INTEGRATING NATIONAL PROGRAMMES TO ELIMINATE LYMPHATIC FILARIASIS AND ONCHOCERCIASIS

STRATEGIC AND TECHNICAL ADVISORY GROUP FOR NEGLECTED TROPICAL DISEASES
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Integrating national programmes to eliminate lymphatic filariasis and onchocerciasis

Strategic and technical advisory group for neglected tropical diseases subgroup on disease-specific indicators

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Abbreviations

APOC  African Programme for Onchocerciasis Control
CDTI  community-directed treatment with ivermectin
EU    evaluation unit
FTS   Filariasis Test Strip (Alere, Scarborough, ME, United States)
GPELF Global Programme to Eliminate Lymphatic Filariasis
ICT   immunochromatographic test (BinaxNOW Filariasis ICT, Alere, Scarborough, ME, United States)
IU    implementation unit
MDA   mass drug administration
OEPA  Onchocerciasis Elimination Program for the Americas
TAS   transmission assessment survey
WHO   World Health Organization
1. Background and opening session

Lymphatic filariasis and onchocerciasis are co-endemic in 28 countries of the World Health Organization (WHO) African Region. Both diseases are targeted for elimination and share the same strategy of preventive chemotherapy to interrupt transmission using ivermectin alone or in combination with albendazole. While many countries are progressively scaling up preventive chemotherapy interventions for either one or both of the diseases, there remain countries that are not on track to meet the elimination targets for each disease. Co-endemicity of loiasis with lymphatic filariasis and/or onchocerciasis is particularly challenging in affected African countries due to the risk of severe adverse events following mass treatment and the observed cross-reactivity of the immunochromatographic test (ICT).

Dr Gautam Biswas, Coordinator, Preventive Chemotherapy and Transmission Control, WHO Department of Control of Neglected Tropical Disease, opened the meeting. Dr Patrick Lammie was elected as the chair and Dr Tony Ukety and Dr Aya Yajima as the rapporteurs. All the invited experts completed a declaration of interests form for WHO experts, which was submitted to and assessed by the WHO Secretariat before the meeting. WHO concluded that all participants could contribute to the discussions of all technical sessions. Annex 1 contains the meeting agenda and Annex 2 the list of participants.

2. Purpose and objectives

Dr Jonathan King explained the need for clear procedures on how best to integrate and coordinate the activities recommended by WHO, including drug distribution, data reporting, and monitoring and evaluation, between lymphatic filariasis and onchocerciasis programmes to accelerate elimination. The specific objectives of the meeting were:

- to define the implementation units (IU) of mass treatment for lymphatic filariasis and onchocerciasis and harmonize the methods of coverage estimation in both programmes to facilitate coordinated and integrated reporting;
- to define the status of co-endemicity of lymphatic filariasis, onchocerciasis and loiasis at the district level and clarify the recommended intervention strategies for each situation;
- to discuss how best to integrate and coordinate drug distribution and reporting of treatment data between the two programmes; and
- to review the progress of operational research and the available evidence supporting integrated surveys and vector surveillance.

3. Harmonizing the interpretation of implementation units, coverage indicators and reporting processes between lymphatic filariasis and onchocerciasis elimination programmes

Mr Honorat Zouré presented the proposed methodology of the African Programme for Onchocerciasis Control (APOC) for revising the boundaries of treatment with ivermectin within the context of elimination and clarified how different reporting indicators are defined in APOC’s annual reporting formats. The original guidance classifies areas as hypo-endemic or non-endemic for onchocerciasis where the prevalence of nodules is less than 20% and mass treatment is not required. The revised methodology considers a nodule prevalence of 5% as a threshold below which it is assumed unlikely that local transmission can sustain itself and thus the area is considered non-endemic for onchocerciasis. It also aims to identify the remaining untreated hypo-endemic areas where local transmission might be sustaining itself.
in the absence of ivermectin treatment (that is, where the prevalence of nodules is equal to or greater than 5%) and thus treatment might be newly initiated.

Dr Yao Sodahlon presented differences and commonalities in definitions of IU, and the intervention goals and strategies of the Global Programme to Eliminate Lymphatic Filariasis (GPELF) and APOC. He questioned whether the IU defined for treatment of onchocerciasis should be changed from communities to districts. Although the methods of mapping both diseases differ, both programmes define an IU as the smallest (or lowest level) administrative unit responsible for implementing mass treatment within which all the eligible population is treated irrespective of individual infection status.

