Supply Chain Management Manual for Neglected Tropical Diseases
Health Managers

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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Key Words

NTDs, MDAs
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ACRONYMS

ADR  Adverse drug reactions
ALB  Albendazole
AZITH Azithromycin
CDD  Community drug distributor
CHW  Community health worker
CMS  Central medical store
DEC  Diethylcarbamazine
DHO  District Health Office
EMA  European Medicine Agency
EPI  Expanded program on immunization
FDA  Food and Drug Administration
GSK  GlaxoSmithKline
HC  Health Center
HF  Health Facility
ITN  Insecticide treated bed-net
IVM  ivermectin (Mectizan™)
JRF  Joint Reporting Form
LF  lymphatic filariasis
MDA  mass drug administration
MDP  Mectizan® Donation Program
M&E  Monitoring & Evaluation
MEB  Mebendazole
MoH  Ministry of Health
MSH  Management Science for Health
NGO  Nongovernmental organization
NPO  National program officer
NTD  Neglected tropical disease
NTDCP  Neglected Tropical Disease Control Program
NTDD  Neglected tropical disease drug
PCT  Preventive chemotherapy
ONCH  Onchocerciasis
PCT  Pharmaceutical management information system
PMIS  Pharmaceutical management information system
PZQ  Praziquantel
QA  Quality assurance
SC  Supply chain
SCH  Schistosomiasis
SCM  Supply chain management
SIAPS  Systems for Improved Access to Pharmaceuticals and Services
SOP  Standard operating procedure
SPS  Strengthening Pharmaceutical Systems
STH  Soil-transmitted helminths
TIPAC  Tool for integrated planning and costing
TRAC  Trachoma
USAID  US Agency for International Development
VHW  Village Health Worker
WHO  World Health Organization
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PURPOSE OF THE MANUAL

With the gradual scaling up of integrated, large scale PCT programs, there is a recognized urgent need to build managerial capacity throughout the supply chain of the donated drugs from the national level managers down to the volunteer community health worker. With time, this will create a critical mass of expertise that will be routinely available to sustain PCT programs for as long as needed.

The purpose of this manual, “A National Health Managers Guide to Supply Chain Management for National Mass Drug Administration against Neglected Tropical Diseases” is to provide a framework to define the issues that national program managers need to be aware of related to supply chain management of NTDDs and the context in which that need to work at that district and community levels to ensure effective and efficient movement and storage of NTDDs. It borrows from contemporary pharmacy practice with emphasis on management of NTDDs but the issues addressed apply to any other drugs and commodities used in campaign based delivery. It is therefore hoped that lessons learned from the management of NTDs can be applied to other health commodities.

The objectives of this manual include the following:

- Supporting donation programs and implementing partners in improving supply chain and inventory management practices, with focus on NTDDs and related supplies.

- Supporting institutionalization of standard operating procedures (SOPs) in the management of NTDDs

- Improving management of records at storage centers and reporting drugs used within an NTD program

- Improving accountability and promoting institutional memory through documentation of all drug management activities that routinely take place throughout the supply chain

- Improving accountability systems related to drug management, storage and distribution

- Provide a list of Best Practices for Supply Chain Management of NTDDs for MDA (appendix 1)
TERMINOLOGY

This document uses the phrase “NTD control” as a generic name for any such integrated approach that involves a system for routinely planning, conducting, monitoring and evaluating these services over the course of several years. In many countries, the responsibility for planning and managing MDAs is devolved to sub-national levels. The names of sub-national administrative areas vary by country. They may be known locally as wards, local government areas, districts or by some other description. In this document, we use “district level” as a generic description of this sub-national level.
LIMITATIONS OF THE NTD SCM MANUAL

While it is designed to provide comprehensive overview, it is not possible to anticipate all issues that may arise in the course of daily work. In such cases, the NTD NPOs and implementing partners should work collaboratively to reach a decision or solution, using these manual and other materials as a guide. This manual is not intended to be used as a “how to” manual for the entire pharmaceutical supply chain system.

The manual is organized into four broad chapters. The first chapter describes the diseases, the medicine, the global NTD initiatives, NTD relations with other health services. The second chapter is dedicated to supply chain management and related information system. The third chapter deals with medicines safety and monitoring and evaluation. The fourth chapter deals with the management of NTD programs. There are several annexes that focus on treatment and dosage. A resource section at the end provides links to additional references.
CHAPTER 1. INTRODUCTION

In response to a request from USAID/NTD program and absence of a comprehensive, user-friendly supply chain management guide for NTD health managers, SIAPS developed this manual with the intention of filling the gap. The manual builds on the several supply chain management materials developed by SIAPS and its predecessor programs SPS and RPM Plus. It is also informed by the observations and findings of the four country assessments and stakeholder workshops that SIAPS predecessor SPS project conducted with USAID funding.

Neglected tropical diseases are a group of 17 infections that impact virtually all of the “bottom billion”—the 1.4 billion people around the world who are living on less than $1.25 a day—who are afflicted with one or more of the seven most common NTDs, which include soil-transmitted helminths (hookworm, ascariasis, trichuriasis), onchocerciasis, schistosomiasis, trachoma, and lymphatic filariasis. NTDs impair physical and cognitive development, cause adverse pregnancy outcomes, and limit adult productivity in the workforce. As a result, they cause billions of dollars in lost wages, all but ensuring that those at risk of infection remain trapped in a cycle of poverty and disease. These chronic conditions also kill more than 500,000 people a year.

Public health interventions using preventive chemotherapy (PCT) to control neglected tropical diseases (NTDs) depend on people in endemic areas receiving the medicines or drugs they need in the places where they live, at appropriate regular intervals. This precise timing is even more critical given the World Health Organization (WHO) goals to control and/or eliminate the spread of these diseases by 2020. The first and fundamental step in the process consists ensuring a high effective and efficient supply chain (SC) that the NTD drugs (NTDDs) are of high quality and available for distribution during a mass drug administration (MDA). After making arrangements to ensure access to such drugs, program managers must be able to follow the progress of the intervention. Monitoring drug coverage when the drugs are swallowed by individuals at the point of delivery is another critical step of the process. Managers must know how many people in need of treatment received the treatment. Without reliable information about drug coverage, program managers and their staff cannot monitor program performance effectively and plan for future MDAs. Working to achieve the objectives of an NTD control program involving PCT requires highly organized cooperation from all NTD control and elimination stakeholder. Appropriate supply chain management has several important consequences for program managers on the quantitative results from MDAs.

In many countries, NTDDs are no longer distributed through standalone vertical campaigns, but as part of a more integrated approach of twice yearly expanded outreach services aimed at achieving the highest possible coverage of communities.

Prior to implementing a NTD control program, a national NTD strategic plan should already have been developed. The national strategy should provide districts with the flexibility to adjust supply chain management that is relevant to local situations, and with a list of recommended practices which districts should follow if they have the capacity to do so. MDAs should only be implemented if the district has the capacity to deliver them to specified standards. Program Managers should make themselves aware of the issues in the strategic plan pertaining to SCM.
Chapter 1. Introduction

The Diseases

**Soil-Transmitted Helminths**

Infections with soil-transmitted helminths (STHs) are caused by intestinal worms (mainly hookworm, ascariasis, trichuriasis) transmitted through contaminated soil, are the most common infections worldwide. Globally, more than 1 billion people are infected with one or more STHs, mainly in areas with warm and moist climates and in places where sanitation and hygiene are poor. Infection with STH contributes to anemia, vitamin A deficiency, malnutrition and impaired growth, delayed development, and intestinal blockages.

**Lymphatic Filariasis**

Lymphatic filariasis (LF) also known as elephantiasis, a mosquito-borne disease, is caused by the parasitic filarial nematodes (roundworms) *Wuchereria bancrofti* (*W. bancrofti*), *Brugia malayi* (*B. malayi*), or *Brugia timori* (*B. timori*). Because the burden of the disease is determined by the intensity and the duration of the infection, the greatest impact of LF is on older age groups. People with the disease can suffer from disfigurement and permanent disabilities due to lymphedema (swelling from fluid build-up caused by improper functioning of the lymph system). Elephantiasis is a crippling condition in which limbs or other parts of the body are grotesquely swollen or enlarged. In addition, people with the disease suffer from hidden internal damage to the kidneys and lymphatic system caused by the filariae. Furthermore, the psychological and social stigma associated with the disease is significant and can adversely affect productivity and quality of life.

**Onchocerciasis**

Onchocerciasis (ONCH) is an eye and skin infection caused by the parasitic worm *Onchocerca volvulus*, which is transmitted by the bite of an infected blackfly (genus *Simulium*). Because the insect that spreads the disease breeds and lives near fast-flowing rivers and streams, onchocerciasis is also known as river blindness. Severely infected people usually develop severe itching, skin discoloration (known as leopard skin) and/or eye lesions. While the disease is not a direct cause of mortality, the socioeconomic consequences of onchocerciasis are profound and extend beyond the individual, affecting families, communities, and countries as a whole. According to the WHO, onchocerciasis is the second leading infectious cause of blindness, after trachoma. Furthermore, the psychological and social stigma associated with the disease is significant.

**Trachoma**

Trachoma (TRAC) is the leading cause of infectious blindness worldwide. This crippling disease is an infection of the eye caused by the bacterium *Chlamydia trachomatis*, which spreads through direct contact with infected people and through eye-seeking flies. While the disease usually clears up on its own, infections can scar the inside of an infected person’s upper eyelid so that with repeated infections the lid turns inward causing the eye lashes to scratch the cornea, which can lead to blinding trachoma.
**Schistosomiasis**

Schistosomiasis (SCH), also known as bilharzia, is a chronic disease caused by parasitic worms that live in certain types of freshwater snails. People who come into contact with water that contains these infected snails are at risk of infection. Schistosomiasis is considered second only to malaria as the most devastating parasitic disease in tropical countries. In sub-Saharan Africa, more than 200,000 deaths per year are due to schistosomiasis. Depending on the species of parasite, schistosomiasis causes renal and bladder dysfunction or liver and intestinal disease, and it contributes to anemia and growth retardation in children.

