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## **Investigators:** 2.1 **Post DEC Side reactions after Mass Drug Administration of DEC in Choudwar, Orissa**

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Global strategy towards elimination of filariasis has been formulated to eliminate lymphatic filariasis from endemic countries using DEC tablets annually. Annual mass drug administration of DEC has been initiated in endemic states of India. Orissa is the one among them. Eighty percent coverage and compliance to DEC therapy is expected to eliminate lymphatic filariasis from endemic communities. But, fear of side reactions and occurrence of adverse events following DEC intake is inhibiting the common men to take the drug even if distributed at the door step free of cost. So, it has been felt very important to look for the extent of occurrence of side reactions and search for health related factors which might be associated with development of adverse reactions.

### **Objectives:**

To observe the adverse reactions reported by the individuals and associated health events of the affected population, following treatment with DEC during MDA programme in Choudwar town of Orissa.

### **Materials and method:**

The old urban settlement of Choudwar Town of the state of Orissa was taken as the study area. After defining the area and population under study a door-to-door survey was conducted. The investigating team consisted of physician, statistician, lab technician, lab assistant and census taker. Every house was covered, starting from one mark or point of a street or lane, ward after ward. Individuals of each household were questioned about their drug intake and side effects experienced. Detail history of adverse reactions was noted from those who reported it. Age, sex, social & economic status, pattern, onset and severity of adverse reactions, treatment taken for side effects, presence of any known disease (e.g., filariasis, acid peptic disorder, blood pressure disorder, worm infestation, diabetes, etc.) of the subject were noted in a preformed format for assessment and investigation. Individuals who reported side reactions were tested for filarial antigenaemia by rapid ICT Test. (Bimax ICTkit)

### **Observation:**

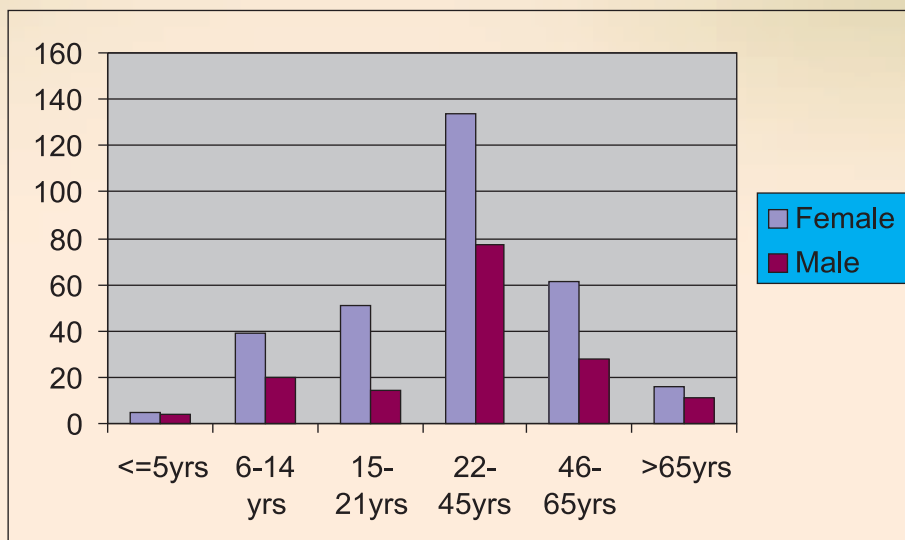
A total population of 13,610 were covered during the survey. Among them 10,517 (77.3%) individuals received the recommended DEC tablets during MDA programme and 7956 (75.6%) of those who received the drug consumed or swallowed the supplied drug. Four hundred sixty (5.8%) of those who consumed the drug reported some side reaction following therapy. Those individuals were questioned and examined by the team and the observations are mentioned in subsequent paragraphs.

