INTRODUCTION

Immunization is a cost-effective preventive public health intervention, averting an estimated 2–3 million deaths every year.[1] An estimated 19.5 million infants worldwide are still missing out on basic vaccines.[2] In Karnataka, there has been a decline in full vaccination coverage between National Family Health Survey (NFHS)-2 (60%) and NFHS-3 (55%)[3] and was 62.6% during NFHS-4.[4] Lot quality assurance sampling (LQAS) has found application in the field of health, particularly valuable for measuring immunization coverage as it helps to identify areas with low immunization coverage where improvement in vaccine delivery need to be made.[5,6] In spite of it being more than 30 years after the launch of Universal Immunization Programme, universality of immunization services is yet to be achieved. Hence, the present study was carried out with an objective to assess the primary immunization status of children aged 12–23 months using LQAS technique in three primary health center (PHC) areas and to estimate the dropout rates.

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MATERIALS AND METHODS

A community-based cross-sectional descriptive study was conducted in three PHC areas, catering to a total population of 52,499, attached to the Department of Community Medicine of a Medical College and Hospital, Bengaluru,

during September–October 2014. The procedures followed were in accordance with the ethical standards as laid by the ICMR-Ethical Guidelines for Biomedical Research on Human Participants.

Inclusion Criteria

Children aged 12–23 months with either mother or reliable respondent available to provide key information and who are permanent residents of the study area and consenting to participate in the study.

Sampling Technique

Lot Quality Assurance Sampling Technique.

Planning the Study as per the WHO guidelines[7]

1. Level of the accuracy of ±8% and 95% confidence level is considered for the study.
2. Estimation of total sample size: The sample size for ± 8% accuracy and 95% confidence is determined as 150 by considering the declarations by the WHO.
3. Estimation of target population from which sample will be selected: Children 12–23 months age make up approximately 3% of population (percent that WHO recommends using when actual rates are not available). The total population of the study area is 52499 and the proportion of children aged 12–23 months is 3%, then 52499 × 0.03 = 1575.
4. Calculate the sampling fraction to decide whether to reduce the total sample size: A sampling fraction shows what proportion of a total population will be included in a study. Sampling fraction = Total sample size/Target population = 150/1575 × 100=9.5%.
5. The number of lots to be studied: For this study, each subcenter is considered as a LOT as it is served by different junior health assistant female/male. Thus, each LOT is considered to contain homogenous sampling units. There are 10 subcenters in the three PHC's.
6. Calculation of minimum sample size for each lot: Minimum sample size = Total sample size/Number of lots = 150/10 = 15. It is the same for all LOTS. This can be increased but not decreased. Thus, it is increased to 19 per Lot, as according to Valadez *et al*.,[8] the sample size of 19 per lot has α and β error <10%. Thus, total sample size is increased to 190.
7. Setting of low and high threshold levels and decision value: Decision value is the cutoff for the performance of an indicator. It is the highest number of children who are not fully immunized in a lot. Considering 85% as acceptable (high threshold) and 65% as unacceptable (low threshold) coverage level, decision value is determined as three based on WHO declaration.[7] This means a minimum of 16 fully immunized or 3 partial/non-immunized children is acceptable in a lot.
8. Select sampling point areas: It is done using the estimated list of households in each lot as shown in Table 1. 19 numbers are selected randomly from 1 to 817 using the random number table. The villages in which the 19 numbers are located (indicated by*) will be those from which children aged 12–23 months will be selected in the lot.

Selection of Household

Locations of 19 interviews for each lot are identified using a random process. To select the household, from the center of the village, the street, side of street and first household is selected randomly. If there is no eligible child in that house, then the door closer to the first household is chosen as the second house and so on until a household containing a child in the age group of 12–23 months is found. If there is more than one child per village, then the above steps are repeated to select the next household with an eligible child.

Method of Data Collection

If any house visited had more than one child aged 12–23 months, then numbers were designated to the children and one child was selected randomly. Mother/guardian of the child was interviewed using a pre-tested, semi-structured questionnaire to collect information on sociodemographic components. Data on immunization status was collected by checking the immunization card of the child or information from the mother or a reliable respondent in the family stating that the child has been immunized was considered. Further, the presence of scar of BCG vaccine was checked.

The following definitions were considered for immunization status: [9]

Fully immunized

Child who had received one dose BCG, three doses of oral polio vaccine (OPV), DPT, and Hep B, and one dose of Measles before 1 year of age.

Table 1: Selection of sampling point areas in Lot 1

Villages in lot 1	Estimated number of households	Cumulative number of households	Interview locations
Village 1	84	84	**
Village 2	102	186	***
Village 3	78	264	*
Village 4	111	375	***
Village 5	90	465	**
Village 6	182	647	****
Village 7	170	817	****

Partially immunized

Child who had received one or more vaccines but not all the above-mentioned vaccines.

