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Research Article

Lymphatic Filariasis Elimination in Uttar Pradesh: Rationale of Revised Block Level Strategy for IDA Impact Assessment

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A B S T R A C T

Lymphatic Filariasis (LF) is one of the various Vector Borne Diseases (VBD) slated for elimination by the Government of India. The target set for LF elimination is less than 1% microfilaraemia (MF) in a given area. Out of 51 districts of Eastern Uttar Pradesh, only Rampur has cleared up to TAS-3 level and is under post-Mass Drug Administration (MDA) surveillance. The state has implemented triple drug therapy (IDA) in MDA in 15 districts, of which districts Bareilly, Lucknow, and Rae Bareilly have observed only one round of IDA, while the remaining 12 districts have observed 2–3 IDA rounds in order to accelerate the number of MDA rounds, resulting in less than 5 rounds of effective coverage. These 12 districts had 237 implementation/ planning units (IUs) as per the revised strategy. Out of these, 165 IUs reported less than 1% MF rate, of which, 96 IUs belonging to nine districts cleared pre-TAS level, with a sample size of 300 tests of persons who were more than 20 years of age from each of the three sites (two from high-risk areas and one randomly selected). From 96 IUs, 40 evaluation units (EUs) with a population not exceeding 5 lakhs in each EU were selected, the IUs being geographically in close proximity, but TAS-1 activities were conducted in 31 EUs belonging to eight districts (districts Chandauli, Kanpur Nagar, Lakhimpur Kheri, Mirzapur, Pratapgarh, Prayagraj-erstwhile Allahabad, Sitapur and Varanasi), performing 105 tests of persons more than 20 years of age from each of the 30 clusters of an EU, followed by night blood survey (NBS) of persons reflecting filarial antigen positivity though filarial test stripes (FTS).

All 31 EUs reflected 2% filarial antigenemia and less than 1% microfilaraemia due to which all of these EUs cleared the TAS-1 stage. It was seen that this exhaustive activity could not reflect the due impact of IDA in circumstances when the sample size of the cluster was reduced in spite of the increase in the number of clusters and consequently the total sample size of the EU.

Keywords: MDA, IDA< Microfilaria, Lymphatic Filariasis, Night Blood Surney, DEC

Introduction

National Center for Vector Borne Diseases Control (NCVBDC), erstwhile National Vector Borne Disease Control Programme (NVBDCP) guidelines envisage that the administration of drugs to 65% of the total population or 85% of the eligible population for five consecutive years will bring down microfilaraemia to less than 1% among the endemic population, ultimately leading to the elimination of the disease. This is further assessed by conducting Transmission Assessment Surveys (TAS)[1] thrice at an interval of two years among the virgin/ protected group of children, i.e. 6 to 7 years. TAS is conducted after ensuring less than 1% microfilaraemia in 10 additional sites selected randomly,[2] which cover almost the majority of blocks of the district (implementation unit) and if any block site reflects more than 1% microfilaraemia, the whole district is not qualified to conduct TAS. Thus, for any district to be eligible for conducting TAS: (a) It must have conducted consecutive five rounds of Mass Drug Administration (MDA), (b) about 65% of epidemiological coverage, and (c) should have less than 1% of MF rate in both random and sentinel sites.

The state has conducted more than 15 rounds and in some districts, more than 20 rounds of MDA, still the majority of the districts have not cleared the TAS-1 stage and one district Rampur, which has cleared the TAS-3 stage, is under post-MDA surveillance. Out of 51 districts, 42 have been subjected to TAS; among these, four districts have cleared TAS-1, and only one district Rampur, could clear TAS-3. Nine districts (Auraiya, Bahraich, Ghazipur, Fatehpur, Jaunpur, Lucknow, Pratapgarh, Sultanpur, and Kannauj) were subjected twice to TAS-1 but none of them cleared it.[3] Out of these nine districts, seven (except districts Auraiya and Kannauj) have a very good National Filaria Control Programme (NFCP) set up. Another nine districts (Balrampur, Farrukhabad, Faizabad, Lakhimpur Kheri, Mau, Sitapur, Shravasti, Sant Kabir Nagar, and Sant Ravidas Nagar Bhadohi) have not qualified even once for conducting TAS-1, when Farrukhabad, Faizabad, Lakhimpur Kheri, and Sitapur have very good NFCP set up. In such a situation, IDA was used to accelerate the number of rounds, resulting in less than five rounds of effective coverage. Under the revised strategy, the blocks of districts were made implementation units (IUs) and evaluation units (EUs) were made on 5 lakhs (0.5 million) population, uniting more than two blocks of geographically close proximity. In the old strategy, the district as a whole was considered an implementation unit and evaluation units were made on 20 lakhs (2.0 million) population, uniting more than two blocks of geographically close proximity. Thus, the implementation units (IUs) became smaller than evaluation units (EUs) in the revised strategy. The subjects selected for the targeted sample survey included persons more than 20 years of age only, whereas the persons who were less than 20 years of age were excluded from the survey in the revised strategy. The programme guidelines envisage that the lymphatic filariasis (LF) disease is contracted in early life and is prevalent in this age group of less than 20 years.[4] In order to eliminate LF, NCVBDC issued meticulously prepared guidelines to achieve the target of elimination of lymphatic filariasis (ELF) through MDA – by administering a single dose of the drug once a year to the targeted age group,[5] but the same could not be achieved. Various issues, gaps, and challenges in observing MDA were raised in order to make corrective measures in the implementation of the activities related to ELF.[6,7]