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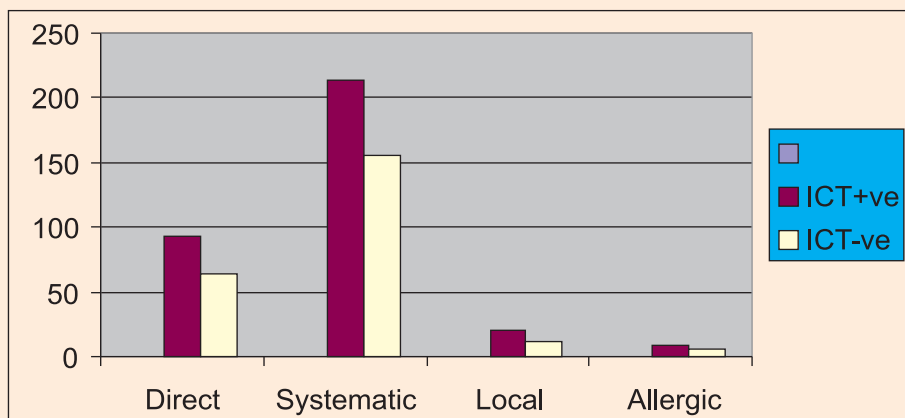
Individuals between fifteen to forty five years of age constituted sixty percent of the whole population affected and forty six percent were in the age range of 22-45 years. Females were the major sufferers. 61% individuals were from low socio economic status families and 38.3% belonged to middle socio-economic status group.



**Fig.1** Age and Sex distribution of individuals who reported side effects

Presence of filarial antigen in the blood of the individuals who reacted to DEC therapy was tested by *W. bancrofti* specific rapid diagnostic kit (ICT kit, Binax, Portland, USA). This test was not done in fifty-eight (12.6%) persons. Antigenaemia was detected in 50.4% subjects, where the test has shown negative result in 37% tests done.

We observed systemic reactions as the predominant type of adverse reaction and more than 90% of affected persons had one or more systemic complain. Head reeling was most frequently reported and observed in 341 (74%=460) individuals. Drowsiness (21.1%), fever (10.4%) and body-ache (9.6%) were the other systemic reactions noted in order.



**Fig. 2** Different types of side effects in relation to CFA status



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Adverse reactions having predominant initiation within first three hours were reeling of head (65.4%), nausea (59.85%), vomiting (52.2%), fatigue (53.6%) and abdominal pain (40.9%). But urticarial rash, ADL, Limb edema and scrotal inflammatory response had late onset beyond 6-24 hours in majority of cases.

Side reactions due to DEC intake are usually attributed to inflammatory response induced by dead microfilaria or adult parasite. But our study reported absence of filarial antigenaemia in a quite large number of persons (170/402) reported to have adverse effects and observed some pathophysiological factors related to human host which might have association with the adverse reactions.

Clinical presence of pallor was observed in 36.1% of individuals. Signs of nutritional deficiency (under nutrition) was noted in 10.7% of side reaction affected population. Symptom of acid peptic disorder was reported by 5% of the population during interrogation and disorders of blood pressure was complained by 2.8% of individuals. Sixty-one persons had suffered from one or multiple episode of filarial lymphangitis/ adenitis or chronic filarial disease expression before consumption of DEC during MDA program. History of epileptic disease was present in three persons. History of worm passage was given by 17 (3.4%) individuals. All these observations were based on clinical observation and personal history.

Majority of individuals (447/460) i.e. 97.2% swallowed the DEC tablets after food and the rest (2.8% only) in empty stomach. Seventy nine percent (364/460) persons had taken the tablets in the afternoon hours, where as 16% consumed at night and 5% in morning time.

