Original Article

Facilitators and barriers in implementation of mass drug administration for lymphatic filariasis elimination in India: A protocol for systematic review and qualitative meta-synthesis

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Abstract

Introduction: Lymphatic filariasis (LF) is a debilitating and disabling parasitic disease of immense public health concern in India with more than 650 million people at risk. Mass drug administration (MDA) is the recommended preventive chemotherapy strategy to eliminate LF. But, its coverage and compliance has been a mixed success. There is an urgent need of evidence to strengthen the program further, which can be done by exploring and understanding implementer as well as beneficiary perspectives. **Objective:** To systematically review the facilitators and barriers experienced during the coverage and compliance of MDA for LF elimination in India from both beneficiary and provider's (health system) perspective. **Methods and Analysis:** We will search at Medline database through PubMed and Embase, along with ProQuest and Google Scholar to retrieve literature. Original qualitative observational studies exploring challenges and enablers in MDA program will be screened by two independent reviewers systematically based on title and abstract followed by full text. The risk of bias will be assessed through critical appraisal skills program checklist for each included article. Data will be extracted in a pre-designed proforma with study characteristics, demographic features, and texts and quotes of qualitative data. Data will be analyzed through thematic analysis and motivation-opportunity-ability-behavior framework using MAXQDA software. **Ethics and Dissemination:** This is a literature-based review with minimal privacy concerns. The findings of this study will be published in a peer-reviewed journal and disseminated through policy brief to program implementers.

Keywords: Barriers, compliance, coverage, enablers, India, MDA, qualitative meta-synthesis, systematic review

Introduction

Lymphatic filariasis (LF) is a debilitating and disabling parasitic disease with profound socio-economic impact.[1] It exhibits various clinical manifestations in humans, yet is one of the neglected tropical diseases (NTDs). LF is commonly seen among disadvantaged populations who lack proper sanitation facilities.[2] This disease is endemic in 80 tropical and subtropical countries with an estimated 750 million population at risk of contracting infection and approximately 80 million cases in the world.[3] In India, LF is

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Received: 23-06-2021 **Revised:** 02-10-2021
Accepted: 23-10-2021 **Published:** 22-07-2022

Access this article online

Quick Response Code:

Website: www.jfmpc.com

DOI: 10.4103/jfmpc.jfmpc_1243_21

How to cite this article: Sinha A, Mohapatra S, Pati S, Sahoo PK. Facilitators and barriers in the implementation of mass drug administration for lymphatic filariasis elimination in India: A protocol for systematic review and qualitative meta-synthesis. J Family Med Prim Care 2022;11:3844-50.

endemic in 18 states with a total of 650 million Indians currently at risk of contracting the disease.[4] It has been reported in 256 districts across 21 states and Union territories affecting >23 million people.[4]

LF affects the "poorest of the poor" and prevents those afflicted from living a normal working, married, and social life. Studies have shown that significant disability adjusted life years (DALYs) are lost due to this disease, as also severe economic losses to the affected individual.[5] Taking into consideration the number of people affected in India, LF is a serious impediment to the development of the country.[6] The World Health Organization ranks LF as second among infectious diseases causing permanent and long term disability due to its complex clinical features.[7] LF infection in endemic areas is a common encounter for primary healthcare providers. Its complex management poses challenges to the physicians as well as patients.[8]

Initially, it was targeted to eliminate LF globally by 2020, later by 2021 (now 2030) which is yet a daunting target. Mass drug administration (MDA) is the recommended preventive chemotherapy strategy of delivering safe, anthelminthic medicines to interrupt LF transmission.[9] The program aims to interrupt transmission through annual single dose of albendazole (400 mg) with diethylcarbamazine citrate (DEC) for continuous 5–6 years to all eligible people living in the endemic areas. MDA drugs act by reducing the density of any parasites present in the blood of infected individuals; hence, the burden of LF reduces to such low levels that further transmission cannot be sustained within the community eventually leading to cessation of new cases. When the level of transmission reduces below the target thresholds, MDA is no longer required.