**NTD Treatment Approach**

Mass drug administration (MDA) – is the administration of medicine to entire populations in at-risk communities in order to prevent, control and eliminate disease. This is different from many other diseases, which must be diagnosed by a health care worker. MDAs can occur annually or several times a year until an area is free of the disease. Some of the seven most common NTDs can be treated with a single drug, while others require a combination of several drugs.

**NTD Medications**

**Albendazole**

Albendazole (Alb) is a broad spectrum anthelmintic drug used for the treatment STH, as well as LF (in conjunction with Diethylcarbamazine or Ivermectin). Albendazole is a WHO Essential Medicine. GSK currently donates 600 million tablets annually of Alb to school age children (SAC) to treat STH and 400 million tablets annually as part of the LF treatment programs.

**Mebendazole**

Mebendazole (Meb) is a broad spectrum anthelmintic drug used for the treatment of STH. Mebendazole is a WHO Essential Medicine. Johnson & Johnson currently donates 200 million tablets of Meb to SAC to treat STH.

**Ivermectin**

Ivermectin (IVM) is a broad spectrum anthelmintic drug used for the treatment for Onchocerciasis and LF (in conjunction with Alb). Ivermectin is a WHO Essential Medicine. Since 1987, Merck has donated an unlimited supply of IVM (Mectizan), and has pledged to continue until the disease is eliminated.

**Diethylcarbamazine**

Diethylcarbamazine (DEC) is an anthelmintic drug used in the treatment of LF (in conjunction with alb). DEC is a WHO Essential Medicine and is now prequalified for use against LF. Easi has pledged the donation of one billion doses of DEC in for the treatment of LF until 2020.
**Praziquantel**

Praziquantel (PZQ) is an anthelmintic drug used in the treatment of SCH. PZQ is a WHO Essential Medicine. Merck Serono has recently increased its donation to 250 million tablets per year until 2020.

**Azithromycin**

Azithromycin (Azith) is a broad-spectrum antibiotic used in the treatment of trachoma. Azith is a WHO Essential Medicine. Pfizer is donating azithromycin until the disease trachoma related blinding is eliminated.

**Donation Programs and Global Initiatives to Prevent, Control, and Treat NTDs**

The high commitment of many international partners is a major strength in the fight against NTDs. In recent decades, the pharmaceutical industry has amassed an impressive track record of partnering with non-governmental organizations on large-scale treatment campaigns for diseases of poverty. The pill donations themselves are valued at more than US $1 billion and represent the largest drug donations in history, and pharmaceutical companies have continued to increase their commitments. In addition, expert strategic working committees have been formed under the guidance of the WHO to review donations and treatment protocols to prevent and treat NTDs.

**New Goals of Elimination by 2020**

In recent years, the world donor community has stepped up its response by creating several global initiatives for the integrated control of these diseases. As a result, donors from around the world have also increased their commitments to increased drug donations for the programs. The largest partnership to date, the London Declaration on NTDs, was announced in January 2012, by pharmaceutical companies, bilateral aid agencies, and other public and private sector partners. This pledge is being tracked with an annual scorecard, reinforcing and demonstrating the commitment of the global community towards the control and elimination of NTDs.

**Integrated NTD**

Historically, many of the NTDs have been tackled individually, with wide variance in the intensity of control efforts for the different disease. While significant progress has been made, many communities with overlapping disease burdens continue to face the detrimental effects of the NTDs. There are proven co-management of the diseases that yield an integrated approach that is safe for communities, is more efficient for governments to manage, and enables greater scale-up of preventive chemotherapy. The WHO recommends a strategy of PCT, which targets a group of NTDs and at-risk-populations rather than any given specific disease. To comprehensively support the integration approach, only disease and program integration will not provide the desired result. The management of NTDDs should so be integrated in terms of...
quantification, donation application, clearance, storage, distribution and delivery. Experiences show that NTDDs logistics management was done haphazardly by individual NTD programs and lacked harmonization and coordination resulting in overstock, stock-out, expiry, inappropriate storage/handling and delays in distribution. There is inadequate involvement of the national agency involved in drug management such as the central medical stores. Except minimal uninformed logistics involvement by CMSs, an active, informed role is not played. Integration in this area can have beneficial effect in terms of cost saving and efficiency.

**Annual Work Plan**

The annual work plan is designed to summarize the key activities to be implemented by national programs, to present timelines and identify gaps in financial and technical resources for implementation. It allows program managers to monitor the progress of the national programs closely and coordinate with the WHO and partners provision of support where necessary.

**Comparison to Other Disease Models**

In many ways the current status of the NTD control/elimination movement is experiencing mirror the issues that occurred with other health interventions such as the Expanded Program on Immunization (EPI) program in the 1980’s, Vitamin A distribution in the 1990’s, HIV/AIDS programs in the early 2000’s. Large influx of funds has resulted in the ability to truly control these associated diseases. However, similarly these programs have experienced issues on how to deal with capacity to deliver the medicines to the people who need them. In the initial years of the programs, the primary focus was to get the medications to the greatest number people as fast as possible. This “emergency/campaign” mode often resulted in competing priorities for funding devoted to different program often resulted in insufficient financial, human, and technical resources for implementing and strengthening those supply chains. As a result, verticalization, supply interruptions and shortages of medications were common in many programs. Over the years, program planners increasingly became aware of the importance of efficient supply chains. Supply chain managers could increase the quality and reach of public health programs by better ensuring the availability of the products they manage and by using available resources efficiently so that wastage is minimized and accountability is enhanced.

The NTD community is now in a similar situation. Many programs have scaled up integrated MDA of medications and not have demonstrated reduced rates of disease in the community. Many implementers now are beginning to see the “return on investment” per MDA reduced and are trying to find ways to increase the efficiency of their programs. One such method is by tightening the efficiency of the supply chain management of their programs.
Chapter 1. Introduction

NTD Complement Routine Health Services

How Do National Priorities and Strategies Contribute to NTD Control?

Effective leadership and governance are critical to long term sustainability of NTD programs: The administrative hierarchy of the ministry of health and responsibilities at each level need to be clearly defined to maximize efficiency of the supply chain and distribution of NTD medications during MDAs. Some of the questions to consider are:

- Are there reforms to improve the health supply chain system or parts of it being carried out in your country?
- Are existing conditions of health reforms supportive of NTD control activities even if they are not a national priority?
- Is there a national policy on NTD control or an institutional framework for NTD control?
- Are NTDs included in the health sector strategic plan and the sub-national health work plans?
- Is there a national coordinating body overseeing all control programs or are coordinating bodies constituted for specific programs?
- Do constraints exist to the leadership and governance systems in the control of NTDs?
- Does collaboration exist between other ministries (e.g. agriculture, education, transportation etc.), universities and other national research institutions are involved in NTD control?

NTDs Have Effects on Other Health Programs

NTDs and HIV

New research is beginning to demonstrate increased susceptibility and enhanced progression of HIV as a result of several helminthic and bacterial NTD coinfections. Soil transmitted helminth infections have an adverse, albeit, largely hidden impact on the AIDS epidemic. Research has demonstrated anti-helminthic treatments in co-infections are associated with a significant increase in absolute CD4+ T cell counts and reductions in viral load. In addition, studies on the treatment of schistosomiasis and lymphatic filariasis in HIV-infected individuals have demonstrated a reduction in viral load, which are comparable to decreases associated with treatment of malaria and sexually transmitted diseases, such as gonorrhea and syphilis. Growing and new evidence from studies in Zimbabwe and Tanzania demonstrate that female genital schistosomiasis occurs in up to 75% of women with S. haematobium infection and shows a 3-4
fold increase in the risk of women acquiring HIV infection\(^1\). Evidence also suggests that maternal helminth infections increase the likelihood of mother to child transmission of HIV, possibly as a result of increased maternal HIV viral load\(^2\).

### NTDs and Malaria

Hookworm and schistosomiasis co-infections have been shown to exacerbate anemia caused by malaria, leading to large numbers of maternal deaths that result during pregnancy and to premature births. Beyond the health benefits that would result from reduced anemia, there is some evidence that selected NTDs stunt the natural immune response of their host and promote increased susceptibility to malaria. Therefore treatment of malaria patients with antihelminthics can result in a significantly lower prevalence of malaria and re-occurring episodes of malaria. Beyond hookworm and schistosomiasis, ivermectin mass drug administration for onchocerciasis and lymphatic filariasis can also disrupt malaria transmission\(^3\).

### Helminth Infections in Maternal and Child Health

Data suggests that 44 of 124 million pregnant women in the developing world (more than one-third) harbor hookworm infection. Hookworm can lead to gastrointestinal blood loss, poor nutrient absorption, and inhibition-suppression of appetite—which can aggravate iron deficiency and anemia in pregnancy. Hookworm and other helminth infections, such as schistosomiasis, have long been known to have adverse effects on maternal health and pregnancy outcomes including maternal anemia and low birth weight. Deworming has been shown to reduce these adverse outcomes\(^4\). Because women are often in contact with contaminated water sources as part of their daily domestic tasks, they are at greater risk of infection for schistosomiasis.

Soil-transmitted helminths are the most common infections worldwide affecting the most deprived communities. According to the WHO, an estimated 228 million pre-school children between 12-59 months of age world-wide suffer from STHs. The evidence demonstrating that worm infections damage a child’s health is definitive\(^5\). Worm infections are associated with a significant loss of nutrients leading to nutritional deficiency. They also suppress the appetite leading to malnutrition, causing delays in physical/cognitive development and weaken immune systems. Roundworms are the most prevalent STH infection in pre-school children and cause a significant vitamin A malabsorption, with a resulting increased risk of mortality. Both forms of hookworm cause intestinal blood loss leading to anemia and micronutrient depletion. Whipworm causes intestinal iron loss, also resulting in anemia. In addition, because children are often in close contact with infected water sources, they are at greater risk of infection from schistosomiasis which causes similar effects on their nutritional status.

