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## Document heading

# A qualitative study on the adverse reactions of mass treatment for lymphatic filariasis in Orissa, India

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## ABSTRACT

**Objective:** To describe the perceptions of community members and programme partners regarding severity, management and impact of adverse reactions on mass drug administration (MDA) compliance. **Methods:** Based on various qualitative data collected from five districts of Orissa, India, where MDA had been implemented during 2002 and 2004. The qualitative surveys included focus group discussions with community members and health workers, and semi-structured interviews with key informants in the community, medical officers at primary health centres, district level health officers and private practitioners. **Results:** It showed that many people suffered from adverse reactions, though the reactions were not serious. The paper reported different ways of management of adverse reactions at the community level. The impact of adverse reactions on MDA compliance was serious, as many people did not consume the drug due to fear of adverse reactions. The rumours of adverse reactions and news in media deterred people from consuming the tablets. **Conclusion:** All categories of respondents indicates the need of more information to address the problem of adverse reactions during MDA. The present paper warrants incorporating the messages on adverse reactions during health communication and social mobilization campaigns of MDA.

## 1. Introduction

Large scale chemotherapy plays a vital role in the control of many parasitic diseases including lymphatic filariasis (LF)<sup>[1]</sup> and the greatest successes were available through the development of single dose therapy and mass treatment in control programmes for a number of diseases<sup>[2]</sup>, including LF<sup>[3,4]</sup>. Under the programme to eliminate LF (PELF), the principal tool is rapid reduction of microfilarial load in the community by annual mass drug administration (MDA) of single dose of diethylcarbamazine (DEC) or ivermectin with or without albendazole<sup>[5]</sup>. Recent research showed that 5–10 rounds of treatment with 75–80% coverage could possibly eradicate the disease by reducing transmission to a very low level<sup>[6]</sup>. Hence, higher rate of drug compliance during MDA is essential to achieve the goal of PELF. Studies on treatment compliance of MDA from India and other endemic countries indicated that the frequency and severity of adverse reactions that occur following the consumption of drugs is one of the reasons of low compliance<sup>[7–10]</sup>. Our

earlier study from Orissa, India reported that occurrence of adverse reactions, rumours of severe adverse reactions and their reports in media deterred people from participating in MDA and affected the compliance<sup>[10]</sup>. However, it is well known that adverse reactions occur following the treatment<sup>[11–16]</sup>. Hence, the issue of adverse reaction should be given attention for the success of the PELF. As the involvement of huge population in the MDA is vital for the success of the programme, it is important to study the perceptions of the community and other programme partners on the issues of adverse reaction. The present paper describes the perceptions of community members and programme partners regarding severity, management and impact of adverse reactions on MDA compliance during two MDAs in January 2002 and September 2004 in the state of Orissa, India.

## 2. Materials and methods

### 2.1. Study area

The data for the present study was collected from five districts of Orissa, where MDA has been implemented. During 2002 MDA, the study was carried out in four districts namely Khurda, Puri, Balasore and Ganjam

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from January to February 2002, while during 2004 MDA, it was undertaken in Cuttack district from September to October 2004. The MDA has been undertaken under the management of district health system through the network of primary health centres (PHCs) in rural areas and through the municipal health institutions in urban areas. The other details of MDA of Orissa are described elsewhere<sup>[10,16]</sup>.

## 2.2. Data

The data for this study were drawn from various qualitative surveys carried out among different groups of communities and programme partners in all the five districts. The qualitative surveys include focus group discussions (FGDs) with community members and health workers, and semi-structured interviews with key informants in the community, medical officers at primary health centres, district level health officers and private practitioners. During 2002 MDA, qualitative data were collected in four districts through FGDs with community members (12 groups) and health workers (8 groups), and semi-structured interviews with key informants in the community ( $n=52$ ), private practitioners ( $n=14$ ), medical officers at primary health centres ( $n=15$ ) and district level health officers ( $n=3$ ). During 2004 MDA, the qualitative data were collected from the urban area, which comprises of FGDs with the community members (15 groups) and semi-structured interviews with key informants in the community ( $n=36$ ), community drug distributors (CDDs) and supervisors of drug distributors ( $n=44$ ) and partners of MDA programme ( $n=16$ ) including doctors who involved in the adverse reactions management. Standard procedures were followed for organisation of FGDs<sup>[17,18]</sup> and semi-structured interviews<sup>[18,19]</sup>. The scripts of FGDs and semi-structured interviews were computerized through a word processor and were analysed by using ATLAS/ti software (Scientific Software Development, Berlin).

