

TRACHOMA SAFE STRATEGY SERIES:

Antibiotics



Transition planning for mass drug administration (MDA) of Zithromax[®]

ICTC International Coalition
for Trachoma Control

Acknowledgements

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Front cover: International Trachoma Initiative

Foreword

This toolkit for transition planning is one of three planning documents recommended by the International Coalition for Trachoma Control for program managers and implementing partners to support transition from elimination efforts (public health interventions) to routine public services. The importance of effective leadership underpinning the success of these programs cannot be overstated.

The series of transition toolkits include:

- Transition planning for trichiasis management services
- Transition planning for mass drug administration of Zithromax®
- Transition planning Facial cleanliness and Environmental improvement

These toolkits can be used in a variety of ways: (i) as a step-by-step planning guide (ii) as a checklist to ensure planning is on the right path (iii) as a reference document on key planning components and (iv) to engage non-trachoma partners in the planning and delivery of transition activities.



MDA distribution in Tanzania. Photo: Birgit Bolton/ International Trachoma Initiative

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Mass drug administration in Sokoto State, Nigeria. Photo: Sumon Ray/International Trachoma Initiative

Background

Mass drug administration (MDA) of antibiotics is recommended by WHO when the prevalence of trachomatous inflammation—follicular (TF) in children aged 1-9 years is $\geq 5\%$. WHO has established that when an impact survey, conducted at least six months following the requisite number of rounds of MDA, indicates the district TF prevalence is below the elimination threshold ($< 5\%$ in 1-9 year olds), MDA should be discontinued as the district enters a two-year pre-validation surveillance period. At the end of this two-year period, a pre-validation surveillance survey is conducted to ensure that the district has maintained its elimination threshold. As an increasing number of districts reach the pre-validation surveillance period, it is recommended that national programs and partners develop a transition plan that focuses on the A component of the SAFE strategy.

The principle objectives of the MDA transition plan are to ensure that:

- a) The remaining stocks of Zithromax® are appropriately managed in accordance with the guidelines established by the International Trachoma Initiative (ITI) and Pfizer Inc.;
- b) Consideration is given to designing a surveillance system to identify any recrudescence of active trachoma; and
- c) Health authorities at each level of the health system and affected communities are aware of the cessation of MDA, the justification for stopping and that WASH activities need to continue.

It is recommended that this ‘transitioning’ process begin as early as possible and certainly no later than the period preceding what should be the last MDA (see timelines for each objective). Ideally, planning should be part of regular district and national trachoma/NTD task force meetings and included in any micro-planning that takes place. The following steps will guide both ministries and NGO partners in the essential activities to support a successful transition.

Critical aspects

A. Post-MDA management of Zithromax®

Prior to the last round of MDA, the national program and partners should engage in detailed planning for drug needs and distribution to minimize the amount of remaining Zithromax® in anticipation that no further MDAs will be necessary. Following the last MDA prior to conducting impact surveys, all Zithromax® should be returned to either the provincial or central level and inventoried. Once the impact survey has determined that TF prevalence among children aged 1-9 years are

below 5% and MDA is no longer necessary, any remaining Zithromax® may be used only for the following purposes:

- 1) For the treatment of patients immediately following trichiasis surgery.
- 2) For the treatment of TF-positive children identified during surveys. *Please note that this option is only possible if there is adequate remaining inventory of powder for oral suspension (POS) to treat children under the age of 7 years.*

Though MDA has ceased, countries with remaining donated Zithromax® will still be expected to adhere to the requirements in the Memorandum of Understanding between the ministry of health and ITI. Notably, once MDA is no longer required, the following principles still apply:

- Ensure that Zithromax® is used only for the control of trachoma as mutually agreed between ministries of health and ITI, and is not transferred or sold in exchange for money, property or services.
- Ensure that Zithromax® is not used for research purposes without the prior, full, written approval of ITI on behalf of the Trachoma Expert Committee.
- Ensure that product safety monitoring and reporting processes are in place. If the ministry of health becomes aware of potential adverse events, at risk scenarios, and product quality complaints that may be associated with Zithromax®, they will inform Pfizer Inc. through the designated Pfizer Inc. regional offices listed in the contact list on **Table 1** in **Annex A** of the MOU.
- The collection, storage, handling, transportation, movement, disposal, and destruction of all expired Zithromax® shall be the responsibility of ministries of health in compliance with Pfizer Inc. destruction procedures and applicable laws.