Therefore, an attempt has been made to assess the rationale of the revised block-level strategy being applied in the IDA impact assessment.

Methodology

The present study was conducted in 2023 when TAS activities were initiated in IDA-observed districts by the state. As per the block level strategy, 15 districts of Uttar Pradesh were due for pre-TAS activities; those which had conducted three IDA rounds (district Varanasi), two IDA rounds (districts Chandauli, Fatehpur, Hardoi, Kanpur Dehat, Kanpur Nagar, Lakhimpur Kheri, Mirzapur, Pratapgarh, Prayagraj-erstwhile Allahabad, Sitapur, and Unnao) and one IDA round (districts Bareilly, Lucknow, and Rae Bareilly). The state initiated pre-TAS activities in 12 districts, that had completed two or three IDA rounds for the IDA impact survey. These 12 districts had 237 implementation/ planning units (IUs) as per the revised strategy, of which 165 IUs reported less than 1% MF rate. Pre-TAS activities were conducted in these 165 IUs using filarial test stripes (FTS) in three additional sites with a sample size of 300 tests of persons more than 20 years of age from each site, followed by night blood survey (NBS) for microfilariae of persons found positive for filarial antigen; of which, 96 IUs belonging to nine districts cleared pre-TAS. Forty evaluation units (EUs) were formed from these 96 IUs, with a population not exceeding 5 lakhs in each EU and IUs being geographically in close proximity, but TAS-1 activities were conducted in 31 EUs belonging to eight districts (districts Chandauli, Kanpur Nagar, Lakhimpur Kheri, Mirzapur, Pratapgarh, Prayagraj-erstwhile Allahabad, Sitapur and Varanasi), performing 105 tests of persons more than 20 years of age from each of the 30 clusters of an EU, followed by NBS of persons reflecting filarial antigen positivity through FTS. Thus, each EU was subjected to 3,150 valid tests with FTS of persons more than 20 years of age followed by NBS of the persons whose FTS was positive for filarial antigen.

Results and Discussion

The results obtained as an exercise for conducting 3,150 valid tests with FTS of persons more than 20 years of age from each of the 31 EUs followed by NBS of the persons whose FTS was positive for filarial antigen are presented in Table 1. It is apparent from the data that uniformity has been maintained by districts in the number of tests conducted except district Chandauli, which performed only

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half the number of tests with FTS in each of the two EUs. The population of clusters ranged from 387 to 27,775, which makes a vast difference and will have a direct impact on the survey because it has been stated while mentioning the rationale of reducing the implementation unit from district block that "LF is heterogeneous in distribution within districts/ IUs across blocks because of which a few blocks in the districts have high MF% while others have MF% less than 1. With district as IU and the current MF survey evaluation method for impact, even if a single site may report an MF rate of 1% or more, the entire district will be considered to have failed and would have to repeat the MDA round". It stands true to the clusters too because of LF's heterogeneous distribution even within clusters. The large, thickly populated clusters have more congenial disease transmission conditions in comparison to small population inhabitation (387 persons) and an equal sample size of tests (105 in the present survey) will definitely escape the filarial (LF) positive cases. The comparison between older and revised guidelines as ready reckoner for use has been summarised in Table 2.

