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Immunization Coverage Evaluation: A Comparison between WHO and IRMS Methodologiest

Introduction

THE Expanded Programme of Immunisation (EPI) was initiated by the Government of India in 1978 with an objective to bring down levels of morbidity, mortality and disability occurring due to diseases like diphtheria, pertussis, tetanus, polio-myelitis, tuberculosis and typhoid among children (aged 0-6 years), particularly among infants, by providing free vaccination services. Tetanus toxoide (TT) vaccination, introduced in 1975-76 to provide immunisation against tetanus to the expectant mothers.was also integrated with Extended Programme of Immunization (EPI) in the same year. The programme, although gave legitimacy to the efforts initiated in this direction, it remained in low key and made almost negligible impact till it was targeted as one of the priority programmes under Universal Immunisation Programme (UIP) during 1985-86. The UIP aimed at coverage of all infants with three doses each of DPT and polio and one dose each of measles and BCG; and two doses of tetanus toxoide to all the expectant mothers. To give extra boost to the programme a special 'Immunisation Mission', with Joint Secretary level officer appointed as 'Commissioner', was established under the Ministry of Health and Family Welfare at the Government of India level in 1989. Since establishment of the Mission, the service statistics have shown an all round improvement in the coverage of children under two years (infants in particular) and expectant mothers by different immunisation vaccines.

As vaccination leads to the immunity against specific diseases among a particular section of population, for strategic planning and monitoring of the programme, accurate measurement of its coverage is an essential step. This also is likely to help in estimating the expected reduction in morbidity and mortality from the vaccine preventable diseases. Stray research available at various levels has pointed out that the data obtained through service

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t Based on the study sponsored by the UNICEF Rajasthan and IRMS, New Delhi; conducted by the IIHMR, Jaipur. 1. Government of India, 1990, *Family Welfare Programme in India, Year Book, 1988-89.* Ministry of Health and Family Welfare, Government of India, New Delhi.

statistics is usually over estimatied. The coverage evaluation surveys are thus recommended as the major source of information to check and verify the validity of the reporting errors in the service statistics. Besides, these surveys conducted from time to time also serve the purpose of assessing the impact of immunisation programme with respect to its targets.

The Problem

As yet, the coverage evaluation surveys are being conducted with the help of widely known *Thirty Cluster Sampling Method*[2], recommended by the World Health Organisation (WHO). In this method, selection of 30 villages from a district is done by adopting probability proportion to size (PPS) systematic sampling procedure. Having selected a village, a cluster of 7 children-is taken from each village and the same process is repeated for all the selected 30 villages in the district. This way the sample consists of 210 children in the form of 30 clusters of 7 children each from a district.

This method of coverage evaluation was first applied to evaluate African small-pox immunisation programme, where the population is generally homogeneous and village size is comparatively small. On the other hand, in Indian context, the villages are generally large and population clusters are heterogeneous with respect to deverse geographical and socio-cultural conditions. Since the evaluation methodology is being primarily employed to evaluate rural based Universal Immunisation Programme, its applicability in socio-culturally diverse society in India needs to be examined, as this method of evaluation is likely to have in-built biases in the results.

In this connection Institute for Research in Medical Statistics (IRMS), New Delhi[3] had carried out methodological investigation on alternative sample survey methodology for estimation of immunisation coverage, in Indian context. The methodology so developed claims that in addition to providing the estimates at the district level within 10% margin of error, as is also true for WHO methodology, it would also be able to identify-the target areas/ groups where the problems are more and require special attention.

All concerned, the IRMS (a division of Indian Council of Medical Research, New Delhi), other national and international research institutions like UNICEF, and policy planners are interested to compare the methodology developed by the IRMS vis-a-vis that developed by the WHO, which is being widely used at present, and test their relative validity and relevance. The present paper based on the study, sponsored by the UNICEF, Jaipur to the Indian Institute of Health Management Research, Jaipur attempts to compare the results obtained by adopting two methodologies in four randomly selected districts of Rajasthan.

Study Objectives

The main objective of the present study is to compare and test the level of differences in immunisation coverage, obtained by employing WHO and IRMS methodologies in selected districts of Rajasthan with same cut-off time period.