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\(^3\) Hotez PJ, Molyneux DH. Tropical anemia: one of Africa’s great killers and a rationale for linking malaria and neglected tropical disease control to achieve a common goal. PloS Negl Trop Dis 2008;2(7):e270


\(^5\) World Health Organization. Working to overcome the global impact of neglected tropical diseases: First WHO report on neglected tropical diseases. 2010
CHAPTER 2. SUPPLY CHAIN MANAGEMENT

Supply chain management is the process of planning, implementing, managing and controlling all activities involved in sourcing, procurement, distribution, and logistics management, with the aim of satisfying the end users as efficiently as possible. Importantly, it also includes coordination and collaboration with middle-level partners who serve as a link to the end users. These middle-level partners can be suppliers and intermediaries who have a stake in the supply chain process and the community drug distributors (CDDs). Organizations planning for effective growth concentrate on their core competences, which may be managerial, while outsourcing logistics to other organizations or partners. Supply chain management therefore seeks to improve collaboration among partners. In order to ensure that commodities are available when and where they are needed, a robust and responsive supply chain must be in place. Coordination of NTD MDAs requires an effective supply chain to ensure that NTDDs are available at the time of the scheduled MDA as not to cause treatment interruptions.

Cornerstones of Pharmaceutical Management: Selection, Procurement, Distribution, and Use

Pharmaceutical management involves four basic functions: selection, procurement, distribution, and use. Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual medicines and dosage forms, and deciding which medicines will be available at each level of health care. Procurement includes quantifying pharmaceutical requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring quality of medicines, and ensuring adherence to contract terms. Distribution includes the clearing of customs, stock control, stores management, and delivery to pharmaceutical depots and health facilities. Use includes diagnosing, prescribing, dispensing, and proper consumption by the patient. Each function builds on the next, forming the pharmaceutical management cycle.

At the center of the pharmaceutical management cycle is a core of management support systems: organization, financing and sustainability, information management, and human resources management. These management support systems hold the pharmaceutical management cycle together. Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to essential medicine supply. Figure 1 shows a graphic display of the pharmaceutical management cycle.
Figure 1. Pharmaceutical Management Cycle.

Pharmaceutical Management in Support of NTD Programs

Effective case management for NTDs requires that effective NTDDs are available and used appropriately in the correct formulations and amounts and according to an appropriate regimen (dose, frequency, duration). Ineffective treatment can lead to insufficient coverage to reach elimination/control goals, thus requiring additional treatment, which can lead to increased cost and loss of productivity, complications, and potentially the development of resistance to limited current medicines. One barrier to effective control of NTDs in the health system is that the medicines needed are often not available at time of scheduled MDA. Furthermore, access to reliable and consistent information about NTD treatment in most endemic countries is poor. Effective control and elimination of NTDs require that health workers and communities have access to NTDDs and supplies at time of MDA. Availability of these items may be influenced by a variety of factors, including poor stock control, provider experience, economic influences, cultural factors, community belief systems, and the complex interactions among these factors.

It is important to note that the NTD pharmaceutical supply system should not be a completely separate supply system. Since the medicines for NTD are essential to public health care in most developing countries, they should be integrated into the national pharmaceutical supply system to avoid duplication, at the same time respecting the special demands of the program as dictated by the unique nature and approach of NTD drugs procurement, distribution and delivery.

As a result of common overlap and similarities in treatment strategies, many Neglected Tropical Disease (NTD) programs — including trachoma, lymphatic filariasis, onchocerciasis, schistosomiasis, and soil-transmitted helminthiasis — are “integrating” program components in an effort to increase cost efficiencies, accelerate program scale-up, and improve program coverage. When integrating NTD programs, the key activities that are integrated are typically related to mass drug administration. However integrating mass drug administrations should be planned and conducted by taking safety, effectiveness and logistics concerns into consideration.
Some drugs may interact with each other or increase the potential for adverse drug reactions (ADRs). The target population of the MDA may not be the same and may affect the effective use of community distributors. If integrated MDA warrants, proper education and awareness must be in place.

**Good NTD Supply Chain Management Practices**

- A detailed Distribution and Transportation Plan should be drawn up well in advance to determine the quantity of NTDD that should be sent to regional/district storage facilities based upon the annual country agreement approved district allocations.

- Review the allocation schedule for distribution and check stock in the central warehouse to ensure sufficient supply for distribution.

- Schedule a distribution plan based on the field distribution dates of the districts.

- The NTD Control Program, Donation organization, implementing partners and CMS should establish a partnership to store, transport and distribute NTD medicines.

- Establish a procedure whereby a physical inventory is to be conducted following the MDA in order to document remaining stock on hand. That data along with any unused medicine should be transported back up the supply chain as quickly as possible following the MDA.

- Bring the storage conditions at all district storage facilities and health facilities into compliance with established storage standards for health commodities. Coordinate storage and distribution of health products that are administered in coordinated disease control campaigns (e.g., Vitamin A and ITN distribution) to avoid duplication and unnecessary effort and expenditure.

- Ensure adequate financial resources are available for distribution and storage of NTDDs prior to MDA

**Special Issues of SCM and NTD Donation Programs**

**Selection and Quantification**

In order to determine which NTDDs each district will need for annual MDAs, accurate mapping of the at risk populations is needed for each disease. In many cases, mapping of the different diseases is almost complete where the disease is endemic, however many others such as loiasis (infection with Loa loa) which has implications for large-scale preventive chemotherapy interventions using ivermectin.

Given the limited selection of available medications, choosing which NTD medication to use for MDAs is limited only to which disease are endemic in the communities. After much research and
years of gradual integration of individual NTD programs, the WHO has developed an algorithm for designing MDA and which medications to select for given the endemicity of the diseases in the districts.

Quantification is the process of estimating quantities and costs of products required for a specific period and determining when shipments of the products should be delivered to ensure optimal and uninterrupted supply.

Quantification has multiple applications including:

- Calculating estimated order quantities, costs and shipment delivery dates
- Planning, mobilizing and securing financial resources
- Estimating storage needs
- Assessing rational use of commodities
- Facilitating procurement and logistics coordination with donors, agents, health facilities and other stakeholders
- Informing manufacturers and suppliers on future demand of commodities for manufacturing, procurement and logistics management decisions

Accurate quantification of pharmaceutical requirements is essential for good procurement, efficient stock management and rational use of medicines.

Accurate quantification can be difficult if there is a lack of reliable data, weak coordination among stakeholders and lack of role definitions, shortage of information on system capacities, and limited ability to update and monitor forecasts and supply plans.

**Quantification Encompasses Forecasting and Supply Planning.**

**Forecasting** is the process of estimating the quantities and costs of products required to meet demand in a particular time frame. It uses consumption, service, demographic and morbidity data, including assumptions on programmatic scale-up, service capacity and related factors for estimating the requirements.

**Supply planning** is the process of determining which health products should be procured, the amount to be procured, the time at which they should be delivered, and the financial costs to be incurred. It uses forecasted quantities; stock on hand, stock on order, lead times, expiry dates, freight and logistics costs, unit costs, minimum and maximum stock levels to estimate the requirements. These plans are part of continuous process used to inform high-level decision making on health products financing, procurement and logistics.
**Forecasting**

Accurate and timely forecasts are critical to the timely provision of the Zithromax® donation that ITI receives from Pfizer Inc. Forecasts are requested from country programs more than 12 months in advance due to the planning, production, and shipping time necessary to meet the annual need for Zithromax®. A five year forecast is required by Pfizer to assess the manufacturing scale-up necessary to attain the elimination of blinding trachoma by the year 2020.

The challenge in NTDDs forecasting of needs which is based on mapping endemic areas for each of the diseases. Another factor in forecasting for determining the prevalence to determine the number of persons eligible for mass drug administration. Once mapping and the determination of which NTDDs will be needed for each district is completed, calculation of the number of at risk populations to target must be calculated under the guidance of national strategic plan of action using demographic information to determine the quantity of NTDDs needed. The current stock in local storage (non-expired, good quality) must be subtracted from the total amount of NTDDs needed to calculate the amount of each drug needed.

**Procurement**

Acquisition of NTDDs is primarily based on philanthropic donations by pharmaceutical companies. NTDs affect the poorest of the poor mostly in sub-Saharan African countries whose financial ability to treat the diseases is limited. Managing NTDs has been a challenge for many years until efforts by few philanthropic organizations and manufacturers came together in the mid-1980s to address the challenges. Compounded with the inaccessibility of target population, prevalence of the diseases, difficulty of the mode of delivery, NTDDs are expensive and not commercially profitable for production for sale. Procurement of NTDDs is done through primarily donations and in selected cases through purchases where the drugs are not available as donations.

The donation program follows a special donation application mechanism in which a country or collaborating partner makes the request for the needed quantity based on the prevalence and number of person affected. Subsequent donations are made on a renewal or continuation application process in which the requester will complete a report that shows the quantity received, the number treated the drugs in balance and what the current request is for.

The donation process doesn’t follow the for-sale, commercial product procurement where suppliers’ selection, prequalification, tendering etc. are not applicable to donations. Once donation approval is received the goods are shipped to the consignee that is agreed upon on the application. The clearance is done either by the NTD program, medical store, partner such as WHO with delegation by the MOH. Duty is usually waived as these are donations for humanitarian purposes.
The delays in receiving complete documentation for clearing the products either due to incomplete documents or change in clearing agent including not having a copy sent to a third party to ensure that delay is not encountered.

**Donations**

In 2012, in the largest coordinated effort to date to combat NTDs, 13 pharmaceuticals, the US, UK, UAE governments, the Bill & Melinda Gates Foundation, the World Bank and other global health organizations announced a new, coordinated push to accelerate progress toward eliminating or controlling 10 neglected tropical diseases by the end of the decade.

As part of the partnerships between the WHO, NGO’s NTD pharmaceutical manufacturers and bilateral donor agencies (as described in the London Declaration), all the drugs necessary to complete an integrated MDA are donated to varying degrees to at risk populations. As such the WHO in cooperation with the donation agencies has developed a Joint Request Form for Selected PC Medicines (JRSM) which is designed to assist countries in quantifying the number of tablets of the relevant medicines required to reach the planned target population and districts in a coordinated and integrated manner against multiple diseases during the year for which medicines are requested. The Excel-based tool is designed to assist countries in quantifying the number of tablets of relevant PC medicines required to reach the planned target population and districts for the year of request. Output of the tool is a joint request for PC medicines, which can be printed, signed and submitted to the WHO to request these medicines.