Table 1.TAS-1 Test Results Performed in IDA Districts with Filaria Test Stripes (FTS) Followed by Night Blood Survey (NBS) for Microfilariae

S. No.	Name of IDA District	Evaluation Unit (EU) No.	Total No. of Clusters in Each EU	Population Range of Clusters	No. of Valid FTS Tests from Each Cluster	Total No. of Valid Tests from Each EU	No. of Positive FTS for Fil. Antigen	% of Positive FTS for Fil. Antigen	No. of NBS for FTS Positive Persons	No. of B.S. Positive for MF	% of B.S. Positive for MF
1	**2**	3	4	5	6	7	8	9	10	11	12
1	Chandauli	EU-1	15	830-1734	105	1575	22	1.40	22	4	0.25
		EU-2	15	816-1978	105	1575	19	1.21	19	3	0.19
2	Kanpur Nagar	EU-1	30	920-3910	105	3150	56	1.78	56	3	0.10
		EU-2	30	468-10090	105	3150	96	3.05	96	7	0.22
3	Lakhimpur Kheri	EU-1	30	685-2099	105	3150	292	9.27	292	9	0.29
		EU-2	30	500-7504	105	3150	204	6.48	204	5	0.16
		EU-3	30	550-27775	105	3150	22	0.70	22	0	0.00
		EU-4	30	1000-5000	105	3150	336	10.67	336	5	0.16
4	Mirzapur	EU-1	30	600-2315	105	3150	396	12.57	396	0	0.00
		EU-2	30	387-4129	105	3150	286	9.08	286	0	0.00
5	Pratapgarh	EU-6	30	602-5002	105	3150	90	2.86	90	0	0.00
6	Prayagraj	EU-1 Rural	30	600-2800	105	3150	1	0.03	1	0	0.00
		EU-2 Rural	30	396-7006	105	3150	4	0.13	4	0	0.00
		EU-3 Rural	30	760-3310	105	3150	6	0.19	6	0	0.00
		EU-4 Rural	30	845-2000	105	3150	0	0.00	0	0	0.00

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	Prayagraj	EU-1 Urban	30	3956-6984	105	3150	10	0.32	10	0	0.00
		EU-2 Urban	30	3026-7265	105	3150	3	0.10	3	0	0.00
		EU-3 Urban	30	3120-8126	105	3150	4	0.13	4	0	0.00
		EU-4 Urban	30	3164-7954	105	3150	2	0.06	2	0	0.00
7	Sitapur	EU-1	30	900-4465	105	3150	125	3.97	125	10	0.32
		EU-2	30	1044-4686	105	3150	205	6.51	205	8	0.25
		EU-3	30	650-5050	105	3150	124	3.94	124	0	0.00
8	Varanasi	EU-1	30	1053-6556	105	3150	21	0.67	21	0	0.00
		EU-2	30	1050-6532	105	3150	1	0.03	1	0	0.00
		EU-3	30	1150-4190	105	3150	17	0.54	17	0	0.00
		EU-4	30	1100-11383	105	3150	97	3.08	97	3	0.10
		EU-5	30	1064-8134	105	3150	54	1.71	54	0	0.00
		EU-6	30	1021-3959	105	3150	19	0.60	19	0	0.00
		EU-7	30	2045-9094	105	3150	0	0.00	0	0	0.00
		EU-8	30	2020-8785	105	3150	1	0.03	1	1	0.03
		EU-9	30	1652-7611	105	3150	39	1.24	39	0	0.00
	Total	31 EUs	30	387-27775	105	94500	2552	2.70	2552	58	0.06

Table 2.Comparison Between Older and Revised Guidelines as Ready Reckoner

	Components	**Previous Programme Strategy**	**Current Strategy**
Implementation unit	Implementation unit	District	Block
	Number of MDA assessment sites	4 sentinel (fixed) and 4 random	1 sentinel and 1 random
	Sample size	500 samples from each site @4000 total slides per district	300 from each site (600 per block)
	Methodology	NBS (MF rate)	NBS (MF rate)
	Sample population (years)	> 2	> 20

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-	Pre-TAS assessment	10 additional sites with a sample of 500 per site through NBS (a total of 5000 samples)	Sample size for both DA and IDA blocks: 3 additional sites per block (2 purposeful site selections of areas with the greatest risk and 1 random selected site) with 300 samples per site (a total of 900 samples) Methodology and sample population: For DA blocks: NBS (MF survey) among the population aged 20 years and above For IDA blocks: FTS among people aged 20 years and above followed by NBS among all FTS-positive people
Evaluation unit	Evaluation unit	Population of 2,000,000	Population up to 500,000
	Transmission Assessment Survey	Survey among the children aged 6–7 years; 1800–2000 sample for both DA and IDA	Survey among the children aged 6–7 years for DA with ~1800 sample size and above 20 years for IDA (Impact Assessment) with ~3150 sample size with NBS among all FTS positives