2. Government of India, 1987, *Universal Immunisation Programme-Evaluation Vaccination Coverage,* Ministry of Health and Family Welfare, Government of India, New Delhi.

3. Institute for Research in Medical Statistics, 1991, *Methodological Investigation on Surveys of Immunisation Coverage,* IRMS, New Delhi.

Hypotheses

With the given objective, the study attempts to test the hypotheses that the estimation of different immunisation coverage is affected by:

(a) heterogeneity in different socio-cultural and economic groups of population; and
(b) comparatively smaller sample size is used in WHO methodology, especially in case of large size villages.

Area Coverage and Methodology

To compare methodologies, employed for coverage evaluation survey, four districts were selected randomly, keeping geographical representation into consideration. While the coverage evaluation in the selected districts using IRMS metholology formed a part of another major study, simultaneously in the same four districts coverage evaluation was also attempted by using WHO methodology to test the difference between the two methodologies at the same period of time. The districts covered include; Sirohi, Churu, Jaisalmer and Bharatpur. The survey was conducted by using the same questionnaire, but by two different teams of investigators to avoid possible biases due to the questionnaire format as well as of the investigators.

In following pararaphs, the two methodologies employed for coverage evaluation survey are briefly described.

(A) *WHO Methodology*

Thirty Cluster Sampling Method (WHO methodology) suggests that the sampling procedure adopted for coverage evaluation is based on cluster sampling technique. A cluster is a randomly selected group and as suggested by the WHO on the basis of employed statistical techniques, needs to contain atleast 7 children in the age range of 0-1 year in case of mother's coverage to provide immunisation as a part of ante-natal care services; and another set of 7 children in the age range of 1-2 years, to cover infants under different immunisation vaccines. It is further recommended that, to estimate statistically reliable coverage for a unit like district; 30 such clusters should be selected by using probability proportion to size (PPS) sampling procedure. It is claimed that the suggested procedure will meet following standards of reliability:

(a) The data which result from the survey will have a level of accuracy of plus or minus 10%.
(b) Nineteen out of 20 times, the data which result from the survey will be within the stated level of accuracy. In other words, the level of confidence will be 95%.

The above standards of reliability will hold good only if the 30 groups are randomly selected. Also, according to this sampling procedure, although conclusions can be drawn for the whole area surveyed but comparison between sub-sections cannot be made.

The selection procedure requires listing of all villages followed by all the urban towns (census enumeration blocks within each town) in a district with their population. Generally this listing is adopted from the *District Census Hand Book* in the same serial number as listed in the census. Subsequently population of all the villages and towns is cumulated. As 30 clusters are to be identified, a class interval, by dividing total population of district by 30, is obtained. Thereafter using systematic random sampling procedure 30 villages / town blocks are selected. This procedure ensures selection of required sample units using PPS sampling procedure.

The methodology further envisages that within each selected village/urban block, first a house is selected on random basis. For this selection, the investigator is supposed to go to the centre place of the cluster, draw a currency note and decide about the direction of house to be taken as first sample unit. Subsequently, adjoining houses are visited till the target sample (7 children — 0 to 1 years or 1 to 2 years — as the case may be) is achieved. In case the targeted number of children could not be covered from the selected cluster (village/ town block), the coverage is made up from adjoining village ward. By following this procedure, from each district, a sample of 210 children, in each case, is selected to evaluate immunisation coverage of infants and mothers—as per the requirement.

(B) IRMS Methodology

The alternate methodology proposed by the Institute for Research in Medical Statistics, New Delhi, for immunisation coverage evaluation consists of a stratified multi-stage random sampling design. The sample consists of 300 children and the same number of mothers from rural areas and 75 each from urban areas, from each of the selected districts.

The methodology envisages that in each district, villages are first classified into four broad strata according to the population size of the villages (villages with population: i) less than 500; ii) 500-1000; iii) 1000-2000 and iv) more than 2000. From each stratum, five villages are then selected, using simple random sampling procedure (without replacement).