The program is in place in India with the yearly mass single distribution of DEC and albendazole to the endemic community. Eight to ten rounds of MDA have been completed in different districts and the results are mixed success; while some districts have eliminated, some qualified for transmission assessment, but others still remain far from this with 10%–12% mf prevailing in several region.[10] Often, the MDA program is implemented at primary healthcare level where physicians are given the responsibility of program implementation. The success of program not only depends upon the beneficiaries' adherence but also to much extent on the motivation of these primary care providers/Medical officers who need to monitor and persuade frontline workers for better coverage.

Hence, it is imperative to explore various challenges faced by the program implementers for coverage as well as to understand the perspective of beneficiaries with regard to compliance with drugs. Since MDA continues in most of the endemic districts, there is an urgent need to synthesize evidence to improve coverage and compliance. Although quantitatively the coverage and compliance have been synthesized in a systematic review[11] earlier, none have qualitatively explored barriers and enablers for evidence-based policies to enhance the program. Hence, this systematic review was planned to generate much-needed evidence to strengthen MDA coverage and compliance with a deep understanding of barriers and enablers through qualitative exploration of the available literature in order to achieve the goal to eliminate lymphatic filariasis.

Objectives

1. To systematically review the facilitators and barriers experienced during the coverage and compliance of MDA for LF elimination in India from both beneficiary and provider's (health system) perspective.

Methods and Analysis

Standards

This study protocol followed preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) reporting guidelines [Supplementary file 1].[12] It will be conducted and reported following PRISMA reporting standards.[13]

Protocol registration

The present review is prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) with registration number CRD42021260296.[14] Any changes made further during the course of this review will be updated here.

Eligibility criteria

Observational studies will be included for review.

Inclusion criteria articles

1. Original articles reporting observational studies, i.e., qualitative and qualitative component of mixed method studies.
2. Articles qualitatively reporting barriers and enablers for coverage and compliance of MDA program in India.

Exclusion criteria of articles

1. Quantitative studies including editorials
2. Systematic review/reviews
3. Dissertations, conference proceeding

Types of participants/population

This study will target beneficiaries as well as providers participating in MDA program for elimination of LF in India.

Inclusion criteria of participants/population:

1. All beneficiaries eligible to receive drugs during MDA program.
2. Community-based stakeholders in MDA program
3. Stakeholders from program implementation team such as program managers, drug distributors, etc.

Exclusion criteria of participants/population:

1. Perspectives/view-points of scientific community who are not a direct stakeholder.

Setting and time frame

This study will include community-based articles or studies in any setting that qualitatively explore barriers and enablers in the implementation of MDA. There was no time bar on initial date, whereas articles published only till 30th June, 2021 will be included.

Report characteristics

We will review all published articles/reports with no bar on language or date of publication to make the search comprehensive and inclusive for this systematic review.

Information sources

A systematic search of electronic databases will be done to retrieve relevant articles: Medline database will be searched through PubMed and Embase. In addition, ProQuest and first ten pages of Google Scholar will also be searched to document barriers and enablers in the implementation of MDA. We will also hand search the citations to further identify relevant literature if any

Search strategy

The basic search syntax consists of three concepts: "lymphatic filariasis," "mass drug administration," and India. The MeSH terms were used in PubMed, whereas Emtree terms in Embase. The used MeSH terms were "Elephantiasis, Filarial"[Mesh] for lymphatic filariasis; "Mass Drug Administration"[Mesh] for mass drug administration; and "India"[Mesh] for India. Also, relevant keywords were used to cover all related terms in the search strategy.

All the three concepts were joined using Boolean operator AND as #1 AND #2 AND #3. Specific search strategies for each database/search engine are provided as a Supplementary file 2.