Over the past seven years, the US government has leveraged $6.7 billion in donated medicines since 2006, resulting in the delivery of more than one billion treatments to approximately 468 million people.

<table>
<thead>
<tr>
<th>Company</th>
<th>Commitment</th>
<th>Target(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eisai Co. Ltd.</td>
<td>2.2 billion tablets of Diethylcarbamazine (DEC) for 2013-2018</td>
<td>Lymphatic filariasis</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>Over 3 billion tablets of Albendazole since 1998. 1 billion/year</td>
<td>Lymphatic filariasis and Soil-transmitted helminths</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>50 million tablets of Mebendazole yearly since 2007</td>
<td>Soil-transmitted helminths</td>
</tr>
<tr>
<td>Merck &amp; Co., Inc.</td>
<td>Unlimited supply of Mectizan; Over 2.9 billion tablets donated since 1987</td>
<td>Onchocerciasis and lymphatic filariasis</td>
</tr>
<tr>
<td>Merck KGaA</td>
<td>250 million tablets of praziquantel/year to 2020</td>
<td>Schistosomiasis</td>
</tr>
<tr>
<td>Pfizer, Inc.</td>
<td>Unlimited supply of Zithromax; Over 145 million tablets of azithromycin since 1998</td>
<td>Trachoma</td>
</tr>
</tbody>
</table>

**The Application Process**

Each donor had an application process and this process in the past used to be the preoccupation of the respective NTD programs in the MOH. The application is made using a specific application format that the donor required. This individual application process has its problems as most of the time the applications were not complete or the times were not adhered to.
However the WHO in collaboration with partners, donors and endemic countries has agreed to an integrated electronic application system which harmonizes the practice and makes response efficient.

Donation programs have instituted an annual application process for new country applications as well as countries applying for additional rounds of NTD treatments. This process is designed to assess a country’s NTDD need over a five year horizon.

The application requests information on up-to-date treatment distribution data, in-country inventory, and an update on prevalence data. The data collected in this process allows the donation program to determine the long term NTDD needs in a particular country as well as evaluate the progress towards the elimination of NTDs. Delays in submission of the annual applications and not adhering to annual application timelines could impact the availability of NTDDs to meet in-country requirements.

**Drugs to be Purchased**

Although most of the NTDDs are donated by major pharmaceutical manufacturers, there are few types of products that do not have donors. In such situations countries or partners purchase the NTDDs from suppliers. These purchases are governed by procurement requirements of the country. In many countries, there may be NTDDs needed not covered by the donation programs such as women of child bearing age, preschool-age children, and people at high risk of infection (e.g. fisherman). For the populations, it may be necessary to purchase NTDDs to supplement the donation program for complete coverage of the at risk populations. Depending on the system that individual countries use (open tender, restricted tender, competitive negotiation, and direct procurement) each NTD manager should make sure that the NTDDs procured meet the highest quality possible. This can be achieved in several ways. While most of the NTDs manufacturers and API sources have not yet received WHO Prequalification (only DEC from Eisai), many countries including the USA Food and Drug administration (FDA) and the European Medicine Agency (EMA) as well as many endemic countries that have had previous NTD programs have approved many of the manufactures drugs for use in MDA’s. Each program will need to evaluate the different providers in order to guarantee the highest quality drug at the most reasonable price.

**Distribution**

Distribution of NTDDs differs from regular distribution of essential drugs in that the NTDDs are required for be delivered to selected endemic target sites on a one time scheduled based on the frequency of the MDA which could be once or twice a year. The distribution for essential drugs is either a pull or push system where the requested quantity is distributed/delivered on a regular schedule such as every two months or every quarter or as requested by the recipient based on individual facility need. If products are not available at the central or regional medical store, the facilities purchase the quantity they need from the private sector. In the case of NTDDs the practice to date used to include collection by the district, health center or NGDO supporting a specified target area from the central medical store or NTD program management office for onward MDAs. This mode of distribution is different from the regular essential drug distribution
The NTDD distribution may not coincide with the regular ED schedule. There were times when a CMS had distributed NTDDs in its custody following ED distribution schedule of every two months disrupting the planned MDA.

The primary distribution management goal for NTDs is to maintain high quality pharmaceuticals to the facilities where they are needed prior to MDA, while assuring that resources are being used in the most effective and efficient way. Distribution costs, which include costs related to storage and transportation, represent the bulk of the total cost to running an NTD program. Designing a system for storing and distribution of NTDDs is complex and vital to ensure proper timing and supplies for planned MDAs. Effective pharmaceutical distribution relies on a good system design and good management.

Integrating NTDD distribution with ED distribution through the national medical store is cost effective and efficient if the special need of NTDD distribution is well explained and formal arrangement for MDA based scheduled distribution is made. The CMS may have its own fleet of trucks or third party transporters which can manage for the distribution of NTDDs. This requires that the quantity to be distributed, the destination and the time it is needed must be provided to the CMS well in advance to plan the logistics of transport and delivery. Having a focal NTD person at the CMS will expedite the communication and coordination with NTD programs, partners and local stakeholders.

A well designed and well managed distribution system should—

- Have Central Medical Store (CMS) and other pharmaceutical management related staff need to be oriented/trained in NTDs and NTDDs management

- Have a specific person delegated to manage NTDDs at the national level and liaise with the individual NTD program managers at all levels of the supply chain.

- Maintain an appropriate stock of NTDDs for planned MDA.
  
  o Regional pharmacy personnel need to be involved in NTD drugs management

- All the districts must receive the NTDDs supply in the full quantity required for the MDA at least two to three weeks before the distribution begins.

- Stored at a central location
  
  o If individual NTDDs as stored by different mechanisms then ensure coordination between staff at the different facilities for proper distribution to MDA sites

- Keep NTDDs in good condition throughout the distribution process
  
  o Physical inspection conducted when the NTD medicines transfer from one level to the next
• Minimize NTDD loss by spoilage and expiry
  o The integrity of manufacturer packing should be maintained throughout distribution process while minimizing exposure to light and heat, and maintaining dry conditions

• Maintain accurate inventory records
  o NTD management information system coordinated between all implementers and all levels of the supply chain
  o Update the stock card immediately after receiving and/or issuing drugs from storage

• If drugs are procured by the CMS as part of its regular inventory, proper coordination must be enacted to guarantee that stocks remain adequate following MDA

• Time distribution of NTDDs to the MDA sites at the appropriate times
  o e.g. the CMS distributes NTD medicines to the districts at least one to two months before an MDA exercise on the basis of the distribution plan prepared by NTD program.

• Use available transportation resources as efficiently and effectively as possible
  o Whenever possible use the same transport network used by CMS for other essential medicines to distribute NTD medicines

• Reduce theft and fraud

• Provide information for forecasting future MDA needs

• Return unused NTDDs to central storage facility

• Incorporate a quality assurance program when possible; inspect the cartons for any damaged or expired product.

• At any time, only one carton should be opened to issue bottles at the community level.

**Inventory Control/Physical Inventory**

The purpose of a physical inventory is to reconcile the on hand inventory on the stock card and the physical inventory at the storage facility. When conducting a physical inventory, all products in storage should be counted. No transactions should take place during the counting process. The physical inventory process should be finished as quickly as possible in order to resume normal operation in the storage facility. The following steps should be followed to conduct a complete physical inventory

• Plan a specific date and time for the physical inventory.
• Identify the persons who shall carry out the inventory.
• At least two people should conduct the inventory.
• To avoid a conflict of interest, the person in charge of the inventory should not participate in the counting process, but should be available at the site to show the inventories.

Use

Distribution of NTD Drugs is traditionally undertaken in the context of mass drug administration through a variety of health systems related initiatives (e.g., community outreach services conducted under the auspices of a ministry or department of health – often in collaboration with a ministry or department of education). Increasingly, experience shows that initiatives to distribute NTDDs through school or community based programs affiliated with the education and health system respectively are at nearing their capacity. However, large numbers of people still not being reached for a number of reasons including the need to scale up capacity increased funding for programs, and gains in efficiency and effectiveness of distribution programs.

Mass Drug Administration

Mass Drug Administration is the administration of drugs to entire populations, in order to control, prevent or eliminate common or widespread disease. Recommended dosage for the different NTDDs can be found in greater detail in manuals described in appendix 2. When planning for an MDA Program managers should be aware that trainings are needed before each MDA campaign. As many CHWs/or community leaders are not informed about NTDs and their consequences on health, appropriate training should be undertaken that addresses the benefits of NTD treatment as well as all aspects of organizing and implementing distribution. Training should be tailored to account for whether this is the first time NTDD distribution is being undertaken and whether it is a routine activity using the same staff or new staff. Training may be quite intensive at the start of a new program; however, as NTDD distribution becomes more routine, refresher or even just-in-time on-the-job training may be more appropriate. The training should take place in advance of the MDA so that each team / location has time to complete training and preparations needed for a distribution event. In addition to CHW trainings, creating a public awareness communications strategy will help to maximize turn out at MDAs and will result in the creation of demand throughout the community for initial and ongoing MDA programs.