Non-immunized

Child who had not received any of the above-mentioned vaccines.

Children who were not fully immunized were linked to the health worker of concerned PHC for further follow-up.

Ethical Consideration

Approval was obtained from the Institutional Ethics Committee of Rajarajeswari Medical College and Hospital, Bengaluru, before the commencement of the study.

Statistics

Data were compiled into Microsoft excel worksheet and analyzed using SPSSv.20. Data are presented as frequency and percentages. Lots are judged as acceptable or unacceptable based on the decision value. Estimate of overall coverage and confidence interval (CI) for the target population in the study area is calculated.[7] The dropout rate is calculated using the formula: (HCAD-LCAD)×100/HCAD, where HCAD is highest covered antigen dose, and LCAD is lowest covered antigen dose.[9]

RESULTS

Of the 190 children, 101 (53.2%) were males, 185 (97.4%) were Hindu by religion, 131 (68.9%) belonged to the joint family, and 78 (41.1%) belonged to lower middle class according to modified BG Prasad classification. Majority, 176 (92.6%) of children were fully immunized by 1 year of age, and 14 (7.4%) children were partially immunized. In this study, no children were found to be unimmunized. Immunization card was unavailable during the survey for 43 (22.6%), of which 29 (67.4%) had misplaced the card, 8(18.6%) had left the card their mother's place, and 6 (14%) had lost it. Majority 181 (95.3%) of the children were vaccinated in the government sector.

Of the 10 lots studied, nine lots were high performing, and only lot three were considered to be low performing as it had 4 partially immunized children. After giving weights to each lot, the estimated immunization coverage and CI in children aged 12–23 months were found to be 93% ± 3.8% [Table 2]. Thus, the true coverage in the study area ranges from 89.2% to 96.8%.

As shown in Table 3, 5.8% of children have not received the measles vaccine, 2.6% had not received third dose DPT, HepB, and OPV. BCG scar had developed in 177(93.2%) of children.

As shown in Figure 1, the lowest dropout rate was of 0.5%, between first dose of OPV, DPT, and HepB and second dose OPV, DPT, and HepB, with increasing dropout rates among the next doses. Between HCAD and LCAD, i.e., between BCG and Measles dropout rate was found to be 4.75%. Dropout rate<10% indicates good utilization rates.[10] Dropout children need to be identified and mobilized for the next vaccination session so that they do not become partially immunized.

DISCUSSION

Lot quality technique is used to monitor the quality of immunization services.[7] Overall, immunization coverage estimate for the target population was 93% with one lot

Table 2: Overall performance of each lot estimated overall coverage for the total target population (LOT sample size=19, Decision value=3)

Lot No.	Lot population	Weight (Wt)	Number immunized	Partially immunized	Overall performance	Proportion immunized (p)†	Estimated coverage‡
1	3749	0.07	19	0	High	1.00	0.070
2	5428	0.11	18	1	High	0.95	0.104
3	1698	0.03	15	4	Low	0.79	0.023
4	4039	0.08	17	2	High	0.89	0.071
5	3626	0.07	18	1	High	0.95	0.066
6	3736	0.07	19	0	High	1.00	0.070
7	3786	0.07	17	2	High	0.89	0.062
8	9092	0.17	18	1	High	0.95	0.161
9	8468	0.16	18	1	High	0.95	0.152
10	8877	0.17	17	2	High	0.89	0.151
Total	52499	1.00	-	-	-	-	0.93

*Weight (wt) = (Lot population)/(Total target population of all lots), †Proportion immunized (p) = (Number immunized)/Lot sample size (*n*), ‡Estimated coverage=Weight×Proportion immunized, Confidence Interval (CI) = $[1.96\times\sqrt{\sum (wt^2\times pq)/n}] \times 100$, where q=1 − p

Table 3: Distribution of children according to vaccines received and missed

Vaccine	Vaccine received	Vaccine not received
BCG	188 (98.9)	2 (1.1)
OPV1/DPT1/Hep B1	190 (100)	0 (0.0)
OPV2/DPT2/Hep B2	189 (99.5)	1 (0.5)
OPV3/DPT3/Hep B3	185 (97.4)	5 (2.6)
Measles	179 (94.2)	11 (5.8)