The comparison between older and revised guidelines has been meticulously presented, wherein it has been tried to reflect that the survey sample size will be larger when making block as implementation unit instead of the district, but the decision makers have not properly analysed the existing data, in which some districts have only 4 or 5 blocks, which had two sites (one sentinel and one random) in MDA assessment and two additional random sites in pre-TAS assessment, thereby collecting and examining at least 1,000 blood smears from two sites in each block, which is larger in size than two sites (one sentinel and one random site) of a block in the current strategy with collection and examination of only 600 blood smears in MDA assessment and 900 blood smears in pre-TAS assessment, diluting the parasite catchment area from two sites in older guidelines to 4 to 6 sites, from where the small sample size may miss the parasite harbouring person in the revised strategy. Moreover, the age group of the targeted population in the old strategy was more than 2 years, which has been revised to more than 20 years, possibly due to the fact that the person belonging to the age group of more than 20 years may reflect the microfilariae positivity confirming the evidence of the disease transmission and if the triple drug therapy has been administered to this age group, it will destroy the microfilariae and such persons will not reflect microfilariae positivity, thereby stopping the disease transmission. It is pertinent to mention here that we have excluded an important age group, i.e. less than 20 years, which constitutes 47% (approx.) of the population and exclusion of children of less than 2 years of age (3.8%), presuming that the age group of less than 20 years may not have proportionate pregnant women and seriously ill persons, will have 43% of the population. It is explained to the community and the technical personnel that the LF disease is contracted at an early age, the manifestations of which are reflected at a later age, hence with non-consideration of such a big part of the population which constitutes half of the targeted population, LF elimination is not justifiable because the people less than 20 years of age also possess high MF positivity, which ranged from 20.00% (16.67%) to 45.00% (42.86%) in surveys conducted in the past with more than 1% prevalence in Uttar Pradesh. Exclusion of the age group of less than 20 years, undoubtedly will lead to 0 (zero) MF reporting areas but in reality, these areas will not be free from MF positivity as individuals belonging to the age group of less than 20 years also possess high MF positivity (20.00% to 45.00%), which will be left liberally free as good reservoir to maintain active LF transmission and the goal of the ELF will be forfeited. The NFCP programme also envisages the presence of microfilaria in the lower age groups. In the current IDA impact survey, district Varanasi, which has

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completed three IDA rounds, declared less than 1% MF positivity, but when the NBS survey was conducted by the Regional Office of Health & Family Welfare (ROH&FW), Government of India, Lucknow team, then the surveyed block reflected more than 1% MF positivity.

While conducting the IDA impact survey, random sampling of households using a cluster-specific sampling interval has been exercised with a sample survey of 3,150 valid tests with FTS from persons more than 20 years of age, from each of the 30 clusters of an EU (population up to 5 lakhs), followed by NBS of persons reflecting filarial antigen positivity through FTS as has been explained in Table 3. In this exercise, 105 samples were tested from each cluster, and irrespective of whether the cluster had a population of 387 or 27,775, it would have reflected the same results as explained earlier. In systematic cluster sampling of the schools, children from all inhabitations represented the total community, which has been avoided in the present strategy, due to which the state has cleared TAS-1 in all 32 EUs. Conducting tests with FTS prior to NBS will reflect filarial antigen positivity when,

1. Both male and female adult filarial worms (Wuchereria bancrofti) are present in the lymphatic system and have a fecundity period for producing microfilariae.
2. Both male and female young worms (Wuchereria bancrofti) are present in the lymphatic system and have not attained the maturity for producing microfilariae.
3. The adult worms have overcome the fecundity period.
4. The individual worm/s of either sex is/ are present in the lymphatic system.
5. The adult filarial worm is present in the dead form and its remains are present in the human body.
6. The test repeat may have vice versa results.
7. The bands may appear without transfer of the blood on the stripes, possibly due to prevailing environmental conditions.[8]
8. The possibility of cross-reactivity with other worms may be present.

The aforementioned circumstances have no epidemiological significance because the transmission evidence can only be confirmed with the presence of microfilariae, which can be had with only the first condition and the remaining others will not reflect the presence of microfilariae in the affected person. Therefore the exercise carried out with FTS is of insignificance and microfilariae can be directly searched in the population, being subjected to tests with FTS. Moreover, the adult worms producing microfilariae may be attaining a non-fecundity period in consecutive years and will stop producing microfilariae.