Where the entire population living in a given district is defined as the target population of community-directed treatment with ivermectin (CDTI) by mapping carried out by APOC, changing the IU from communities to districts is feasible. However, in Cameroon and Uganda, such a change would result in significant, unnecessary distribution of ivermectin. Additionally, in areas where lymphatic filariasis and onchocerciasis are co-endemic for loiasis, expanding the IU from communities to districts is considered contraindicated by the Mectizan Expert Committee owing to the risk of severe adverse events occurring in populations infected with *Loa loa* who are naive to treatment with ivermectin.

Mr Alexei Mikhailov summarized the current mechanism of drug application, review and data reporting of preventive chemotherapy medicines to WHO as well as the WHO definitions of the three main coverage indicators: geographical coverage, national coverage, and programme coverage. He presented also an example of a well-integrated, coordinated data reporting form submitted by Burkina Faso for treatment of lymphatic filariasis and onchocerciasis. *Annex 3* lists the definitions of coverage indicators used by APOC and those recommended by WHO to monitor preventive chemotherapy.

### 3.1 Discussion

**Treatment boundaries**

- Where the entire population living in a given district is defined as the population targeted for CDTI by APOC mapping, the district should be defined as the IU. The main concern is defining the IU where onchocerciasis is present only in part of the district. Transmission of onchocercal infection is closely associated with the location of vector breeding sites and the human behaviour of communities in river basin areas; typically, a transmission zone does not correspond with the administrative boundary of a district. Changing the IU from a transmission zone to a district might therefore have resource implications. Where only a part of a district is defined as a transmission zone and preventive chemotherapy is thus required, extending an IU to a district was considered unwarranted and subject to a case-by-case decision.

- Thresholds for treatment decisions should be based on the scientific evidence. Currently, the thresholds proposed for prevalence of nodules and microfilaria are based mostly on the results of modelling in hyper-endemic and meso-endemic settings; data are scant from settings of low endemicity.

- Operational research is ongoing to determine whether a small focal breeding site is indeed capable of sustaining prevalence of local transmission in isolated foci and at the end of transmission zones.

- The group recalled that at the inception of APOC, treatment focused on highly endemic areas in river basin areas because of resource constraints and a control-only

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programme target, whereas the GPELF decided to cover the entire district even if this required more resources to achieve elimination.

**Implementation unit and reporting**

- The group agreed that the population requiring preventive chemotherapy for lymphatic filariasis and onchocerciasis is defined as the ‘total population living in areas where PC is required.’ The definitions of geographical, national and therapeutic (or epidemiological) coverage were agreed between APOC and WHO. The main cause of confusion was the definition of ‘targeted’ population, which is used as a denominator of programme coverage. The ‘targeted’ population should be understood by both programmes as ‘the eligible population targeted by a given PC package’.
- Country representatives urged APOC and WHO to harmonize the reporting tools to reduce the reporting burdens at national level.
- The importance of thorough review of the request for preventive chemotherapy medicines at WHO regional and global levels was emphasized after a point was raised that often national programme managers do not review the data auto-generated by embedded formulas in the Joint Application Package forms before submitting them to WHO; specifically, this was noted as an issue in the Joint Request for Selected Preventive Chemotherapy Medicines and Joint Reporting Form. For onchocerciasis, manual entry of data might be required in some cells (for example, in case the targeted population is villages instead of districts).

4. **Defining the endemicity of lymphatic filariasis, onchocerciasis and loiasis in districts and clarifying intervention strategies**

Dr Jonathan King summarized the treatment strategies recommended in different settings of co-endemicity for lymphatic filariasis, onchocerciasis and loiasis from the following WHO documents and other published literature (see also Annex 4):

- *Provisional strategy for interrupting lymphatic filariasis transmission in loiasis-endemic countries* (WHO, 2012);
- *Meeting of the Neglected Tropical Diseases Strategic and Technical Advisory Group’s Monitoring and Evaluation Subgroup on Disease-specific Indicators* (WHO, 2014);
- *Recommendations for the treatment of Oncho with Mectizan® in areas co-endemic for Oncho and Loiasis* (Mectizan Expert Committee and Technical Consultative Committee, 2004); and

Dr Michel Boussinesq presented the categorization of adverse events following mass treatment for onchocerciasis with ivermectin in areas co-endemic for loiasis, the threshold density of *L. loa* microfilaria before treatment in daytime blood smears and the prevalence of *L. loa* microfilaria at community level above which the risk of adverse events is likely to