Mass Drug Administration/Delivery Strategy

Managers should plan NTDDs delivery strategies appropriate for local conditions. A number of approaches may be adopted:
Table 1. Mass Drug Administration Delivery Strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>House-to-house administration</td>
<td>The community-directed distributor (CDD) collects the drug from a designated center and goes from house to house to administer the antibiotic. This approach ensures coverage of all households but is labor intensive, especially in areas where population density is low and household members might not be present during the time of drug distribution.</td>
</tr>
<tr>
<td>School based deworming</td>
<td>School-based deworming is a safe, simple, and cost-effective treatment and education delivery approach. With more schools than clinics, and more teachers than health workers, the existing and extensive education infrastructure provides the most efficient way to reach the highest number of school-age children. With support from the local health system, teachers can administer treatment to large numbers of school-age children with minimal training.</td>
</tr>
<tr>
<td>Child Health Days</td>
<td>Child health weeks are regular events organized to deliver an integrated package of preventive services known to be highly cost-effective for improving child health and survival that are run in conjunction with routine services at health facilities. Child health weeks aim to reach all children under the age of five years at least every six months during a limited time period (i.e., a day, week or month). The package of essential preventive health services is defined by local circumstances and needs and can include vitamin A supplementation, deworming, insecticide-treated bed nets (ITN’s) or other services as deemed appropriate.</td>
</tr>
<tr>
<td>Central point distribution:</td>
<td>Drug distribution points are set up at sites selected to be accessible to the community. CDDs administer the antibiotics to beneficiaries who come to the central point. Supplying drugs and ensuring potable water at a central point involves increased logistics. People wait at a central distribution point to receive the NTDD.</td>
</tr>
</tbody>
</table>
| Administering drugs in special population groups: | • Certain population groups can easily be reached at particular locations: students in schools, patients in hospitals, workers in commercial establishments, major building sites, industries, prison inmates, and displaced persons in refugee camps.  
  • Areas of community aggregation: Market places, bus and railway stations, fairs and festivals, religious gatherings, and other sites where people congregate can also be used to reach the community. |
| Urban distribution:             | If an urban district is found to have a TF rate of greater than 10% in children, MDA can be authorized in that urban area.                                                                                       |
| Community Campaigns             | This approach is usually administered through government and non-government health infrastructure and is based upon massive social mobilization. Examples include bednet and micronutrient campaigns. NTD programs can utilize this method by distributing NTDDs to the district health office, on to health posts, and then through village workers during community gatherings. One successful example of this approach that African Program for Onchocerciasis Control uses community health workers (CHWs) to distribute ivermectin for the treatment of onchocerciasis. |


Pre-MDA, Peri-MDA and Post-MDA Considerations

Prior to a MDA, the program manager needs to be aware of –

- Planning MDA around agricultural/migration patterns
- Planning MDA when schools are not taking exams or on vacation
- Creative ways to increase coverage in addition to the normal MDAs such as integration with EPI campaigns, Child Health Days and other public events which are using community distribution and schools.
- Adequate storage area in a secure, dry cool place and away from direct sunlight for all NTDDs in sufficient quantities for person expected.

When implementing a MDA program managers need to be aware of –

- Program managers should be aware of any other public health intervention that is distributing drugs in the same area and of its timing. This is to minimize the risk of targeted people suffering from adverse reactions due to interactions between drugs distributed by different programs.
- That people who are about to receive drugs are adequately informed about possible adverse reactions and about what they should do in the event of such a reaction.
  - Ensure that care and support are available for individuals who experience adverse reactions.
  - It is important that medical or community health personnel are available throughout the rounds of treatment.
  - Any serious adverse experience should be carefully recorded and the relevant authorities should be informed. An example of a recording form for serious adverse experiences is provided in Appendix 4.
- Scored tablets should be broken into smaller pieces, or crushed, for administration to young children; forcing very small children to swallow large tablets may cause choking or asphyxiation.
- Additional supplies needed at each MDA location include, health cards and tally sheets for recording NTDD administration, training materials for health workers and volunteers and educational materials.
  - Health cards should include patient information, date, and NTDDs administered, and dose (e.g., John Smith, November 5, 2009; Albendazole; 400 mg)
Following a MDA program managers need to be aware of –

- Providing CHWs and staff at all levels of the supply chain clear guidelines on procedures for disposal of pharmaceutical waste products.
  
  o If incineration facilities for appropriate disposal are unavailable, alternate procedures should be developed (e.g. shipping waste back to CMS along with unused medications)
  o Alternatively, some waste such as used bottles (proper guidance of produces should be given) can be washed and used for personal use by CHW

- Returning unused pills to the CMS is critical to guarantee that these returned products are safe and effective as delays may result in prolonged exposure to air/humidity and unsanitary handling. Thus, their use in the next campaign may not be recommendable.

- Timely compilation and sending the Distribution and Inventory reports to the national NTD program by all districts and regions is critical for the development of future NTDD applications to the donors
  
  o Development of a tool/manual for medication register, stock inventory and reporting for NTDs would help expedite this compilation.

**NTD Drugs Information Management System**

Any fully functioning pharmaceutical supply system should include a pharmaceutical management information system (PMIS). Design of a PMIS should be based in the differing information needs of users as each level if the supply chain. PMIS for should be integrated with other data collections systems and computerized whenever possible with the ability to prepare individual NTD reports. A successful PMIS require effective use of information generated which includes –

- Efficient data processing and appropriate use of technology available to share information with different levels of the supply chain.

- Action plans to respond to positive and negative feedback

The PMIS is an organized system for collecting, processing, reporting, and using information for decision making.

Key NTD Management Tools include household registration and treatment register, MDA reporting forms, stock card, transfer card, SAE reporting form, and other forms that the program may find useful such as expiry tracking tool, individual patient passport etc.

Information for each subsystem is collected by means of –
• Record keeping documents such as patient record forms, inventory control cards for recording receipts and issues
  - Actual quantity of NTDDs distributed such as tally sheets making forecast of next round
  - Districts and health centers that are involved in NTD MDAs need to maintain a specific folder for NTD which gives the list of the sub-counties and parishes, number treated in each; the quantity of NTDDs received, the quantity administered, the quantity lost/damaged, what is left on hand and any adverse reaction observed

• Information reporting forms, Stock inventory registers (used medications, left over stock) that are up-to-date, allowing for the estimation of real needs for the next MDAs

• Analytical reports that report back information to the units that collected the data.

Inventory Control /Transaction Records:

Stock Cards Transfer Forms

These two forms will keep track of all the product movements in the distribution channels. All levels should use these two forms to record updated stock and the history of all transactions or adjustments. (i.e., product receiving, issuing, distribution, and physical inventory reconciliation). Records of all the stock cards should be kept for at least 5 years at each location. In efforts to assist countries many organizations have developed tools to assist with this. These include the JRF and TIPAC described below

A Tool for Integrated Planning and Costing

A Tool for Integrated Planning and Costing (TIPAC) is a USAID funded Microsoft Excel–based program that helps users accurately estimate the costs and funding gaps of public health programs. The NTD TIPAC can be used in conjunction with existing national NTD strategic plans and budgets in order to effectively plan and coordinate future program resources. The TIPAC is not a substitute for the strategic process of developing a national plan of action or program budget. However, the tool should strongly align with these documents and can help with resource planning and revising a national plan to meet resource constraints. TIPAC can be utilized to automatically generate the annual work plan.

Reporting

In an effort to consolidate and standardize forms across the World Health Organization regions related to reporting the distribution of NTDDs following an MDA, the WHO developed a Joint Reporting Form (JRF). The purpose also provides national health authorities and data managers with a standardized tool to address these reporting challenges facilitate integration and thereby further contribute to improving overall program management. National authorities are requested to complete this form for submission to the World Health Organization any time before 15 August of the current year for reporting data on PC interventions implemented during the previous year.
CHAPTER 3: PHARMACOVIGILANCE

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of drug-related problems. The goal of Pharmacovigilance is to safeguard public health and improve rational medicines use through efficient and timely collection, assessment and communication of risks and benefits to support local decision making.

Drug safety includes:

- ADRs and Side effects
- Interactions
- Poor drug quality and counterfeit products
- Medication use errors
- Lack of efficacy due to AMR

ADR is noxious and unwanted reaction to drugs that occurs at a dose used in human for diagnosis, treatment or prophylaxis. Many unwanted effects of drugs are medically trivial, and in order to avoid inflating the figures of drug-induced disease, it is convenient to retain the term side-effects for minor effects, which is related to the pharmacological properties of the drug. The term adverse reaction should be considered for harmful or seriously unpleasant effects occurring at doses intended for therapeutic, prophylactic or diagnostic effect and which calls for reduction of dose or withdrawal of the drug and/or forecast hazard from future administration. Reporting ADR is essential to obtain the necessary information on safety of products. It helps to detect adverse reactions, which were not observed on the development phase of a particular drug on population subgroup such as children, pregnant women, the old and patients with complicated disease, which are not normally exposed during the clinical trial. It is also essential for the early detection of unknown reactions and interactions, detection of increase in ADR frequency, identification and quantification of risk factors, detection of counterfeited and substandard drugs in the market.

Women, children, the elderly and patients with chronic illnesses and immune-compromised may be at greater risk of exposure to unsafe medications and drug interactions than other groups. Although millions of doses of anthelmintics have been used since registration of these drugs for human treatment was approved. Each drug has an excellent safety record; adverse reactions are minimal and transient, and serious adverse experiences are extremely infrequent, the use of multiple NTDDs for co-infections make safety of high importance to ensure the desired outcomes are obtained. Multiple assessments of the co-administration of the three drugs (albendazole, ivermectin and praziquantel) indicate that there is no clinically relevant pharmacokinetic interaction between the three drugs when given concurrently as single oral doses in healthy volunteers; no additional adverse reactions are therefore expected as a result of their co-administration in non-infected individuals. In practice, both infected and uninfected people are treated in community programs. Temporary minor reactions following treatment occur mainly in infected people and usually result from the body’s response to the dying of worms: heavily infected people are more likely to experience such reactions. Generally, the
number of people reporting adverse reactions is highest at the first round of treatment and tends
to decrease during subsequent rounds.

However, precautionary measures are recommended to ensure the smooth and safe
implementation of large-scale drug delivery programs including exclusion of seriously ill
individuals, people who previously have had SAE to NTDDs, women in the first trimester of
pregnancy. As praziquantel can exacerbate central nervous system pathology due to
schistosomiasis, paragonimiasis or Taenia solium cysticercosis, as a general rule this drug should
not be administered in large-scale interventions to individuals reporting a history of epilepsy
and/or other signs of potential central nervous system involvement such as subcutaneous nodules
suggestive of cystercosis. Special measures should be taken when ivermectin is used in MDA
interventions in areas where Loa loa is endemic. Finally since azithromycin is a bacterial
antibiotic, special precaution should be taken to help prevent antibiotic resistance from forming

Several studies demonstrated no significant difference has been found in the occurrence of
adverse birth outcomes (abortion, stillbirth, birth defects) between women inadvertently exposed
to praziquantel, ivermectin, or the combination of ivermectin and albendazole (during large-scale
chemotherapy interventions), and women not exposed to the drugs. Very little is currently known
about the effects of DEC on birth outcome; however hundreds of millions of people have been
treated with DEC which suggests the safety of this drug in women inadvertently exposed to it
during pregnancy.