Study records

Selection process

In the first stage of review, titles and abstracts of all included studies will be screened by two independent reviewers. The selected studies will be categorized as relevant, irrelevant, and unsure based on potential eligibility. Articles categorized as irrelevant by both the reviewers will be eliminated. Followed by this, full texts of included articles will be obtained. Another round of sieving will be conducted for these articles strictly based on inclusion and exclusion criteria laid in the protocol by two other reviewers. Any differences over the eligibility of these articles will be resolved by the entire team in consensus.

Data management

Data from included studies will be extracted and entered in a preformed data extraction sheet [Supplementary file 3] by two researchers independently. These separate sheets will then be assessed by a third person who compares to identify differences. Potential inconsistency if any will be set on through discussion by the team in harmony. If any relevant data will be found missing or unclear, authors of the articles will be contacted through email.

Data items

The data required from each article are authors, study setting, year of publication; demographic attributes such as approach, participants (beneficiary/provider), data collection methods; analysis and major topic discussed. The detailed findings and related text quotes will be extracted from each included study. We will also extract data from abstract and conclusion sections of the articles to give a summary of the findings of each study.

Expected Outcomes

1. Factors that facilitate the coverage and compliance of MDA for lymphatic filariasis elimination.
2. Barriers in implementation/compliance of MDA program.
3. Evidence on gap areas where policy level change is required for effectiveness of MDA.
4. MDA program could be improved to reach the target of filariasis elimination.

Risk of bias (quality) assessment

Two independent reviewers will appraise the quality (risk of bias) of each included article. The quality of included articles will be appraised using ten items of critical appraisal skills program (CASP) checklist used for qualitative studies (https://caspuk.net/casp-tools-checklists/). It is based on three broad issues to be considered while appraising qualitative studies: i) are the results of the study valid? (Section A); ii) what are the results? (Section B); iii) will the results help locally? (Section C).

Data synthesis

Retrieved data from included articles will be analyzed using thematic analysis approach. We will use MAXQDA software for qualitative synthesis of data. Thematic analysis technique helps in the identification of themes evolving from the data. Themes will be explored through the relationships within coded data. A pre-formed code list based on careful reading of abstracts will be formed which can be modified later to accommodate emergent themes if any. The code list will contain broad themes as iteratively agreed upon by the reviewers based on the findings of each study.

The analysis will first be done through line by line coding followed by developing themes to understand concepts and their interrelationship. It is based on the Integrated motivation-opportunity-ability-behavior (MOAB) framework model by Willmott and Parkinson, 2017.

Ethics and dissemination

This systematic review synthesizes data from published articles in public domain. Individual data is not required for this literature based study; hence, there is no concern for privacy. The findings will be published in a peer-reviewed journal and disseminated with concerned stakeholders in form of policy brief as well as to the scientific community.

Discussion

This systematic review will synthesize evidence to strengthen implementation of MDA program in India. With more than 650 million people at risk of contracting LF, it is imperative to sufficiently deliver drugs to all eligible population with an equally good compliance which requires both implementers as well as beneficiaries to support the program. Qualitative research methods help in understanding the depth of a subject matter where more realistic exploration not based on prejudices can be made. This will make the present review more focused as summarizing the real field experiences of providers and beneficiary's perspective will uncover the grey areas. This will further help in policy and program strengthening.

It will be of great use for program implementers who often are primary care physicians. This evidence will pave a way for them to manage and motivate frontline workers and other providers in increasing coverage and compliance of MDA. Also, a strengthened program would imply lesser patients in times when the country is undergoing epidemiological shift leading to increase in non-communicable diseases, which will reduce physician burnout and longer appointments for other patients.

Strengths and limitations

This is a first attempt to perform qualitative meta-synthesis to strengthen NTD control program in India with a methodologically rigor and sound review. But, we anticipate a dearth in qualitative literature which might affect the true nature of this review but could definitely prove to be a way forward for future direction in this field.