Figures in parenthesis indicate percentages. OPV: Oral polio vaccine

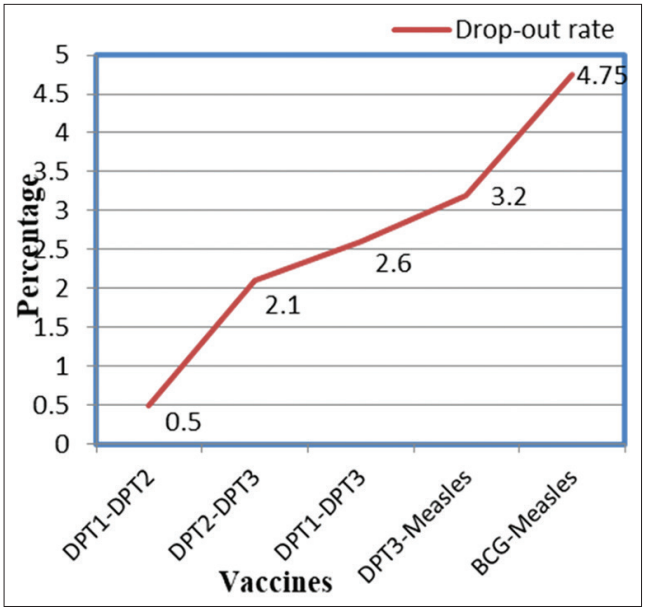

Figure 1: Dropout rates of children between each dose of vaccine

identified as low performing. It was good to know that there were no unimmunized children in the study area. In the present study, one of the 10 lots studied had immunization coverage below the acceptable levels. The present study had least dropout rate of 0.5% between DPT1 and DPT2. Between consecutive doses, dropout rate was high between DPT3 and measles (3.2%) which could be because of the gap of 6 months or more between the doses. Our country being in the phase of measles elimination, necessary measures need to be taken to address the dropout at all stages, by giving reminder for the mothers so that vaccination is not missed for children, use of tracking tools such as tracking bag, mother and child registers at PHC's, also facilitate timely tracking of dropouts and thus improving the coverage rates.

As per DLHS-4 for Karnataka,[11] 77.6% children aged 12–23 months were fully vaccinated, 1.4% not received any vaccination, BCG, three doses of DPT and polio vaccine and measles vaccine was received by 97.2%, 88.2%, 89.6%, and 89.6% children, respectively. As per DLHS-4, in Bengaluru 90.6% children were fully vaccinated, 98.1%, 94.3%, 96.2%, and 96.2% had received BCG, three doses of DPT and polio vaccine and measles vaccine, respectively.[12] Compared to DLHS-4 report, the coverage estimates obtained in the present study are higher for all vaccines (>95%) except for measles vaccine which was 94.2% and no children were found unimmunized. In a study by Lahiri *et al*.,[13] the number of valid doses in percentages was BCG - 96.14%, DPT1 - 83.64%, DPT2 - 79.48%, DPT3 - 77.47%, OPV1 - 83.64%, OPV2 - 80.25%, OPV3 - 78.09%, Hep B1 - 65.74%, Hep B2 - 56.64%, Hep B3 - 45.99%, and Measles -73.3%. In a similar study using LQAS technique by Pradeep *et al*.[5] the overall immunization coverage was 84.21%, and all the sub centers had high performance for immunization. Similar coverage estimates as our study was seen in study by Datta *et al*.,[14] where 90.9% children were fully immunized, 0.3% were non-immunized, and coverage for individual vaccines was 99.7% for BCG, coverage for Measles and hepatitis B vaccine was 95.45% and for DPT and OPV was 97.3%. In the study by Sivasankaran *et al*.,[15] 97.7% of children were vaccinated against measles, and two health sub-centers were low performing. In the study by Bhuiya *et al*.,[16] the number of inadequately performing areas was one area each for DPT and BCG, five areas for measles. Dropouts are those children who started vaccination but did not complete the schedule. It reflects the poor perception of parents/caregivers' about the benefits of vaccination or the immunization service delivery system, or both, combined with other barriers that force them to place immunization on a low priority. Since December 2014, Mission Indradhanush has made tremendous efforts to bridge the gap in immunization.[10] In a study in the rural area, the dropout rate between BCG and DPT3 was 2.1%, 3.9% between BCG-Measles and DPT3-Measles dropout rate was 1.8%. In comparison to the present study, higher dropout rates were found in coverage evaluation survey with a dropout rate of 5% between DPT1 and DPT2; 9% between DPT2 and DPT3; 13% between DPT1 and DPT3; 15% between BCG and Measles, 18% between BCG and DPT3; and 10% between DPT1 and Measles.[17] The difference in dropout rates is mainly because of the improved vaccination coverage noted with years which also indicated better utilization of immunization services in the community.

Strengths of the Study

LQAS technique used helps make judgments about individual lots surveyed, and findings can be used immediately by local managers and health. As every child is selected at random, a child who could be residing on the outskirts of the village will also have equal chances of being selected, unlike in other survey methods. Only a small sample is needed to classify a supervisory area as not having reached the average coverage.[7] The study follows STROBE guidelines

Limitation

The results of the study cannot be generalized beyond the study area. LQAS technique is time-consuming as almost

every village in the lot needs to be visited to obtain a representative sample.

CONCLUSION

Present study area showed good immunization coverage rates with only one lot considered as low performing and dropout rate in the study was high between DPT3 and measles. LQAS technique can be used in rural areas so as to identify sub-areas with poor coverage, to better assign resources to improve the coverage.

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