Despite excellent empirical safety profiles, none of the anthelminthic drugs considered in this
manual is licensed for use in pregnancy or in the first trimester of pregnancy; thus there remains
ambiguity about the ethics of exposing women of reproductive age to such drugs. Women have
the right to refuse or delay treatment if they are unsure about pregnancy, and programs must
ensure that treatment is subsequently available to women who choose to exercise this right. In
areas where schistosomiasis and soil-transmitted helminthiasis are endemic, risk–benefit
analyses have revealed that the health advantages of treating women of reproductive age and
pregnant women far outweigh the risks to their health and to the health of their babies The
exclusion of drug combinations involving either DEC or ivermectin in relation to pregnancy is a
necessary precaution in the absence of definitive safety information.

### Adverse Drug Reactions

ADRs are inevitable consequences of pharmacotherapy. It is well known that all drugs carry the
potential to produce both desirable and undesirable effects. No drug is absolutely safe under all
circumstances of use or in all patients and ADRs may occur even if a drug is correctly selected
and dosed.

Countries have adopted a WHO ADR reporting form (also known as the yellow form) for
reporting adverse drug events for all drugs on a regularly basis. Many countries have
pharmacovigilance units that are custodian of such information. Serious ADRs are sent to a
WHO collaborating agency in Upsalla for further follow up and communication with
manufacturers. NTD programs are required to manage and submit SAE’s in forms provided by
the donor pharmaceutical manufacturers as part of the donation application process. However, in many instances these reports are not shared with the pharmacovigilance or other appropriate entity of the MOH. Since SAEs are a concern of the national program as well as the donors, it will only be logical that such reports are made part of the national ADR reporting system without compromising the reporting requirement of the donation programs.

**Serious Adverse Experiences**

A serious adverse experience (SAE) is defined as an adverse experience following treatment with a drug that results in any of the following:

- Death
- Life-threatening condition
- In-patient hospitalization or prolongation of an existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly or birth defect
- Cancer
- Overdose (accidental or intentional)

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in the definition above: Such events should also be reported. Any serious adverse experience should be carefully recorded and the relevant authorities should be informed. An example of a recording form for serious adverse experiences is provided in Appendix 3. The manual “Preventive in human helminthiasis chemotherapy” includes dose recommendations and information on how to deal with contraindications (e.g., pregnancy and Loa Loa regions).

**Quality Assurance**

The purpose of quality assurance (QA) in pharmaceutical supply system is to help ensure that each medicine reaching a patient is safe, effective, and acceptable quality. A compressive QA program includes both technical and managerial activities, spanning the entire supply chain from pharmaceutical selection to use.

Established quality standards are published periodically in pharmacopeias and in some government publications. For purposes of NTD medications, the most important characteristics are identity, purity, and strength, uniformity of dosage, bioavailability, and stability. Pharmaceutical quality is affected by starting materials, manufacturing process, packaging, transportations and storage conditions. A QA program should include training and supervision of staff members at all levels of the supply process and suitable information system.
If a pharmaceutical does not meet the established quality standards, passes expiration date, or has been degraded by improper storage conditions, the possible consequences include

- Lack of therapeutic effect, leading to prolonged illness
- Toxic and adverse reactions
- Waste of limited resources
- Loss of credibility of the health care delivery system

A comprehensive QA program must ensure the following-

- Pharmaceutical suppliers with acceptable quality standards are selected for NTDDs procured outside the donation programs
- Packaging upon delivery to port of entry meets contract and usage requirements
- Transportation and storage conditions do not compromise product quality
- Product quality issues are properly reported to the NTD managers and CMS Pharmacists
- Product recall procedures following MDA are implemented to ensure quality of NTDDs not used

**Monitoring and Evaluation**

Monitoring and evaluation (M&E) drug coverage when the drugs are swallowed by individuals at the point of delivery. Managers must know how many people in need of treatment received the treatment when and where it was offered. Without reliable information about drug coverage program managers and their staff cannot monitor program performance effectively or make estimate of the quantity of NTDDs needed for future MDAs. Working to achieve the objectives of an NTD control, selection of indicators to monitor is critical. Program involving PC requires regular and careful monitoring of drug coverage. Quantitative results from monitoring drug coverage have several important consequences for program managers.

1) Reliable drug coverage contributes to informed decisions and policy formulation for NTD control and future MDAs.

2) Difficulties encountered during rounds of large scale treatments can be revealed, such as the identification of places where fewer people received drugs than intended. Corrective action can then be taken.

3) Providers of drugs and funds to support drug delivery, including the governments of disease-endemic countries, can be assured that their support is cost effective. Confidence in and justification of the program are maintained.
4) Workers and volunteers involved in drug delivery can be informed about their efforts. This is important feedback which can contribute to maintaining staff morale.

5) Compliance is reinforced when target communities learn that high coverage has been achieved.

6) Advocacy for more support for NTD control is strengthened by knowledge that many people in need are getting treatment.

7) Forecasting for drug supplies for future treatment rounds is helped by the best information about drug coverage.
CHAPTER 4. ROLES AND RESPONSIBILITIES OF PERSONNEL INVOLVED IN NTDDS

A range of different entities and personnel with varying levels of expertise and experience, including NTD program managers, national medical warehouse pharmacist, supply chain managers, and community health workers, may be involved in managing forecasting, requisitioning, storage, distribution and administration of NTD medications. Clarifying the individual roles and responsibilities for entities and persons involved in these functions is critical to maximize the effectiveness of the program.

Roles and responsibilities depend on the relevant level of the health care system (national, district, and community level). All personnel involved in distribution, storage and administration of NTD medications (e.g. health professionals including supply chain workers, CHW, and teachers) should work in conformity with the national strategic plan and in conjunction with the National NTD Program. Another key aspect of the overall approach to the national NTD control and elimination program is that routine NTD reporting by the personnel involved in MDAs should always be part of the NTD drugs supply chain management system. This means notifying NTD program managers, the number of people treated, Adverse Events/Serious Adverse Events, and number of left over medications from the MDA.

Below is a list of key roles and responsibilities at the varying levels for the supply chain system. While the list is not exhaustive, it highlights what each level of the supply chain must do to guarantee effective and efficient treatment for NTDs.

National Level

Role of the NTD Program Coordinator

- In collaboration with implementing partners and stakeholders, formulates operational strategies and plans of actions, develop technical guidelines/protocols and coordinate and monitor MDAs (which include school based and community based approaches) in the country., Coordinates and oversees the operations of the different NTD program managers

- Oversees the selection, procurement and distribution of the NTD medications

- In conjunction with PMs and other relevant partners, reviews donation applications and submits application for donations

- Ensures good coordination among the donation organization, procurer, supplier, program, and consignee to prevent delays in clearance that can result in costly demurrage fees.

- Reports yearly on progress in NTD distribution and left over medications
Chapter 4. Roles and Responsibilities of Personnel Involved in NTDDs

- Has overall responsibility reporting to the National Medicines Safety Monitoring Program (Pharmacovigilance Unit) and donation program on SAEs.

- Coordinates with the National Pharmacovigilance Unit for comprehensive analysis of SAE reports and follow-on actions

- Provides feed-back any relevant information on SAE outcomes to the district/community levels for awareness building purposes

- Delegates to and coordinates with the national medical store on all MTD drugs supply chain related functions including the return of unused medication to the CMS

**Role of the Central Medical Store (CMS)**

- The Central Medical Stores (CMS) is responsible for NTDD storage at central level (and regional level if it has branches), stock control and distribution to operational districts

- Distribute NTDDs based on distribution plan (schedule, target sites, quantities etc.) provided by the NTD program to ensure MDAs are conducted as planned

- Follows on donation applications, tracks shipments, receives all necessary documents for clearance etc., clears customs, warehouses appropriately, distributes to approve entities expeditiously, and receives unused NTDDs after MDAs and reports quarterly to NTD program on stock status.

- Assign a focal NTD person who will be responsible for communicating with NTD programs and respond to questions related to NTDDs stock status.

**District and Community Levels**

**Role of the District Health Office**

- Provide leadership, ownership, guidance and coordination for all NTD related activities and entities in the district

- Plan the advance receipt of NTDDs; train all involved in MDAs using the national MDA guideline; mobilize necessary resources; schedule MDAs so that they are conducted in the shortest time possible; ensure all NTD records and reporting forms are delivered to each site in advance; ensure data is collected immediately after MDAs, collated, analyzed, validated; reports (including any SAE reports) submitted on time to the higher level; and unused NTDDs transferred to CMS promptly.
Supply Chain Management Manual for Neglected Tropical Diseases Health Managers

- Monitor and supervise MDA activities including checking the recording and reporting of the number of people receiving NTDDs during MDA and for providing feedback to health center staff and national NTD program officer about MDA coverage.

- Through its NTD focal point person (usually the NTD program coordinator) ensure cascaded planning, coordinating with implementing organization, and reporting MDA activities in their respective district.

- Assign the district pharmacist to be the focal person for the custody, distribution of requested NTDDs and reporting on stock movement to and from to health centers/schools.

- Health center staffs are responsible for recording the number of people receiving NTDDs on the outreach tally sheets, transferring the data from the tally sheet and sending tally sheets to district level supervisor.

**Role of the Community Distributors**

The participation of the community from the start of the planning phase is a key factor in the success of the control program. Communities are critical to the success of MDAs and ensure the necessary logistic support, provide additional practical information and help to underpin the long-term sustainability of the program. Representatives of schools (teachers), community (parents, community leaders) and government should be informed as early as possible about:

- the epidemiological situation of NTDs in the area;
- the health risks posed by the infections;
- the likely benefits of the control program.