From each selected village, 15 children in the age range of 12 to 23 months to cover children and another 15 children of ages below one year for mothers coverage are selected. One of the following three methods has been recommended for selection of the desired number of children in order of preference:

(a) *MF-l Register:* Multipurpose worker of each village is supposed to maintain a register (MF-I) of members of each household, which is updated every year. This register, if available, is utilised for identification and selection of the children of the desired age groups (0-11 and 12-23 months, as the case may be) by adopting simple random sampling (without replacement) procedure.

(b) *Birth and Death Register:* It is also generally maintained at the village level. In this register, the names of children born in a year with their date of birth, are entered. The children are generally identified by their father's name.

(c) If none of the above two registers are available/maintained or updated in the selected villages regularly, then different clusters of settlements/basties resided by different

communities like Harijans, Kumhars, etc., are identified and the population size, location and other relevant information relating to these basties available with Health Worker/ Anganwadi Worker/ Patwari / Chowkidar / other knowledgeable individuals in the study village are collected.

Having identified different basties in the village, a list of two types of basties separately for SC/ST communities and those resided by other communities along with their population size is prepared. The number of children to be covered from the two sets of basties is then allocated in proportion to their population size. Atleast 4 children have to be covered from each of the selected basties. This procedure expects to provide self weighting for different strata of population at village level.

After the basties are identified the investigator goes to the centre of the basti and identifies the different directions in which houses are located. He then selects one of the direction randomly with the help of the last digit of a currency note. He then approaches the first house on his left and enquires if there is a child of desired age group. In case there is no such child he proceeds to the immediate next house and enquires about the child. The process is continued till he finds a household with a child of desired age group and collects the required information. In case of non-availability of either a responsible member or vaccination card in the household, the selected household is not considered and is skipped. If a child of desired age to the non-regular member of the household who is residing in the house for 6 or more months is present, his particulars are also taken. This process continues till the investigator covers the desired number of children.

If the desired number of children in the target age are not available in a particular basti, the number of children fall short of, are covered from the adjoining basti, preferably of the same caste group. If the number of children in the small size villages are less than 15, that is compensated by selecting more children from the larger villages, i.e., from stratum IV.

For coverage evaluation of both mothers and children under different immunisation vaccines, exactly same procedure as described above is followed.

In case of urban areas of the district (i.e. towns and cities with population more than 5,000 and having characteristics of urban area), the methodology envisages to cover seventy five children between 12 months to 23 months of age and 75 mothers having children upto 1 year of age. Out of these, two-fifth are surveyed from the District Head Quarter and one-fifth each from three towns selected randomly from the urban areas of the district The number of children / mother covered is fixed at 75 keeping in view the rural/urban ratio of 80:20. S ince each of the urban town is divided into wards and sub-wards, 2 wards from the district headquarters and one each from the three towns are selected randomly. The selection procedure for the children and mothers from the wards remained similar to one adopted to cover urban areas in WHO methodology.

This methodology also ensures, as in case of WHO methodology, an accuracy level of plus or minus 10% with 95% level of confidence.

Sample Survey

As discussed, the present investigation required a coverage of 210 mothers and equal number of children (infants) per district for immunisation coverage evaluation according to

WHO methodology; and 375 mothers and equal number of children (infants) per district according to IRMS methodology. The actual coverage of mothers and infants in four sample districts is given in Table 1.

TABLE 1 : SAMPLE COVERAGE BY DISTRICT AND PLACE OF RESIDENCE

Place of Residena	*Districts*									
	Sirohi		*Churu*		*Jaisalmer*		*Bharalpur*		*Total*	
	WHO	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*
Rural	175	310	178	331	175	278	175	300	703	1219
Urban	35	75	35	75	35	75	35	75	140	300
Total	210	385	213	406	210	353	210	375	843	1519

As suggested in WHO and IRMS methodologies, the number of interviews in each selected district centered around 210 and 375 respectively. The following section discusses the results obtained in terms of immunisation coverage by employing the two suggested methodologies.