## **Conclusion:**

Side reaction to DEC mass treatment is occurring, though not too high in prevalence. It is affecting mass psychology in consuming the drug in subsequent dose schedules. For successful continuation of the elimination programme, important measures to be taken should be: (1) Minimising occurrence and severity of the side reaction if possible by modifying the drug or host factor; (2) Making the common men understand that the adverse event which might be experienced will be well tolerated and be well controlled and the benefit that the community gets is much greater than the discomfort it gives. The present study reported that 37.1% of the persons who reported side reactions do not have filarial infection (ICT-ves) in them and systematic abnormalities like anaemia, malnutrition, acid peptic disease, etc. are present in different proportion in the affected population.

So well documentation of the side reactions in controlled studies emphasizing on the existing systemic pathophysiology of the host (i.e. human being) to find out correlation or association with the occurrence of different adverse reactions is essential, so as to take preventive measures to minimise them.

## 2.2 Brief Report of Investigation into the cause of outbreak of jaundice in Badakodanda village, Bhanjanagar, Ganjam, Orissa

### Background:

Hundreds of people of Badakodanda village, of Ganjam district, developed jaundice in a short period which was the report of local newspapers during second week of June 2005. Disease Surveillance Cell of Directorate of Health Services, government of Orissa initiated the preventive and treatment measures. Subsequently, on request from the said department, the outbreak was investigated by the team from Regional Medical Research Centre (RMRC) during 5.7.2005 to 7.7.2005. The work adopted and observations there of is given in the following lines.

### Field visit and laboratory procedures:

The team of investigation consisted of a physician, lab. technician, one lab assistant, two census takers and one field attendant. The team conducted the field work from 5.7.05 to 7.7.05 in the affected Badakodanda village under Community Health Centre (C.H.C.) Bhanjanagar, Ganjam, Orissa with help of concerned health personnel and field level health workers.

A house to house survey was done and persons with complaints of jaundice, fever, anorexia, vomiting, etc. were examined. Members of the affected household without any symptoms were also examined in detail. The clinical history and examination were recorded in preformed questionnaire formats. Affected individuals were given therapeutic advice and immediate primary treatment, whereas households were instructed how to take precautionary measures to prevent spread of the infection. Drinking and food habits and toilet habits of the affected population were looked into, to seek for the source of contamination and spread of the agent.

Blood samples (2 ml of venous blood) were collected from individuals with consent for serological and biochemical tests. The collected blood samples were centrifuged and serum was separated in the field. Coded serum samples were stored and transported in icebox to RMRC laboratory.

Presence of IgM antibody to hepatitis A and E virus was tested in the Institute laboratory by ELISA method using Bio ELISA hepatitis detection kits. Biochemical test on a subset of the samples was conducted to quantitatively measure the liver function at the Dept. of Biochemistry, SCB Medical College, Cuttack.

### Result of observation:

Report of the field level health worker regarding onset of jaundice and individuals affected was looked into and attempt was taken to examine in detail maximum number of

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### Collaboration:

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the affected households possible during the period of investigations. We examined a part of the total affected households in detail. During the field visit members of 140 households, covering the whole village, were surveyed in detail. Out of these, 108 numbers of families were affected involving 122 numbers of individuals.

The examined population were Hindus by religion and from middle to low socio-economic status. Out of the total 122 patients examined 6 (4.9%) were below 15 years of age and 71 (58%) were males.

AGE (years)	MALE	FEMALE	TOTAL
5-14	4	2	6(4.91%)
15-45	49	31	80 (65.57%)
46-65	13	14	27 (22.13%)
>65	5	4	9 (7.37%)
<b>Total:</b>	<b>71(58.19%)</b>	<b>51(41.80%)</b>	<b>122</b>

Major symptoms complained by the individuals were fever, joint pain, body ache as prodromal symptoms before appearance of jaundice whereas, anorexia, nausea, vomiting, epigastric pain were noted during the icteric period. More than one third complained of pruritus and urticarial rash during the second half of icteric phase. The average period of persistence of visible jaundice was two weeks and average period of persistence of symptoms was three weeks. None of them were severe enough to be hospitalised. And more than two third were recovering from illness during examination. *Cause of Jaundice and pathogen.*

The acute onset of symptoms, mild to moderate presentation, clustering of cases during a short period and the range of symptoms and presence of icterus, hepatic tenderness and urticarial rash provisionally pointed the episode towards an epidemic of acute viral hepatitis caused by an enterically transmitted hepatitis virus.