Information should be provided to the community in a simple and clear style. Any percentages and prevalence must be presented in practical terms (for example, rather than saying that “there is 80% prevalence” it is preferable to say “in a class of 50 children, 40 are infected”) and preferably in the local language(s). If the modalities of the intervention (for example, administration of drugs, provision of health education to achieve behavioral change) and its short-term and long term objectives (for example, improved health status, better performance in school) are fully explained at the outset, there will usually be strong family and community support for the program.

Community distributors (e.g. community health workers-CHWs, community-based distributors-CBDs, health extension workers-HEWs, village health volunteers etc.) and school distribution personnel are responsible to:

- administer NTD drugs for the specific NTD according to the guideline making sure that the right dose is given to the right patient making sure special precautions are taken for special groups such as pregnant women, under five year olds, the elderly and patients with other conditions
Chapter 4. Roles and Responsibilities of Personnel Involved in NTDDs

- record the names and the NTDDs taken and the dosage;
- provide health education about the importance of the NTDDs and proper hygiene and sanitation to prevent reinfection,
- mobilize the community during outreach activities and supporting health center staff to identify people who did not attend the outreach session,
- report serious adverse events to supervisor;
- return unused/damaged medication to the supervisor and follow guidelines provided by the program on the disposal/reuse of empty containers.

**Role of Nongovernment Organizations**

NGOs have played a key role in supporting NTD programs in organizing MDAs, training, financing, NTDDs logistics and reporting. These experiences can be further continued by focusing on providing capacity building to national NTD programs and districts as a means of instilling ownership and sustainability. NGOs can play a role in providing technical assistance and resources at NTD program management level, at districts and during MDAs by participating in planning, training, logistics, expediting reporting and helping in reverse distributions.

**Role of Donors/Donation Program**

Key to the success of NTD programs is the availability of the required medicines. Philanthropic pharmaceutical companies, global agencies and other philanthropies such as WHO, the Gates & Melinda Foundation, USAID, DFID, the Carter Center etc. have made immense advocacy material and financial contributions to see that NTDs are controlled/eliminated by the year 2020. Donation programs role can include:

- Timely review and approval of donations
- Advance submission of necessary documents (such as invoices, quality assurance reports, etc.) to the NTD program with copies to the CMS to track shipments and avoid delays in clearing customs.
- Ensure adequate shelf life of products remaining by taking shipping time, customs clearance and delivery to MDA sites into consideration.
- Consider NTDDs packaging which contribute to ease of administration, hygiene and sanitation during MDA, and inventory control (e.g. bulk tablets in bottles vs strip packing)
ANNEX A. DISEASE SPECIFIC GOALS, TREATMENT REGIMEN, AND TARGET POPULATION

Trachoma

**Endemic areas** - District-wide distribution of antibiotics should be added in any district with prevalence of TF higher than 10%. The F and E components should be put in place whenever TF prevalence exceeds the 5% mark in children aged 1-9 years. In addition, surgery programs should be put in place when district TT prevalence exceeds 0.1%.

**Target population** – If the baseline district prevalence of TF in 1–9-year-old children is 10% or greater, antibiotic treatment of all residents should be undertaken annually for 3 years.

**Treatment regimen** - Azithromycin can be taken orally in tablets (or liquid for infants), and one dose per year will treat active trachoma (20 mg/kg in children; 1 g in adults) Alternatively, topical tetracycline eye ointment applied to the eyes every day for six weeks will treat active trachoma. Children under 6 months of age should apply Tetracycline eye ointment twice daily for 6 weeks. The only contraindications to the use of Azithromycin/tetracycline are being too ill to be measured or a history of previous serious adverse reaction.

Lymphatic Filariasis

**Endemic area** - Implementation unit where the average resident population, or any subunit of population, has an antigenaemia or microfilaraemia positivity rate equal to or greater than 1%.

**Target population** - (LF target population = eligible population) The population in an implementation unit that is targeted for treatment. For LF, the target population is the same as the eligible population, that is, those individuals who are eligible to receive the drugs, based on the criteria for drug safety, and is usually 85–90% of the total population.

**Treatment regimen** - Once yearly treatment with single doses of two medicines administered together: Albendazole (400 mg) plus either Ivermectin (150–200 mcg/kg) or DEC (6 mg/kg) for 4–6 years.

Where co-administration of DEC plus Albendazole is used as the MDA regimen, pregnant women, children aged under 2 years and the severely ill should be excluded from MDA.

Where co-administration of Ivermectin plus Albendazole is used, pregnant women, lactating women in the first week after birth, children measuring less than 90 cm in height and the severely ill should be excluded from MDA.

IVM+ALB in loiasis-endemic areas. -Special measures should be taken when ivermectin is used and in combination with albendazole in MDA interventions against lymphatic filariasis in areas where Loa loa is endemic.
Annex A. Disease Specific Goals, Treatment Regimen, and Target Population

**Schistosomiasis**

**Endemic Areas**

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence among school-aged children</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk community</td>
<td>−50% by parasitological methods (intestinal and urinary schistosomiasis) or −30% by questionnaire for visible haematuria (urinary schistosomiasis)</td>
</tr>
<tr>
<td>Moderate-risk community</td>
<td>−10% but &lt;50% by parasitological methods (intestinal and urinary schistosomiasis) or &lt;30% by questionnaire for visible haematuria (urinary schistosomiasis)</td>
</tr>
<tr>
<td>Low-risk community</td>
<td>&lt;10% by parasitological methods (intestinal and urinary schistosomiasis)</td>
</tr>
</tbody>
</table>

**Target Population**

**Eligible population for PZQ**

- School-age children.
- Adults considered being at risk, from special groups (pregnant and lactating women; groups with occupations involving contact with infested water, such as fishermen, farmers, irrigation workers, or women in their domestic tasks) to entire communities living in endemic areas.

**Ineligible population for PZQ**

There is no documented information on the safety of PZQ for children under 4 years of age (or under 94 cm in height). These children should therefore be excluded from mass treatment but can be treated on an individual basis by medical personnel.

**Treatment regimen** - Frequency of implementation

Once or twice a year for ALB or MBD. The frequency of PZQ varies according to the risk of SCH: PZQ treatment should take place once a year in high-risk communities, once every 2 years in moderate-risk communities, and twice during the period of primary schooling age in low-risk communities.
### Table 2: Recommended treatment strategy for schistosomiasis in preventive chemotherapy

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence of any</th>
<th>Treat</th>
<th>Also treat</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk community</td>
<td>-50%</td>
<td>all school-age children (enrolled and not enrolled) twice each year²</td>
<td>• preschool children;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• women of childbearing age, including pregnant women in the 2nd and 3rd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>trimesters and lactating women;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• adults at high risk in certain occupations (e.g. tea-pickers and miners)</td>
</tr>
<tr>
<td>Low-risk community</td>
<td>-20% and &lt;50%</td>
<td>all school-age children (enrolled and not enrolled) once each year</td>
<td>preschool children;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• women of childbearing age, including pregnant women in the 2nd and 3rd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>trimesters and lactating women;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• adults at high risk in certain occupations (e.g. tea-pickers and miners)</td>
</tr>
</tbody>
</table>

### Table A2.1 Recommended treatment strategy for STH in preventive chemotherapy¹

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence among school-aged children</th>
<th>Treat</th>
<th>Also treat</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk community</td>
<td>-50% by parasitological methods (intestinal and urinary schistosomiasis) or -30% by questionnaire for visible haematuria (urinary schistosomiasis)</td>
<td>all school-age children (enrolled and not enrolled) once a year</td>
<td>adults considered to be at risk (from special groups to entire communities living in endemic areas; see Annex 6 for details on special groups)</td>
</tr>
<tr>
<td>Moderate-risk community</td>
<td>-10% but &lt;50% by parasitological methods (intestinal and urinary schistosomiasis) or &lt;30% by questionnaire for visible haematuria (urinary schistosomiasis)</td>
<td>all school-age children (enrolled and not enrolled) once every 2 years</td>
<td>adults considered to be at risk (special risk groups only; see Annex 6 for details on special groups)</td>
</tr>
<tr>
<td>Low-risk community</td>
<td>&lt;10% by parasitological methods (intestinal and urinary schistosomiasis)</td>
<td>all school-age children (enrolled and not enrolled) twice during their primary schooling age (e.g. once on entry and once on exit)</td>
<td>Praziquantel should be available in dispensaries and clinics for treatment of suspected cases</td>
</tr>
</tbody>
</table>

### Soil Transmitted Helminths

#### Endemic Areas

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence of any STH among school-age children</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk Community</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Moderate-risk community</td>
<td>&gt;20% and &lt;50%</td>
</tr>
<tr>
<td>Low-risk Community</td>
<td>&lt;20%</td>
</tr>
</tbody>
</table>
**Target Populations**

- Preschool children
- School-age children
- Women of reproductive age (including pregnant women in the second and third trimesters and lactating women)
- Adults working in occupations where STH risk may be high (eg. tea-pickers, miners, etc.)

**Treatment regimen**

The strategy for the control of morbidity due to STH that is currently recommended by WHO is the periodic administration of anthelminthic medicines (mainly single-dose 400mg albendazole or 500mg mebendazole) to at-risk populations:

The recommended frequency of treatment is once or twice a year, determined by the initial prevalence of infection among school-age children. The aim is to reduce and maintain low the intensity of infection and thus protect at risk individuals from morbidity due to STH.

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence of any STH among school-age children</th>
<th>Frequency of mass treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk Community</td>
<td>≥50%</td>
<td>Twice a year</td>
</tr>
<tr>
<td>Moderate-risk community</td>
<td>&gt;20% and &lt;50%</td>
<td>Once a year</td>
</tr>
<tr>
<td>Low-risk Community</td>
<td>&lt;20%</td>
<td>None (case-by-case treatment)</td>
</tr>
</tbody>
</table>

**Onchocerciasis**

**Endemic area** – Onchocerciasis is considered an important public health problem when the prevalence of microfilaria in the skin exceeds 40% of the total population of a community, or when the Community Microfilarial Load (CMFL; a measure of the intensity of the infection in the community) exceeds 5 microfilariae per skin snip (mf/s).