Methodology Comparison for Immunisation Coverage

The two methodologies, as suggested by the WHO and the IRMS have been compared through the actual data collected in four districts of Rajasthan, by employing both methodologies, simultaneously. The four selected districts represent the state geographically. In the beginning, it was envisaged that methodology testing will be carried out in three randomly selected districts. However, the random selection missed the plain areas of the State. To give adequate representation, fourth district was also included as study area which was selected randomly from among the plain areas of the State. Table 2 gives some of the general characteristics of the four selected districts as obtained through 1981 and 1991 censuses. All the characteristics of the districts show a wide variation among them.

While decennial rate of growth of population varied from as low as 14.4 percent in desert district of Jaisalmer to as high as 30.5 per cent in semi-desert district of Churu, the variation in density is quite high from 9 in Jaisalmer to 325 persons per square km in plain district of Bharatpur.

Table 2 further shows that all the socio-demographic characteristics varied largely among the four selected districts; sex-ratio (from 810 to 950); literacy level (24% to 34%); SC population (15% to 21%); ST population (1% to 23%); and percentage of cultivable land (from 50% to 96%). The advantage of such large variation in district characteristics in methodology testing study is that, it would be able to depict: under what different terrain and conditions (set-ups), the two methodologies introduce biases in immunisation coverage results and under which set-ups, variation in adopted methodologies will have the least impact on the results.

TAHLE 2 : SOCIO-DEMOGRAPHIC INDICATORS OF FOUR DISTRICTS

	Indicators	*Districts*			
		Jaisalmer	*Churu*	*Sirohi*	*Bharatpur*
1.	Type of Region	Desert	Semi-desert	Hilly/Semi-plain	Plain
2.	Decennial growth rate (%)	14.4	30.5	20.5	26.7
3.	Density	9	91	127	325
4.	Sex Ratio (F/M x 1000)	810	940	950	835
5.	Literacy (%)	23.9	27.2	26.0	33.7
6.	SC Popn. (%)	14.5	19.5	18.7	21.3
7.	ST Popn. (%)	4.4	0.5	23.1	3.0
8.	% Cultivable land	89.4	95.9	50J	75.4
9.	% Irrigated land among cultivable land	0.0	0.0	24.6	31.9

SOURCES :(i) Refer Census of India, 1991 for items 2 to 5.

(ii) Refer Census of India, 1981 for items 6 to 9.

In the following section, the immunisation coverage results have been presented and discussed by taking different sets of districts. It may be mentioned that the immunisation coverage, as reported by service statistics are on much higher side and comparison of those with the obtained results will not lead to any meaningful analysis. Keeping this in view, no attempt is made to compare the survey results with that of results obtained through the service statistics, and the analysis is restricted to comparison of two methodologies only.

Immunisation Coverage Levels in the Study Districts

Table 3 compares the results obtained for immunisation coverage of infants and mothers in all the four districts, using both the methodologies. It depicts that while coverage of children under DPT, Polio and BCG was around 40 per cent, it was comparatively lower for coverage of children under measle vaccine (29%) and also coverage of mothers by tetanus toxoide (30%). The overall variation between the two methodologies was found to be insignificant at 5% level. The major differences, however, were found in infants coverage under BCG vaccine and mothers' coverage under tetanus toxoide vaccine.

Table 3 thus depicts that virtually not much differences were found in the estimates obtained by the two methodologies, and if there were any, virtually got compensated due to variation in the characteristics of districts. It is worth mentioning here that, our hypotheses were: the difference in the two methodologies could be due to (a) sample size difference and (b) by omission of the outer/isolated segment of the population because the starting point in WHO methodology is centre of village, mostly in case of relatively larger villages.

The hypotheses thus suggest that the density is one single variable which could have an impact on results, besides the sample size. As depicted by Table 2, in terms of population

TABLE 3 : ESTIMATED IMMUNISATION COVERAGE LEVEL IN SIROHI, CHURU, JAISALMER AND BHARATPUR DISTRICTS

Vaccines		*WHO*	*1RMS*	1 Z 1 *value*
DPT : doses	I	55.3	50.2	2.35*
	II	46.9	44.3	1.42
	III	41.0	38.5	0.97
Polio : doses	I	53.9	49.8	1.88
	II	46.1	43.8	0.95
	III	40.6	38.3	1.45
Measles		31.0	28.6	1.56
BCG		44.2	39.1	2.39*
TT : doses	I	38.2	32.0	2.93*
	II	34.4	29.8	2.55*
Sample Size *(N)*		843	1519	$X^2 = 4.2$