### **Serological tests results:**

IgM antibody to hepatitis E virus was detected in 76 (62%) serum samples tested (n=122).

### **Biochemical test results:**

Biochemical test for hepatic function was conducted in a subset of 45 samples. Serum billirubin (total) of the elevated in 73.8 % of cases.

### **Search for Source of Transmission and cause of Spread:**

The source of water supply to the entire village was found to be from a river stream, which is supplied through water pipes after filtration through a filtration well. No

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common food source like hotel, carterer, or festive occasion was found to be the suspected source causing jaundice. So the common water supply was presumed to be the source, which might have been fecally contaminated. More than fifty percentage of the studied population use open field for defecation and they do not adopt proper hand washing with soap and water after toilet. So combined effect of contamination of water supply causing generalised transmission and improper hand wash after toilet contributing to household secondary cases, is the most probable cause of spread of the viral agent. Isolation of the agent from water, food and/or faeces would have given the confirmatory results, which could not be done at present available facilities.

## Interpretation:

The reported outbreak of jaundice from Badakodanda village under Bhanjanagar C.H.C was confirmed to be an epidemic of Acute Viral Hepatitis caused by hepatitis E virus.

The large scale spread in a short time period can be originated from a sporadic case and the faecal shedding of the virus contaminated the common water supply to the village, which led to the primary infection enmass. Possibilities of household transmission via food and water due to improper hand wash and continued faecal contamination of the water supply can lead to secondary infection and subsequent continuation of the epidemic if not prevented.

## Recommendation:

Following measures can be undertaken to arrest transmission of the virus and prolongation of the epidemic along with clinical stabilization of the individual patients.

1. Chlorination of the drinking water supply.
2. Finding out and sealing any leakage during filtration and water supply through piping.
3. Reinforcing boiling of drinking water at household level
4. Advice for proper hand washing with soap water after toilet use.
5. The village people should be educated to use the field away from (at least 150ft) the river stream supplying water to their village, for toilet purpose, if latrine facility is not available.
6. Advice to take freshly cooked food as much as practicable
7. Individual patients should consume their normal diet as were taking earlier and not to reduce the amount or restrict any food items which are not eaten in excess.
8. Affected pregnant mothers should be given extra medical care and be advised to seek specialised treatment, as most often they end in complications.

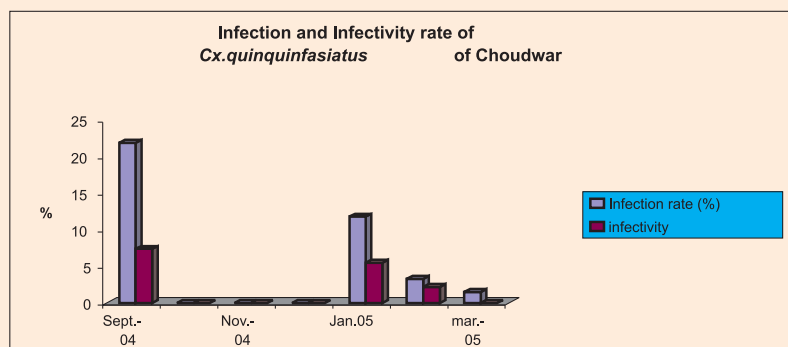
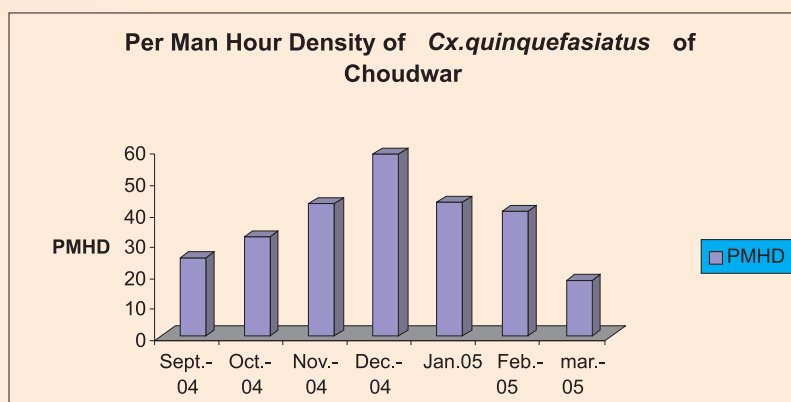
## 2.3 Effect of Annual single dose of DEC in filariasis transmission