## 3. Results

The qualitative data obtained from community members and programme partners in both the rounds of MDA showed that though people suffered from adverse reactions, the magnitude of the adverse reactions was not so serious. Adverse reactions such as giddiness, vomiting, nausea, headache, head reeling, swelling of entire body and fever were the major complaints. Some people suffered from swelling of body parts, abdomen pain, etc. though their number was less. During the 2004 MDA, head reeling, nausea and giddiness were among the major reactions as said by majority of community members (80%). In an FGD, one respondent said, "Some persons had vomiting after consuming the drug while some others had head reeling. Some people had fever at night". Another key-informant during the interview said, "I noticed it (side reaction) but it was very rare. One person in this ward had vomiting". Also, a majority of CDDs (78%) confirmed that some people experienced head reeling, vomiting and fever. Eight supervisors were engaged in the study area during 2004 MDA in addition to four doctors who were involved in the adverse reaction management. According to them the magnitude of adverse reactions was not so acute during the 2004 MDA. The similar views also expressed by the health workers, CDDs and other programme partners who involved in 2002 MDA and 2004 MDA. A social worker in the urban

community said, "Side reactions were observed among a very few people. No, it was not a problem". One private practitioner, who involved in adverse reactions management said, "Sleepiness was the main reaction noticed among a few persons. Nothing major had occurred".

The data also indicated different ways of management of adverse reactions during MDA. Along with DEC, some other common drugs including analgesic, antipyretics, antacids, anti-allergics, etc. were supplied to CDDs and health workers to manage the adverse reactions. One of the health workers during 2002 of MDA said "Those who suffered from some reactions, I asked them to go to Primary Health Centre and to consult the doctor there". One CDD who involved in 2004 MDA said, "Some people complained of head reeling. We convinced them and asked to take the drug after eating some thing. Some drugs were also provided to us to give to those get side reactions". Majority of CDDs usually expressed that they tried to convince people by saying that "You are experiencing these reactions as DEC is killing microfilaria in the body". One community member said, "The people who had distributed the medicines had also given medicines for side reactions in some cases". The CDDs informed their supervisors about those cases. Doctors of mobile health units also supervised the cases. One key-informant, during interview said, "Doctors helped in side reactions management and they had also told about side reactions prior to drug distribution. Doctors had assured people that they should not panic about it". As said by most of the key-informants it is found that some patients received medicines from CDDs or from other doctors by their own. But majority did not seek any treatment. A typical quote by a key-informant is "For the management of adverse reactions in most of the cases drug distributors gave medicine. Some people went to doctor at their own but majority of people did not require any medical help, they took rest for some time and felt better". During a focus group discussion, a female respondent narrated, "We prepared lemon juice by adding salt and sugar. After drinking a glass of that drink we felt better". Community leaders and elected ward councillors assisted during the management of adverse reactions by consoling people and by informing supervisors and doctors of the mobile health team.

Although the people suffered from minor adverse reactions, they laid some impact on the compliance during both the rounds of MDA. During 2002 MDA, the occurrence of adverse reactions after consuming drugs highly influenced the programme. The subsequent mop-up activities were also suspended in many places. The alleged news of deaths and suffering published in newspapers further hampered the programme. In an FGD, 35 years old man said, "Government is trying to prevent disease, but people are afraid to take these medicines. Something may happen after eating these medicines. So we are not willing to swallow". A female health worker during FGD said, "Due to side reactions most of the people have not taken the tablets. We convinced some people to swallow. Still some have not taken tablets". During 2004 MDA also around 50% of community members revealed that, many had not swallowed the drug due to fear of side reactions. During FGD, a male respondent said, "My wife had kept the tablets for us, but I threw them because of the fear that something may occur after consuming the tablets". The data revealed that almost all people had swallowed the drug on the first day of distribution and adverse reactions appeared on second

day onwards and it had impact on the rate of compliance. One CDD, during in-depth interview said, "On the first day, there was no problem. But when people read and heard about side reactions, they refused to accept tablets from us". One of the partners of MDA programme said, "Prior to the distribution of drug people knew about the occurrence of adverse reactions. Hence, few people even did not receive the drug due to fear of reactions". Only one out of four supervisors said "The issues of adverse reactions had a negative impact on the compliance rate". The supervisors and some CDDs complained that the private practitioners exaggerated the issues of adverse reactions and because of media hype around 20% people got irritated and did not swallow the drug, during the mop up days. But most of the CDDs and health workers think that adverse reactions has less impact on the compliance rate as people had swallowed the drug on the first day of drug distribution. However, one of the CDD revealed that, "People hesitate to swallow the drug as after first day of distribution, news were published in the newspapers that people are suffering after swallowing the drug".