Annual inventory reports will be requested by ITI to be able to track the use of the drug and to monitor the number of doses remaining until the inventory in-country is zero.

B. Post-endemic surveillance

One aspect countries should consider as part of their transition planning is the need for a surveillance system. As a program that only seeks elimination of trachoma as a public health problem, national programs and partners should recognize that disease could return to endemic levels if not monitored. A post-validation surveillance plan is required as part of the dossier for validation of elimination, though (owing to a lack of evidence) generic guidance on what should be done is difficult to formulate. It is recommended that post-validation surveillance systems be designed as collaborations between health

ministries, academic institutions and other supporting partners. Planning for this should take place during the pre-validation period of the first district to reach this stage. Following a successful surveillance survey, this first district will provide the opportunity to test and refine approaches and as other districts successfully complete their surveillance surveys, a surveillance system can be scaled up. During planning, the national program should identify opportunities to integrate trachoma surveillance with other infectious disease programs that have entered the surveillance phase.

In conducting post-elimination surveillance, it is possible that active trachoma will be detected and require treatment. Planning for the surveillance should also include a plan to procure of generic azithromycin to respond to recurrence.

C. Communication with districts and communities

With many districts receiving multiple rounds of treatment, district health authorities and the communities in those districts should understand the reasons why MDA is no longer being continued. Communication throughout the district should ensure that the evidence for stopping is presented, that WASH activities need to be continued to sustain the results of antibiotic MDA and that the disease may recur and under what circumstances MDA may need to resume. If there are other MDA programs, it needs to be clear that this only pertains to the trachoma program, so the success of those other initiatives is not jeopardized.

As part of the planning for effectively communicating the end of the MDA, the national program and partners should research if any other community level programs have ceased activities and what approaches they took to justify the reasons for stopping. It may also come to light, that for various reasons they decided such an initiative was not warranted, in which case it is important to understand why and whether the same logic is applicable to the end of trachoma MDA. Coordination with ongoing programs in the same districts will also be important as discussed above.

Steps in planning

Step 1: National level: Advance communication triggering district-level transition planning

Planning for transition should be organized nationally, with micro-planning and implementation undertaken district-by-district. National guidance is required. Clear communication from the national to the district level will likely lead to greater prioritization of this activity. Different approaches may be needed for countries that are highly decentralized and decision-making rests at the district level. Creation and promotion of a district-level “Trachoma Fact Sheet” (see ICTC resources on www.trachomacoalition.org) may be helpful in ensuring that there is a common understanding of the key criteria

for transition and how the criteria apply to the identified district.

Step 1 goal: District and national level authorities have the necessary **knowledge** and **evidence on trachoma elimination** to ensure a smooth transition. The evidence needed will come from the impact surveys following the prescribed number of MDA rounds and then reinforced by the surveillance surveys two years later. Achievement of elimination of active trachoma at the district level needs to be celebrated. That said, elimination may not be “forever”; sustaining elimination and supporting transition requires advocacy, resourcing and communication. Clear communication to all stakeholders is essential.