DEC is highly effective microfilaricidal drug. Use of these drugs at community level results in reduction of human infection and consequently transmissions. In some areas due to high vector density effective reduction in transmission does not occur. Choudwar town of Cuttack district though a semi urban area is highly endemic for filariasis.



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Single dosage of DEC mass drug distribution was done on 15.9.04. Baseline data on vector density, infection rate, infectivity rate and infective stage of parasite per mosquito (I3 load) were collected before and after the mass drug distribution. The month wise vector density (PMHD) of *Culex quinquefasciatus* is presented in fig 5. It varies from 18.3 to 58.6 in different months of the year. Figure 6 depicts the infection and infectivity rate of *Cx. quinquefasciatus*. It clearly indicates that soon after the drug distribution no infective larvae could be detected up to three months (October to December). However, from the month of January, 2005 infection in the vector appeared. There was 45.7% and 26% reduction in infection and infectivity rate compared to the base line data. Still the infection could be



State health authority requested to evaluate the National vector borne disease control programme's activity in two districts of Orissa i.e. Boudh and Jagatsingpur. The work was carried out and the report of the activity was submitted.

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#### 2.4 Referral services render for hemoglobinopathies:

Referral Services were rendered for diagnosis to the cases referred from local PHCs, hospitals and Medical colleges and Hospitals in Orissa. In one series diagnostic services were provided to 68 families referred during period from April 2004 to March 2005, for electrophoresis, a total of 176 subjects were screened. Out of 176 cases, 20 (11.4%) were diagnosed as homozygous sickle cell disease, 56 (31.8%) sickle cell trait; 3

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(1.7%)  $\beta$ -thalassemia Major, 6 (3.4%)  $\beta$ -thalassemia trait; 1 (0.6%) Hb AE, and 90 (51.1%) cases were found normal. Of the 176 cases, 135 (76.7%), 38 (21.6%) and 3 (1.7%), respectively belonged to general castes, scheduled castes and scheduled tribes. Genetic/marriage counselings were given to affected families.

In another Series, a total no of 137 (83 male and 44 female) cases were referred from various medical colleges and peripheral hospitals of the state for investigation and confirmation of diagnosis for various haematological disorders. Most of the cases were having complains of refractory anaemia , progressive weakness and jaundice. Out of 137 cases, 119 belong to General category, 11 to Scheduled tribe, 4 to Scheduled caste and 3 to Muslim community. A detailed clinical examination and laboratory investigation such as haematological profile by automated cell counter (MS9), quantitative analysis of Hb, Hb A2, HbF and its electrophoresis was carried out by established methods. Out of total 137 cases -% were found to be electrophoretically normal (Hb AA), -% were HbAS , -% HbSS, -% S beta thalassaemia, -% beta thalassaemia minor, -% beta thalassaemia major and -% E beta thalassaemia .The community wise distribution of the Hbpathies has been shown in table 1. Molecular characterization of these samples revealed the presence of IVS1-5 (G->C) mutation in all the cases of beta thalassaemia.