With regard to suggestions given regarding minimizing the impact of adverse reactions, all categories of respondents indicated that more information is needed to wipe out the fear of adverse reactions during MDA. Majority of respondents from the community held the opinion that organizing a camp with doctors during MDA days will build confidence among the community. In an FGD, one respondent said, "People will be informed before hand if there is a camp (for getting treatment of adverse reactions) and if any problem occurs, they can go there for treatment". Propagation through continuous advertisements, telecasting interviews of doctors explaining the harmlessness of the drug, availability of health staff, etc. are some of the options given by the community members and programme partners. They also thought that it is essential to motivate those 20%–25% of people who have a negative attitude towards the consumption of the drug for the success of MDA. Some key-informants also said that government should take care of media hype regarding issues of adverse reactions. Some doctor said drug should be distributed in a single day to minimize the damages due to adverse reactions.

#### 4. Discussion

To achieve success in PELF, it is essential that microfilaraemias are cleared or at least reduced to very low levels in almost all of those living in endemic areas for at least five consecutive years. Both MDA compliance (the percentage of the population of a targeted district who are recorded as having ingested the drug during the MDA) and geographical coverage (the percentage of at-risk communities where MDA are regularly conducted) have to be kept high [20]. Frequency of adverse reactions had deterred people from participating in MDA and thus affects the compliance of MDA[7–10]. In India, a significant proportion of people do not consume the tablets even after receiving them. The main reason is the fear of adverse reactions[8,10]. In 2002 MDA in Orissa, 25.5% of eligible people did not consume the drugs though they received, and the fear of adverse reactions is the cause among 82% of them[10]. The household coverage surveys during 2002 and 2004 MDA indicated that around 16% of people who consumed the drug reported one or more adverse reactions.

This rate is high (50%) in a group of individuals who were monitored for 6 days from the day of consumption of drugs during the 2002 MDA[16]. However, mostly these reactions are mild and systemic. The probable reasons for adverse reactions and association of filarial infections are discussed thoroughly[16]. The present qualitative study also reveals the magnitude of the problem and its impact on the MDA compliance. Hence, an active surveillance system has to be developed and integrated with the programme to minimise its impact on compliance. Though reactions were not so severe, some people became panic and did not accept the programme positively and they expressed the need for medical camp during MDA. Also, the fear of adverse reactions should be addressed during community mobilization activities. Again rumours of severe adverse reactions and their reports in media deterred people from participating in MDA and affected the compliance. The print media exaggerated and highlighted the severity of adverse reactions, which may be due to insufficient advocacy among the media. The media attributed some natural deaths to the consumption of these drugs that hampered the compliance during the mop up days. While, in several endemic communities, the MDA compliance is affected by the occurrence of adverse reactions. In Papua New Guinea, adverse reactions were associated with increased rates of compliance of the following year, possibly because adverse effects were perceived as indicators of the efficacy of the treatment[21]. In the present study also, CDDs managed to take people into confidence by saying the positive aspect of adverse reactions. This message should carefully be incorporated in health communication campaigns. It is clear from the earlier study that some of the partners, including private practitioners do not know the rationale and benefits of MDA[22]. These people have much influence in the community. People, particularly in urban areas consult their family practitioners before taking any medicine. During evaluation surveys, the authors found that some people did not ingest the drugs, because their family practitioners advised not to take the drugs. Hence, the benefits of the programme and positive indications of adverse reactions should carefully be incorporated in health communication, in addition to developing an active surveillance system for adverse reactions management during MDA. To elevate the programme to high priority among the community, community mobilization and community participation should be strengthened, since the best mass treatment strategies rely heavily on active community participation[23,24]. The health communication strategies should be culturally specific and with more involvement of endemic communities. To achieve a positive behavioural change towards the higher MDA compliance, better understanding of the programme and enthusiasm of all partners of the programme is the need of the hour.