Planning decisions / suggested activities	Supporting documentation	Responsible	Scheduled date of completion	Status	Comments
<p>1. Communication from national level ministries of health to district and regional authorities triggering transition planning process.</p> <p><i>Recommend communication sent about three months prior to projected date for impact survey (in which TF prevalence is anticipated to be <5%).</i></p>	<p>District-level TF prevalence data.</p> <p>District-level supporting documentation regarding MDA for previous years.</p> <p>Dates for next scheduled surveillance survey.</p>	National ministries of health with assistance from coordinating partner.			
<p>2. Organize a district-level transition planning meeting with all relevant stakeholders (ideally prior to conducting surveys). A draft agenda outline is included in the Annex of this document.</p>					
<p>3. Review current inventory of Zithromax® in the districts and consolidate at the national level. Communicate inventory count to ITI.</p>	Zithromax® inventory spreadsheets	National & district Central Medical Stores			
<p>4. Develop plan for the utilization of remaining Zithromax® inventory and share with ITI for comment.</p>	Zithromax® utilization plan	National health ministry with assistance from ITI			
<p>5. Develop a plan for post-elimination surveillance for districts that have had successful surveillance surveys.</p>		National health ministry with guidance from WHO and other disease programs			

Step 2: District level communication/advocacy regarding cessation of mass drug administration of Zithromax®

The district level transition plan lays out how communication and advocacy regarding cessation of MDA is undertaken for [a] district health authorities and health unit teams and [b] the general population. Adequate communication is needed to ensure that health workers and the general population understand the rationale for cessation of MDA as well as the continuing need for

WASH activities to ensure that active trachoma does not reemerge. The planning should include strategies to sustain the engagement of health workers and communities and who will support them.

It is also important for health authorities to understand under what situations MDA might need to be re-started and to appreciate that small changes in TF prevalence (in which 95% confidence intervals overlap) do not indicate an increase in active trachoma.

Planning decisions / suggested activities	Responsible	Scheduled date of completion	Status	Comments
1. Prepare a plan for informing the relevant health care authorities (including health unit personnel) regarding the cessation of MDA.	District health ministry with partners			
2. Prepare/disseminate information to the general population about the cessation of MDA (and the importance of continuing WASH activities).				
3. Consolidate remaining antibiotics and return to the CMS or other sites, as outlined in the plan.				
4. Review existing policies and procedures to ensure that all health facilities have tetracycline eye ointment as an essential medicine and if not plan an advocacy strategy.				

Step 3: Plan for compilation of data to inform decision-making and dossier preparation

A successful transition across the entire program area nationally should lead to validation of elimination of trachoma as a public health problem. For that reason,

Careful documentation and reporting are essential. Documentation of previous MDA (pre-elimination) is critical for preparation of the national dossier and for identifying any problems.

Planning decisions / suggested activities	Responsible	Scheduled date of completion	Status	Comments
1. Compilation of MDA data (year, coverage %, and # treated) at district level and confirmation at national level)				

Annex: Suggested agenda at district level transition planning meeting for active trachoma

- Overview of WHO guidelines for when to start AFE and when to discontinue MDA.
- Overview of WHO guidelines for elimination of trachoma as a public health problem (role of impact surveys, surveillance surveys, transition and dossier development).
- Important role of WASH to sustain reductions in TF prevalence as well as reducing water-borne diseases and other NTDs in which WASH is a critical component in disease suppression and elimination.
- Overview of history of trachoma in the district (including data from all surveys).
- Recent history of MDA and WASH activities (last three years).
- Confirm the national role and responsibility in communication with district authorities.
- Discuss the steps to ensure WASH activities continue.
- Discuss dissemination of information regarding cessation of MDA and maintenance of WASH to [a] health workers, and [b] to the general population.
- Plan for district/national celebration of achievement of elimination of active trachoma.

International Coalition for Trachoma Control (ICTC)

VISION:

Global elimination of trachoma as a public health problem by the year 2020.

MISSION:

To act as a catalyst for the implementation of the SAFE strategy in support of endemic countries' trachoma control programs.

ICTC has a highly committed and professional multi-stakeholder membership, including Non-Governmental Development Organizations, donors, private sector organizations and research/academic institutions that demonstrate a commitment to GET 2020 and the WHO-endorsed SAFE strategy.

ICTC members at time of publication:



ICTC observers at time of publication:



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