Table 3.Summary of Differences between Standard TAS and IDA Impact Assessment under Block Level Strategy

Variables	Standard TAS	IDA Impact Survey
Criterion	A number of consecutive DA (DEC + albendazole) rounds with effective coverage more than or equal to 5, and if the EU is conducting the first TAS assessment	a) IDA is used to accelerate the number of MDA rounds, resulting in less than 5 rounds of effective coverage. b) When IDA is delivered in response to a failed TAS and it is uncertain whether two rounds of additional IDA will be sufficient to impact the antigenemia prevalence
Target population	Children 6–7 years of age; often operationalised as 'primary school entrants'	Adults aged 20 years and above
Selection of clusters	Systematic random sampling or cluster sampling of schools or communities within the EU	Random sampling of communities using probability proportionate to estimated size sampling
Selection of individuals within a cluster	Random sampling of individuals with a fixed sampling interval, using either List A or List B	Random sampling of households using a cluster-specific sampling interval
Sample size	1,800–2,000	3,150
Diagnostic tests	FTS (W bancrofti); Brugia Rapid (Brugia spp.)	FTS (W bancrofti) or Brugia Rapid (Brugia spp.) with confirmatory testing of all positive individuals using microscopy to identify MF (via thick blood smear)

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Threshold for decision-making	The average prevalence detected by FTS or Brugia Rapid in the EU is less than 2% (using the upper, 1-sided 95% CI)	The average prevalence of MF in the EU is less than 1% (using the upper, 1-sided 95% CI)
Applying the critical cutoff value	Compare the number of observed positive results in the TAS with the critical cutoff value in the decision rule table. If the number of positives is less than the critical cut-off, then the area "passes" the TAS.	Step 1: Compare the number of observed positive results in the TAS with the critical cut-off value in the EU Decision Rule table. If the number of positives is less than the critical cut-off, then proceed to Step 2, otherwise the area "fails" the TAS. Step 2: Compare the number of MF-positive results in each cluster with the Cluster Decision Rule table. If all clusters are less than the critical cut-off, then the EU "passes".

Hence, the exercise simply indicates a waste of both time and money. It clearly shows that the agencies participating in the elimination of LF seem to be indulging in the marketing of FTS rather than participating in achieving the goal of LF elimination when they are well aware of the fact that the LF disease is contracted at an early age and the age group of less than 20 years has been avoided. This act of IDA impact can never reflect a true picture of the disease prevalence in the community or the occurrence of disease transmission. It is good to change the strategy when the desired impact is not being achieved but there should be some rationale for the revised strategy.

Instead of going in the right direction, the steps are deviating from taking corrective measures. It was suggested earlier that the targeted level of the community must consume the drug, for which participating agencies can play their active role and the proper assessment of the disease must be done by involving the NFCP personnel making them responsive to qualitative surveys but no attention has been paid in this direction. The blood slides sent by some districts for cross-checking have reflected no improvement over the facts reported earlier.

Conclusion

From the foregoing discussion, it can be concluded that the change in strategy for the IDA impact survey is an over-exhaustive and monetary wastage exercise, which can never reveal the true picture of the impact of IDA as the persons belonging to the age group of more than 20 years targeted for the survey will not reflect the presence of the parasite, which ensures the transmission and if somehow microfilariae are reported from some persons, they will be escaped in consecutive years due to completion of fecundity period in advanced age people. The exclusion of the age group of less than 20 years, undoubtedly will leave MF harbouring persons unrecorded and the inclusion of people more than 20 years of age will consequently report less than 1% MF in older persons of the filarial endemic areas, which will not be less than 1% MF positivity in reality, because people who are less than 20 years of age constitute equal proportion in targeted population and possess high MF positivity (20.00% to 45.00%), which would act as a reservoir of active LF transmission, thereby neutralising the efforts made in the direction of achieving ELF. The reduction of the sample size of a cluster to 105 in comparison to the earlier practice will definitely escape the MF-positive persons in large inhabitations (localities). Moreover, the quality of blood smears, with which MF has been reported negative due to poor quality of blood smears, will reflect a person MF negative for life long, though remain positive of MF, as areas declared free from MF, reflected more than 1% MF in Varanasi by the ROH & FW team. Thus the quality of the blood slides is also not found in accordance with the standard in the samples, sent by some of the districts for cross-checking.

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