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## References

- [1] Savioli L, Crompton DWT, Ottesen EA, Montresor A, Hayashi S. Intestinal worms beware: development in anti-helminthic chemotherapy usage. *Parasitol Today* 1997; **13**: 43–4.
- [2] Stephenson I, Wiselka M. Drug treatment of tropical parasitic infections: recent achievements and developments. *Drugs* 2000; **60**: 985–95.
- [3] Das PK, Ramaiah KD, Vanamail P, Pani SP, Yuvaraj J, Balarajan K, Bundy DA. Placebo-controlled community trial of four cycles of single dose diethylcarbamazine or ivermectin against *Wuchereria bancrofti* infection and transmission in India. *Trans R Soc Trop Med Hyg* 2001; **95**: 336–41.
- [4] Esterre P, Plichart C, Sechan Y, Nguyen NL. The impact of 34 years of massive DEC chemotherapy on *Wuchereria bancrofti* infection and transmission: the Maupiti cohort. *Trop Med International Health* 2001; **6**: 190–5.
- [5] Ottesen EA. The global programme to eliminate lymphatic filariasis. *Trop Med International Health* 2000; **5**: 591–4.
- [6] Ottesen EA, Duke BOL, Karam M, Behbehani K. Strategies and tools for the control/elimination of lymphatic filariasis. *Bull World Health Organiz* 1997; **75**: 491–503.
- [7] Ramaiah KD, Das PK, Appavoo NC, Ramu K, Augustin DJ, Kumar KN, et al. A programme to eliminate lymphatic filariasis in Tamil Nadu state, India: compliance with annual single-dose mass treatment and some related operational aspects. *Trop Med International Health* 2000; **5**: 842–7.
- [8] Babu BV, Satyanarayana K. Factors responsible for coverage and compliance in mass drug administration during the programme to eliminate lymphatic filariasis in the East Godavari District, South India. *Trop Doctor* 2003; **33**: 79–82.
- [9] McLaughlin SI, Radday J, Michael MC, Addiss DG, Beach MJ, Lammie PJ, et al. Frequency, severity and costs of adverse reactions following mass treatment for lymphatic filariasis using diethylcarbamazine and albendazole in Leogane, Haiti 2000. *Am J Trop Med Hyg* 2003; **68**: 568–73.
- [10] Babu BV, Kar SK. Coverage, compliance and some operational issues of mass drug administration during the programme to eliminate lymphatic filariasis in Orissa, India. *Trop Med International Health* 2004; **9**: 702–9.
- [11] Ismail MM, Jayakody RL, Weil GJ, Nirmalan N, Jayasinghe KS, Abeyewickrema W, et al. Efficacy of single dose combinations of albendazole, ivermectin and diethylcarbamazine for the treatment of bancroftian filariasis. *Trans R Soc Trop Med Hyg* 1998; **92**: 94–7.
- [12] Dreyer G, Pires M, de Andrade LD, Lopes E, Medeiros Z, Tenorio J, et al. Tolerance of diethylcarbamazine by microfilaraemic and amicrofilaraemic individuals in an endemic area of bancroftian filariasis, Recife, Brazil. *Trans R Soc Trop Med Hyg* 1994; **88**: 232–6.
- [13] Richards Jr. FO, Eberhard ML, Bryan RT, McNeeley DF, Lammie PJ, McNeeley MB, et al. Comparison of high dose ivermectin and diethylcarbamazine for activity against bancroftian filariasis in Haiti. *Am J Trop Med Hyg* 1991; **44**: 3–10.
- [14] Addiss DG, Beach MJ, Streit TG, Lutwic S, LeCont FH, Lafontant JG, et al. Randomised placebo-controlled comparison of ivermectin and albendazole alone and in combination for *Wuchereria bancrofti* microfilaraemia in Haitian children. *Lancet* 1997; **350**: 480–4.
- [15] Jayakody RL, de Silva CSS, Weerasinghe WMT. Treatment of bancroftian filariasis with albendazole: evaluation of efficacy and adverse reactions. *Trop Biomedicine* 1993; **10**: 19–24.
- [16] Babu BV, Rath K, Kerketta AS, Swain BK, Mishra S, Kar SK. Adverse reactions following mass drug administration during the programme to eliminate lymphatic filariasis in Orissa State, India. *Trans R Soc Trop Med Hyg* 2006; **100**: 464–9.
- [17] Khan ME, Anker M, Patel BC, Barge S, Sadhwani H, Kohle R. The use of focus groups in social and behavioural research: some methodological issues. *World Health Stat Quart* 1991; **44**: 145–9.
- [18] Hudelson PM. *Qualitative Research for Health Programmes. Document No. WHO/MNH/PSF/94.3*. Geneva: World Health Organisation; 1994.
- [19] Pelto PJ, Pelto GH. *Anthropological research: the structure of enquiry*. Cambridge: Cambridge University Press; 1978.
- [20] Molyneux DH, Zagaria N. Lymphatic filariasis elimination: progress in global programme development. *Ann Trop Med Parasitol* 2002; **96**: S15–40.
- [21] Bockarie MJ, Tisch DG, Kastens W, Alexander ND, Dimber Z, Bockarie F, et al. Mass treatment to eliminate filariasis in Papua New Guinea. *New England J Med* 2002; **347**: 1841–8.
- [22] Babu BV, Nath N. The programme to eliminate lymphatic filariasis in Orissa, India: the attitude of some programme partners. *Ann Trop Med Parasitol* 2004; **99**: 101–4.
- [23] Biritwum RB, Sylla M, Diarra T, Amankwa J, Brika GP, Assogba LA, Traore MO. Evaluation of ivermectin distribution in Benin, Cote d'Ivoire, Ghana and Togo: estimation of coverage of treatment and operational aspects of distribution system. *Ann Trop Med Parasitol* 1997; **91**: 297–305.
- [24] Matubazi D, Duke BOL. Onchocerciasis control in Uganda: how can self sustaining, community based treatment with ivermectin be achieved? *Ann Trop Med Parasitol* 1998; **92**: 195–203.

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