* Difference is significant at 5% level.

density, Jaisalmer (9 persons per sq km) and Bharatpur (325 persons per sq km) districts are way apart. Generally in low density area, where village size is very small (Jaisalmer villages are mostly small and in form of hamlets), a sample of 7 children is likely to cover all the segments of population. This is likely to make the sample unbiased. However, in such cases, the hamlets situated in interior are omitted, especially when large number of sample units are to be covered. This is likely to introduce upward bias leading to higher coverage, in case the IRMS methodology is used. On the other hand, when the population density is high, the segregated segments of the population, get intermixed. This has been a characteristic of large number of Indian villages. In such cases, the population of different segments is likely to be more homogeneous, depending, however to the extent the inter-mix has taken place. In such conditions, the biases would be minimum, and both the methodologies are likely to yield the similar results.

With the same argument, those districts/villages which are of medium size and most likely the different segments of their population have maintained the identity, are likely to give upward biased results, when WHO methodology is used.

To make the situation clearer, the observations are made for each district separately. Table 4 gives the immunisation coverage for children and mothers by all the vaccines under consideration.

As argued, Sirohi and Churu districts which could be termed as relatively normal districts in terms of population density and other related variables—when compared with State and all India averages—show a significant difference in the results obtained by the two methodologies. Expectedly higher estimates arc obtained when WHO methodology is used. The differences are found highly significant in case of Churu district. On the other hand, in Jaisalmer district while the differences in immunisation coverage estimates by adopting two methodologies were again found significant, an upward bias was observed in case of IRMS methodology. Interestingly in Bharatpur district with very high population density

(representating the plain areas), almost negligible differences in the immunisation coverage estimates obtained by employing the two methodologies were found (Table 4).

TABLE 4: ESTIMATED IMMUNISATION COVERAGE LEVEL IN EACH DISTRICT USING WHO AND IRMS METHODOLOGY

Vaccine		*Districts*											
		Sirohi			*Churu*		*Jaisalmer*				*Bharatpur*		
		WHO	*IRMS*	IZI *value*	*WHO*	*IRMS*	IZI *value*	*WHO*	*IRMS*	IZI *value*	*WHO*	*IRMS*	IZI *value*
DPT :	I	76.7	64.9	3.01*	54.0	40.1	3.27*	38.1	47.3	2.11*	52.4	48.8	0.70
doses	II	69.0	60.5	1.94	46.0	32.8	3.13*	29.0	41.1	2.90*	43.3	43.2	0.00
	III	63.8	55.1	2.12*	37.6	27.1	2.77*	24.3	34.8	2.76*	38.6	37.3	0.48
Polio :	I	73.3	64.9	2.01*	53.1	39.7	3.05*	36.7	46.5	2.33*	52.4	48.5	0.70
doses	II	67.6	58.2	2.40*	44.6	33.5	2.64*	29.0	41.1	2.90*	43.3	42.7	0.00
	III	62.4	54.8	1.66	37.6	27.3	2.77*	23.8	34.6	2.76*	38.6	36.8	0.48
Measles		55.2	44.7	2.34*	26.8	14.0	3.89*	13.8	29.5	4.33*	28.1	27.2	0.26
BCG		70.9	56.6	6.90**	40.4	28.8	2.72*	29.5	35.7	1.48	36.2	35.5	0.00
TT :	I	56.3	44.4	2.78*	38.4	23.0*	3.86*	21.9	23.1	0.28	35.7	34.1	0.49
dpses	II	50.7	42.1	2.10*	34.1	23.8*	2.61*	19.0	17.0	0.61	33.3	32.5	0.00
Total N		210	375		210	375		210	375		210	375	
X^2				19.44*			57.62**			26.83**			0.82

*** Difference is significant at 5% level**

**** Difference is highly significant at 5% level**

***Note:* The tabulated value of *if* at 9 d.f. for 5% level of significance is 16.92.**

The above discussion thus clearly brings out that while in normal Indian villages with sectoral formation (e.g., in Sirohi and Churu districts) an upward bias was found in estimates obtained by using WHO methodology, in case of small and hamlet type of villages (e.g., Jaisalmer) the upward bias was found when IRMS methodology is used. The differences in both the cases were statistically significant. Interestingly in high density district like Bharatpur, where sectoral segregation in villages is negligible, the two methodologies came out with similar estimates and no significant differences in the estimates were found (Table 4).