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2 WHO defines an adverse event as a medical incident that takes place after a preventive chemotherapy intervention and is suspected to be caused by the medicines used in the intervention. A serious adverse event is defined as any untoward medical occurrence that at any dose results in death, requires hospitalization or prolongation of existing hospital stay, results in persistent or significant disability/incapacity, or is life threatening. (See also: *Assuring the safety of preventive chemotherapy interventions for the control of neglected tropical diseases.* Geneva: World Health Organization; 2011).
The severity of adverse events after treatment with ivermectin correlates with the density of *L. loa* microfilaria in treated individuals. Adverse events following treatment with ivermectin for onchocerciasis occurring in individuals infected with *L. loa* are classified into mild reactions, marked reactions (functional impairment), and serious neurological events (coma and death) that are considered severe (or serious) adverse events. A density of *L. loa* above 30,000 microfilaria/ml is considered to be high risk for serious adverse events after CDTI. A risk of functional impairment occurs when the density of *L. loa* exceeds 8000 microfilaria/ml. However, there is currently no absolute threshold at which there is no risk of marked or serious adverse events.

The Mectizan Expert Committee and the Technical Consultative Committee currently recommends that CDTI should be avoided in areas where the prevalence of *L. loa* microfilaria exceeds 20% or the prevalence of eye-worm history is equal to or greater than 40% at the community level. The density of *L. loa* microfilaria can be assessed using a mobile, phone-based microscope to determine from small quantities of blood which patients to exclude from treatment with ivermectin. Dr Boussinesq raised operational research questions about the cost–effectiveness of various potential test and treat or not-treat strategies in areas endemic for onchocerciasis and loiasis, which would depend on various factors such as the size of the target population, the availability of potential medicines including doxycycline and the frequency of treatment. Research is ongoing to determine whether such technology and test and treat approaches are feasible for implementation in public health programmes.

Annual mass drug administration (MDA) with albendazole alone, preferably twice a year, and integrated vector management, is currently recommended as an alternative treatment strategy to eliminate lymphatic filariasis in areas co-endemic for loiasis. The published results after 12 months (two rounds of MDA) and the unpublished results at 24 months (after four rounds of MDA) were presented from an ongoing study in the Congo. In areas where lymphatic filariasis and loiasis are co-endemic, albendazole administered twice a year was found to be effective in reducing the prevalences of both microfilaria and/or antigen and the density of microfilaria in the target population. Dr Boussinesq also presented data from research studies showing a clear association of ICT-positivity with high loads of *L. loa* microfilaria indicating cross-reactivity of ICT with circulating antigen of *L. loa*, as has been reported elsewhere.

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Dr Maria Rebollo presented an algorithm proposed for helping national programmes to review the status of co-endemicity of lymphatic filariasis, onchocerciasis and loiasis at subnational level and determine which treatment strategies are warranted according to WHO guidelines and other referenced documents. An effort was made to work with APOC to review the status of endemicity by district in all the 10 countries where loiasis is endemic. Where the status of endemicity is unknown, the recommended action would be to complete mapping, or to list possible options for eliminating onchocerciasis in areas with *L. loa*. The intention is to produce a tool for programme managers to enter data on endemicity and generate a report listing the recommended strategy.

4.1 Discussion

- There is no WHO recommendation on treatment strategies using ivermectin to eliminate onchocerciasis in hypo-endemic settings where *L. loa* is present; treatment for low-prevalence onchocercal infection in areas endemic for loiasis requires careful assessment of benefit to harm.
- The participants reinforced the importance of provision of specific training at the field level on identifying and managing serious adverse events in areas endemic for loiasis where CDTI or MDA is being implemented.
- The proposed test and treat strategies are assumed to be resource intensive and need to be validated.
- Applying a community-level prevalence threshold of *L. loa* that minimizes the risk of serious adverse events may be more feasible than test and treat, but may require surveys in every community in which co-endemicity for the diseases is suspected.
- Given the recently identified correlation of ICT-positivity and *L. loa* microfilaraemia, an additional diagnostic is warranted to confirm filarial infection when mapping, monitoring or evaluating infection in areas endemic for loiasis (as discussed during a previous meeting of the Subgroup).\(^{10}\) The available options are limited and include assessment of Wb123 or microfilaria and/or polymerase chain reaction of night blood. Night blood assays detect microfilaria. The Alere Filariasis Test Strip (FTS) is expected to have the same cross-reactivity as the ICT when circulating loads of *L. loa* microfilaraemia are high. The FTS should still be used to evaluate lymphatic filariasis in areas of *L. loa* as a negative test indicates absence of infection. However, additional assays will be needed to confirm positive results for *W. bancrofti*.
- Dr Boussinesq noted that lymphatic filariasis seems to be highly focal in central Africa where loiasis is co-endemic (e.g. Congo and Central African Republic). Dr Moses Bockarie explained that lymphatic filariasis is focal only in those areas where the infection is transmitted by *Anopheles* mosquitoes and thus the GPELF should continue to use districts as the IU for MDA.