Summary

To summarize, a systematic review will be conducted with an aim to synthesize qualitative evidence in order to improve the outcomes of MDA implementation. Both beneficiary and provider's perspective will be reviewed and presented with the help of MOAB framework, which is a novel concept in this study.

Acknowledgements

We are thankful to Dr Banamber Sahoo, Library & Information Officer, ICMR-Regional Medical Research Centre, Bhubaneswar for providing remote access to electronic databases and helping us in developing search strategy.

Supplementary Materials

Supplementary file 1: PRISMA checklist; Supplementary file 2: Detailed search strategy for all databases; Supplementary file 3: Data extraction proforma.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Supplemental File 1: PRISMA-P 2015 checklist

Section and topic	Item No.	Checklist Item	Reported on page #
		A) Administrative Information	
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	Identify protocol as an update of a previous systematic review if applicable	Not Applicable (NA)
Registration	2	Name of registry and registration number	2 + 4
		B) Authors	
Contact		Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Yes
Contributions		Describe contributions of protocol authors and identify the guarantor of the review	Yes
Amendments		If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support			
Sources	5a	Indicate Sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	NA
Role of sponsor or funder	5c	Describe roles of funder (s), sponsor (s) and/or institution (s), if any, in developing the protocol	NA
		C) Introduction	
Rationale	6	Describe the rationale for the review in the context of what is already known	2+3
Objectives	7	Provide an explicit statement of the question (s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
		D) Methods	
Eligibility Criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information Sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search Strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	5 Supplementary file 2
		E) Study Records	
Data Management	11a	Describe the mechanism (s) that will be used to manage records and data throughout the review	6
Selection Process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5+6
Data Collection Process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data Items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6+7
Data Synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency	NA
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	NA
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	7
Meta-bias (es)	16	Specify any planned assessment of meta-bias (es) (such as publication bias across studies, selective reporting within studies)	6+7
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed	6+7

Supplemental File 2: Detailed Search strategy

CONCEPT	MeSH	KEY WORDS
Lymphatic Filariasis	"Elephantiasis, Filarial"[Mesh]	"Elephantiases, Filarial"[tiab] "Filarial Elephantiases"[tiab] "Filariasis, Lymphatic"[tiab] "Filariases, Lymphatic"[tiab] "Lymphatic Filarias*"[tiab] "Filarial Elephantiasis"[tiab] "Elephantiasis, Bancroftian"[tiab] "Bancroftian Filarias*"[tiab] "Filariases, Bancroftian"[tiab] "Filariasis, Bancroftian"[tiab] "Bancroftian Elephantias*"[tiab] "Elephantiases, Bancroftian"[tiab] "Malayi Filariasis"[tiab] "Filariases, Malayi"[tiab] "Filariasis, Malayi"[tiab] "Malayi Filariases"[tiab] "Elephantiasis, Malayi"[tiab] "Elephantiases, Malayi"[tiab] "Malayi Elephantias*"[tiab] Eephantias*[tiab]
Mass Drug Administration	"Mass Drug Administration"[Mesh]	"Drug Administration, Mass"[tiab] "Mass Drug Administration*"[tiab] "Mass Administration*"[tiab]
India	"India"[Mesh]	India[tiab]

PubMed Search Strategy

#1 "Elephantiasis, Filarial"[Mesh] OR "Elephantiases, Filarial"[tiab] OR "Filarial Elephantiases"[tiab] OR "Filariasis, Lymphatic"[tiab] OR "Filariases, Lymphatic"[tiab] OR "Lymphatic Filarias*"[tiab] OR "Filarial Elephantiasis"[tiab] OR "Elephantiasis, Bancroftian"[tiab] OR "Bancroftian Filarias*"[tiab] OR "Filariases, Bancroftian"[tiab] OR "Filariasis, Bancroftian"[tiab] OR "Bancroftian Elephantias*"[tiab] OR "Elephantiases, Bancroftian"[tiab] OR "Malayi Filariasis"[tiab] OR "Filariases, Malayi"[tiab] OR "Filariasis, Malayi"[tiab] OR "Malayi Filariases"[tiab] OR "Elephantiasis, Malayi"[tiab] OR "Elephantiases, Malayi"[tiab] OR "Malayi Elephantias*"[tiab] OR Eephantias*[tiab]