Reasons for Non-acceptance of Immunisation Vaccines

Although not much inference can be drawn when compared the reasons obtained by comparing the methodologies by districts. It is interesting to note that 'lack of information' figured as the main reason in Churu and Jaisalmer districts when IRMS methodology is used, as compared to in Sirohi (almost equal) and Bharatpur districts (only 18% against 29% in case of WHO methodology). The district background and characteristics reflect that the reasons

TABLE 5 : MAJOR REASONS FOR NON-ACCEPTANCE/DISCONTINUATION OF IMMUNISATION VACCINE (DISTRICT WISE)

% Distribution for District

Major Reasons	*Sirohi*		*Churu*		*Jaisalmer*		*Bharatpur*		*All*	
	WHO	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*	*WHO*	*IRMS*
Lack of Information	26.3	26.2	37.4	40.7	25.3	37.9	28.6	17.6	29.4	31.0
Lack of Motivation	12.3	21.2	6.9	0.3	8.3	2.7	1.2	13.9	6.8	8.5
Other Obstacles	61.4	47.0	55.8	58.9	66.3	59.3	70.1	68.3	63.8	60.5
Total *N*	114	187	163	312	205	258	164	294	646	1051

mentioned in case of IRMS methodology are much closer to the truth than those obtained by using WHO methodology (Table 5). It is obvious that 'terrain-wise difficult areas' will face more problem in receiving information and those 'easier' ones in terms of 'lack of motivation'. The detailed reasons for non-acceptance or discontinuation of immunisation vaccines are given in Appendix-I.

"phe Results

The results obtained by comparing the two methodologies depict some interesting findings. According to the observations, while in normal Indian villages with sectoral formation (in terms of socio-economic segregation of population, e.g., in Sirohi and Churu districts) an upward bias in estimates was found when WHO methodology was used. Oh the other hand, in case of small and hamlet type of villages (as usually found in Jaisalmer and similar districts with low population density), the upward bias was found when IRMS developed methodology was used. The differences in both the cases were statistically significant. Interestingly in high density districts like Bharatpur where sectoral segregation in villages is negligible, the two methodologies came out with almost similar estimates and no significant differences were found in any of the estimates made for coverage of children and mothers under different immunisation vaccines.

The analysis further revealed that when the estimates are clubbed together for increasing number of districts, the bias effect seems to even out. The clubbing of the estimates for all the four districts brought out that the differences became statistically insignificant in most of the vaccine coverage estimates.

The study thus remained inconclusive as far as the use of two methodologies is considered in larger context. However, it clearly shows that in certain type of areas IRMS developed methodology scores better rating over WHO methodology, especially when coverage evaluation is attempted in medium size villages with existence of socio-economic segregation — which still remains the main characteristic of the Indian villages.

APPENDIX-I

Reasons for Non-Acceptance of Immunisation (4 Districts)

Reasons	*Methodology adopted*	
	WHO	*1RMS*
Lack of Information	29.4	31.0
Unaware of the need for immunisation	10.2	16.3
Unaware of the need for taking 2nd and 3rd doses	2.3	2.6
Place and time unknown	3.4	3.0
Fear of side effects	13.4	9.1
Lack of Motivation	6.8	8.5
Postponed till another time	1.7	1.3
No faith in immunisation	5.1	7.2
Other Obstacles	63.8	60.5
Place of immunisation too far	3.6	1.5
Inconvenient of the clinic	1.5	0.0
Long waiting time	0.1	0.0
Vaccinator absent/not available	35.4	39.7
Child's sickness	3.8	2.9
Mother's busyness	17.6	16.5
Other	1.5	0.0
Total *N*	582	105.1