**Table1: Caste wise distribution of Hb pathies amongst the referred cases**

Category	Total	AA	AS	SS	SB	$\beta$ thal major	$\beta$ thal minor	E $\beta$ thal
General	119	44 (56.9%)	19 (15.9%)	8 (6.72)	2 (1.68%)	15 (12.6%)	27 (22.68%)	4 (3.36%)
SC	4	1 (25%)	3 (75%)					
ST	11	5 (45.5%)	1 (9.1%)	1 (9.1%)		2 (18.2%)	2 (18.2%)	
Muslim	3		2 (66.7%)	1 (33.4%)				
<b>Total</b>	<b>137</b>	<b>50 (36.5%)</b>	<b>25 (18.2%)</b>	<b>10 (7.3%)</b>	<b>2 (1.5%)</b>	<b>17 (12.4%)</b>	<b>29 (21.2%)</b>	<b>4 (2.9%)</b>

## 2.5 Monitoring malaria control activities in Orissa

The Directorate of National Vector Borne Disease Control Programme requested the centre for intensive monitoring for effective control of malaria. Four endemic districts of Orissa namely, Cuttack, Sonepur, Boudh and Jagatsinghpur, were selected and monitored for a year.

In each district, two PHCs are selected and visited every month for monitoring the malaria control activities. The issues covered during monitoring are epidemiological

**Status: EM ( NVBDCP)**

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**Period :** Oct. 2004 to March 2005



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trends, early detection and prompt treatment components, integrated vector control, laboratory functioning, spray activities, and manpower, etc.

The scientists made visits to district headquarters offices, PHCs, sub-centres, drug distribution centres (DDCs), fever treatment depots (FTDs), etc. and submitted reports periodically to the Directorate of National Vector Borne Disease Control Programme.

## 2.6 OPD SERVICE TO THE PATIENTS WITH FILARIASIS AT CAPITAL HOSPITAL, BHUBANESWAR

During the reporting year a total of 528 new cases were clinically examined and diagnosed and treated for different clinical presentations of lymphatic filariasis. Of which the majority 232(44) presented with lymphoedema (LMD) grade I followed by adenolymphangitis (ADL) 179(33.9). Among the acute ADL cases 56(31.3) had only lymphangitis, 38(27.2) had lymphadenitis in the inguinal region, 23(12.8) had both acute lymphangitis and lymphadenitis. Out of which 62(34.6) acute ADL attack was found in chronic lymphoedema cases due to secondary infection known as Adeno Dermato Lymphangio Adenitis(ADLA). All the cases were given treatment and footcare management procedure was demonstrated and advised these patients. A total of 23 lymphoedema cases given decompression therapy.

The Details of the clinical conditions of the OPD cases

Clinical condition	Male	Female	Total (%)
Acute ADL	104()	75()	179( )
LMD* gr I	147(63.4)	85(36.6)	232(44.0)
LMD gr II	21(65.6)	11(34.3)	32(6.1)
LMD gr III	15(75.0)	5(25.0)	20(3.8)
Hydrocele	11		11(2.1)
Orchitis	2		2(0.4)
Nodule	7(77.7)	2(22.3)	9(1.7)
Abscess	1		1(0.2)
TPE	1	1	2(0.1)
Haematuria		1	1(0.2)
Arthritis	6(50.0)	6(50.0)	12(2.3)
Others**	20(74.1)	7(25.9)	27(5.1)

\*LMD-Lymphoedema

\*\* Includes Urticaria, Myalgia and peripheral neuritis/neuralgia

### Detail clinical presentation of cases with Acute ADL attack

Clinical symptom	Male N%	Female N%	Total %
Lymphangitis(LNG)	20(35.7)	36(64.3)	56(31.3)
Lymphadenitis(LND)	33(91.6)	5(8.9)	38(21.2)
ADLA*	36(58.1)	26(41.9)	62(34.6)
LNG+LND	15(62.2)	8(34.8)	23(12.8)

\*ADLA – Adenodermatolymphangioadenitis