#2 "Mass Drug Administration"[Mesh] OR "Drug Administration, Mass"[tiab] OR "Mass Drug Administration*"[tiab] OR "Mass Administration*"[tiab] OR "programme to eliminate lymphatic filariasis"[tiab] OR "global programme to eliminate lymphatic filariasis"[tiab]

#3 "India"[Mesh] OR India[tiab]

#1 AND #2 AND #3

((("Elephantiasis, Filarial"[Mesh] OR "Elephantiases, Filarial"[tiab] OR "Filarial Elephantiases"[tiab] OR "Filariasis, Lymphatic"[tiab] OR "Filariases, Lymphatic"[tiab] OR "Lymphatic Filarias*"[tiab] OR "Filarial Elephantiasis"[tiab] OR "Elephantiasis, Bancroftian"[tiab] OR "Bancroftian Filarias*"[tiab] OR "Filariases, Bancroftian"[tiab] OR "Filariasis, Bancroftian"[tiab] OR "Bancroftian Elephantias*"[tiab] OR "Elephantiases, Bancroftian"[tiab] OR "Malayi Filariasis"[tiab] OR "Filariases, Malayi"[tiab] OR "Filariasis, Malayi"[tiab] OR "Malayi Filariases"[tiab] OR "Elephantiasis, Malayi"[tiab] OR "Elephantiases, Malayi"[tiab] OR "Malayi Elephantias*"[tiab]) AND ("Mass Drug Administration"[Mesh] OR "Drug Administration, Mass"[tiab] OR "Mass Drug Administration*"[tiab] OR "Mass Administration*"[tiab] OR "programme to eliminate lymphatic filariasis"[tiab] OR "global programme to eliminate lymphatic filariasis"[tiab])) AND ("India"[Mesh] OR India[tiab])

Search Strategy for Embase

#1 elephantiasis OR 'lymphatic filariasis' OR 'bancroftian filariasis' OR 'malayi filariasis' OR filaria OR filariasis

#2 'lymphatic filariasis'/exp OR 'bancroftian filariasis'/mj OR 'filariasis'/mj OR 'elephantiasis'/mj

#3 #1 OR #2

#4 'mass drug administration'/exp

#5 'mass drug administration' OR 'mass administration' OR 'community drug administration'

#6- #4 OR #5

#7 'india'/exp

#8 India

#9- #7 OR #8

#10- #3 AND #6 AND #9

Search Strategy for ProQuest

(Filariasis OR Lymphatic filariasis OR elephantiasis OR malayi filariasis OR Bancroftian filariasis) AND (mass drug administration OR community drug administration OR mass administration OR programme to eliminate lymphatic filariasis) AND (compliance OR coverage OR drug distributor OR community based treatment OR community participation OR community drug distributors OR acceptability OR implementation) AND (India OR Indian)

Search Strategy for Google Scholar

("lymphatic filariasis" OR elephantiasis OR filariasis) AND India AND ("mass drug administration" OR "drug distribution" OR "community drug administration") AND (compliance OR coverage OR "drug distributor")

Supplementary File 3: Data Extraction Proforma (to be used in excel format)

Serial No	Authors	Study Title	Journal Title	Year of Publication	Country	Study Characteristics				Category of participants (MDA Beneficiary/Provider)	Participant Characteristics		
						Study Design	Study Setting	Sample Size	Sampling Methods		Mean age	Sex	Duration of disease (if applicable)

Abstract	Major Findings	Specific Quotes	Conclusion	Summary	Strengths and limitations of study