**Target Population** - Eligible population - The entire population in meso- and hyperendemic communities (prevalence of infection –40% or prevalence of palpable nodules –20%), except those excluded (see ineligible population). Ineligible population - Pregnant women, lactating women in the first week after birth, children <90 cm in height (approximately equivalent to 15 kg/body weight), and the severely ill.

**Treatment Regimen** - Frequency of implementation - Repeated at yearly intervals (standard option); in some countries, the national plan recommends administration of IVM at 6-monthly intervals. IVM dosage according to tablet height pole.

IVM in loiasis-endemic areas - Special measures should be taken when ivermectin alone is used in MDA interventions against onchocerciasis in areas where Loa loa is endemic.
### Summary of Drug Treatment Regimens for PCT ready NTDs

<table>
<thead>
<tr>
<th>Disease</th>
<th>Drugs and dosages</th>
<th>Threshold for implementation of preventive chemotherapy interventions b</th>
<th>Frequency of Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphatic filariasis (in countries where onchocerciasis is co-endemic)</td>
<td>IVM according to height (using IVM tablet-pole) plus ALB 400 mg</td>
<td>Prevalence of infection –1%</td>
<td>Once a year</td>
</tr>
<tr>
<td>Lymphatic filariasis (in countries where onchocerciasis is not co-endemic)</td>
<td>DEC 6 mg/kg (using age as criterion for dose) plus ALB 400 mg</td>
<td>Prevalence of infection – 40% or prevalence of palpable nodules – 20%</td>
<td></td>
</tr>
<tr>
<td>Onchocerciasis</td>
<td>IVM according to height (using IVM tablet-pole)</td>
<td>Prevalence of infection – 40% or prevalence of palpable nodules – 20%</td>
<td></td>
</tr>
<tr>
<td>Schistosomiasis</td>
<td>PZQ 40 mg/kg (using PZQ tablet-pole)</td>
<td>Presence of infection</td>
<td>According to prevalence of infection</td>
</tr>
<tr>
<td>Soil-transmitted helminthiasis (ascariasis, trichuriasis, hookworm disease)</td>
<td>ALB 400 mg or MBD 500 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Active trachoma (TF) prevalence &gt; 5% in 1–9 years old at district level&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Once a year</td>
</tr>
<tr>
<td>Trachoma</td>
<td>Azithromycin 20 mg/kg (using tablet-pole) max 1 g in adults</td>
<td>Active trachoma (TF) prevalence &gt; 5% in 1–9 years old at district level&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Once a year</td>
</tr>
</tbody>
</table>

<sup>a</sup> LEV 2.5 mg/kg or PYR 10 mg/kg is useful where trichuriasis does not pose a significant problem.
<sup>b</sup> For details, see Annex 6.
<sup>c</sup> TF >10% at district level: district-wide mass treatment. If TF <5% at district level, some communities might still require community wide treatment.

### Special instructions for dosage of children

#### Different age groups and special risk groups in preventive chemotherapy

The following sections offer guidance on preventive chemotherapy for different age groups and special risk groups. The dosages apply to large-scale treatment programs without diagnosis.

#### Preschool children (aged 1–5 years)

- ALB 200 mg for children aged 12–23 months
- 400 mg for children aged 2–5 years
- MBD 500 mg for children aged –1 year
- PZQ according to height for children aged –4 years or –94 cm (refer to PZQ dose pole, designed to deliver a dose of at least 40mg/kg)
- IVM according to height for children –15 kg or –90 cm (refer to IVM dose pole)
- DEC1 6mg/kg for children aged –2 years standard dose for children aged 2 to 5 years 100 mg
School-age children (aged 6–15 years) and adults (aged >15 years)

- ALB 400 mg
- MBD 500 mg
- PZQ according to height starting from –94 cm (refer to PZQ dose pole)
- IVM according to height starting from a weight –15 kg or a height –90 cm (refer to IVM dose pole)
- DEC 16mg/kg standard dose for school-age children 200 mg (59) standard dose for adults 300 mg
ANNEX B. SUPPLY CHAIN MANAGEMENT RELATED GUIDES AND MANUALS

General Pharmaceutical Management: Selection, Procurement, Distribution, and Use

- Preventive Chemotherapy in human helminthiasis. WHO 2006
- Zithromax in the Elimination of Blinding Trachoma: A Program Manager's Guide. ITI 2010
  - Management of APOC funds by the national onchocerciasis task forces (NOTFs): financial and administrative procedures. APOC 2004
  - Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis (in countries where onchocerciasis is co-endemic). WHO 2000
  - Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis (in countries where onchocerciasis is not co-endemic). WHO 2000

Selection

- The NTD Mapping Tool
  - WHO Trachoma Grading Card, WHO
  - Guidelines for Rapid Assessment for Blinding Trachoma, WHO. 2000
  - Final Assessment of Trichiasis Surgeons, WHO. 2005
  - Sampling for Loa Loa and Mapping Disease Endemicity WHO 2002
  - Guidelines For The Evaluation of Soil-Transmitted Helminthiasis and Schistosomiasis at Community Level. WHO 1998
  - Bench Aids for the diagnosis of intestinal parasites (2012 version with corrections)

Procurement

- WHO Joint Request Form
- Zithromax in the Elimination of Blinding Trachoma: A Program Manager's Guide. ITI 2010
- Applying for Zithromax from the Pfizer through the International Trachoma Initiative

Distribution

- Zithromax in the Elimination of Blinding Trachoma: A Program Manager's Guide. ITI 2010
Annex B. Supply Chain Management Related Guides and Manuals

- NTD Logistics Management SOPs. END in Africa, FHI360, USAID. 2013
- Guidelines for the Storage of Essential Medicines and Other Health Commodities. WHO. 2003

Use

- Preventive Chemotherapy in Human Helminthiasis. WHO 2006
- Zithromax in the Elimination of Blinding Trachoma: A Program Manager's Guide. ITI 2010
  - Implementing the SAFE Strategy for Trachoma Control. TCC 2006
  - Trachoma Epidemiologic Survey Protocol WHO. 1993
  - The SAFE Strategy for Trachoma Control. WHO 2000
  - Curriculum and training module on the community-directed intervention (CDI) strategy for faculties of medicine and health sciences (2nd edition). APOC. 2012
  - Community-directed treatment with ivermectin (CDTI): a practical guide for trainers of community-directed distributors. APOC. 1998
  - Helminth Control in School Age Children. WHO 2011
  - How to deworm School Age Children, Instructions for Teachers. WHO 2011
  - How to add deworming to Vitamin A distribution. WHO 2004
  - Lymphatic filariasis: managing morbidity and preventing disability. An aide-mémoire for national programme managers. WHO 2013
  - Health education materials: Intestinal Worms

Annual Work Plan

- WHO Annual Work Plan
  - The conceptual and operational framework of onchocerciasis elimination with ivermectin treatment. APOC. 2010
  - Guidelines for developing a CDTI sustainability plan for 3rd year projects. APOC. 2004
  - Guidelines for developing a CDTI sustainability plan for 5th year projects. APOC. 2004
  - Soil-transmitted helminthiases: eliminating soil-transmitted helminthiases as a public health problem in children:
Supply Chain Management Manual for Neglected Tropical Diseases Health Managers

- Guidelines for development of national plan and project proposal for sustainable community-directed treatment with ivermectin (CDTI). APOC. 1999
- Sample Approved Country Work Plans

NTD Drugs Information Management System

- A Tool for Integrated Planning and Costing, RTI, USAID, 2013
- Joint Reporting Form

  - Guidelines for writing an annual technical report of CDTI project to be submitted to Technical Consultative Committee (TCC). APOC 2004
  - Guidelines for writing an annual technical report of NOTF secretariat to be submitted to Technical Consultative Committee (TCC). APOC 2004

Quality Assurance

- Chapter 19: Managing Procurement; in the MDS-3: Quality Assurance
- Assessing the efficacy of anthelminthic drugs against schistosomiasis and soil-transmitted helminthiases. WHO 2013

ADRs

- Assuring Safety of Preventive Chemotherapy Interventions for the Control of Neglected Tropical Diseases

M&E

- Monitoring drug coverage for Preventive Chemotherapy. WHO 2010
  - Monitoring And Epidemiological Assessment of MDA for LF. WHO 2011
  - Community self-monitoring of ivermectin treatment: a facilitator’s guide. APOC
  - Guidelines for conducting an evaluation of the sustainability of CDTI projects. APOC 2004
  - Independent participatory monitoring of CDTI projects: guidelines and instruments. APOC 2002
  - Guidelines For The Evaluation of Soil-Transmitted Helminthiasis and Schistosomiasis at Community Level. WHO 1998
ANNEX C. SAMPLE ADVERSE EVENT FORMS

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Date of birth</th>
<th>Sex</th>
<th>Weight</th>
<th>Height</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Information on suspected drug(s)/medication:**
- Brand name (if applicable)
- Generic name (if applicable)
- Prescription number
- Dosage form, route, frequency
- Date of reaction
- Date of onset
- Date of resolution
- Duration of reaction
- Treatment

**Adverse drug event description (include all available laboratory test results):**

- **Reaction onset:**
  - Discontinued drug: YES/NO
  - Reaction occurred after discontinuation of drug: YES/NO
  - Reaction occurred after discontinuation of suspected drug: YES/NO

- **Treatment of reaction:**

- **Outcome:**
  - Died due to adverse event: YES/NO
  - Recovered with sequelae: YES/NO

- **Follow-up:**
  - None: YES/NO
  - Follow-up: YES/NO

**Reported by:**
- Name:
- Profession:
- Email address:
- Telephone:
- Name of health institution:
- Date:

**Contact information:**
- National Drug Surveillance Unit
- P.O. Box 5030
- Tel: 251/111-123456
- Email: drug.surveillance@health.gov.et

**Additional information:**
- Local and international contacts
- Relevant medical history
- Other medications

**Documentation:**
- Laboratory test results
- Medical records

**Follow-up:**
- Future monitoring
- Long-term treatment

**Conclusion:**
- Final diagnosis
- Long-term prognosis

**Reporting:**
- Mandatory reporting
- Periodic reporting

**Follow-up:**
- Medical follow-up
- Legal action