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\(^{10}\) Strengthening the assessment of lymphatic filariasis transmission and documenting the achievement of elimination: meeting of the Neglected Tropical Diseases Strategic and Technical Advisory Group’s Monitoring and Evaluation Subgroup on Disease-specific Indicators. Geneva: World Health Organization; 2014.
5. Intervention strategy: single versus semi-annual preventive chemotherapy for onchocerciasis in the context of integration with lymphatic filariasis programmes

Dr Wilma Stolk presented the outcome of mathematical modelling of annual and semi-annual mass treatment to accelerate elimination of lymphatic filariasis and onchocerciasis.

She compared the results of two different modelling approaches to estimate the impact of semi-annual treatment with ivermectin; one using ONCHOSIM the other EpiOncho, the results of which have been published.11,12 Based on these models, 6-monthly treatment with ivermectin for onchocerciasis reduces the duration of the elimination programme by about 35% but increases the number of treatment rounds required for elimination, provided that treatment coverage is sustained. The models indicate that improving coverage alone during annual preventive chemotherapy with ivermectin also decreases the total number of estimated treatment rounds required to interrupt transmission. Twice yearly treatment with improved coverage is therefore a way to reduce duration to elimination. In terms of cost, semi-annual treatment is estimated to increase annual cost of drug distribution by 60% but reduces cost per treatment round by 20%. The benefits of semi-annual versus annual treatment are estimated to be greater in settings where pretreatment prevalence is highest. Semi-annual treatment applied in such settings and late-starting areas may have long-term programmatic cost savings.

The areas Dr Stolk suggested for changing the frequency of treatment from once to twice a year would be those areas with high levels of endemicity or vector competency before control interventions, late starter countries and countries with operational issues (for example, low coverage, atypical response to treatment). The models rely on assumptions around coverage. Systematic non-compliance is assumed to be the critical factor in the overall success of any preventive chemotherapy intervention. The pattern of non-compliance to MDA or CDTI in a population differs by country and could be totally random or systematic. She emphasized that the model assumed that a randomly selected small portion of the population is non-compliant during each round of treatment.

Based on the LYMFASIM model, changing from annual to semi-annual treatment would halve the duration in years required for elimination.13 In contrast to the model simulations for onchocerciasis, the model for lymphatic filariasis suggests that the total number of treatment rounds required to achieve elimination targets with semi-annual MDA remains the same as annual MDA. As a result of the efficiency gain, the total programme cost required to eliminate the disease is expected to be reduced. Dr Stolk suggested areas for changing treatment frequency from once to twice a year as those that have not started MDA or scaled up fully and those with pockets of high prevalence of microfilaria. However, the model needs to be validated against longitudinal data from treatment programmes. Additional data are needed to validate the model.

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5.1 Discussion

- It was noted that Member States are committed to eliminating onchocerciasis and lymphatic filariasis by the target dates in accordance with resolutions of the World Health Assembly and regional committees. Partners and donors have made additional commitments to support programmes achieve elimination by the set target dates.
- The group generally encouraged strategies that would decrease the time required to achieve elimination and would further support meeting elimination of both diseases by the set dates.
- Semi-annual treatment for elimination of onchocerciasis is not a new strategy. The Onchocerciasis Elimination Program for the Americas (OEPA) has regional resolutions to recommend semi-annual treatment for elimination in the WHO Region of the Americas. Eligible populations in countries endemic for the disease in this region have been treated twice or more per year. Onchocerciasis has been eliminated from Colombia, Ecuador, Mexico and likely now Guatemala under these strategies\(^{14,15,16}\). Burkina Faso, Ethiopia, Sudan and Uganda have implemented semi-annual treatment programmatically.
- In Burkina Faso, semi-annual treatment for onchocerciasis and lymphatic filariasis since 2010 in four co-endemic districts of the south-west region has significantly reduced the prevalences of onchocercal and filarial infections. As a result, the country has been exploring the possibility of harmonizing semi-annual treatment between the two programmes in co-endemic areas to accelerate elimination of both diseases.
- In Uganda, semi-annual treatment of onchocerciasis with ivermectin alone and annual deworming against soil-transmitted helminthiases with albendazole alone is ongoing. Adding one more distribution of albendazole to achieve semi-annual treatment for lymphatic filariasis is operationally feasible. In many districts where semi-annual deworming is ongoing, it can serve as an entry point for semi-annual treatment for lymphatic filariasis by adding ivermectin and expanding the target population to adults.
- Expanding distribution of ivermectin has ancillary impacts on other parasitic diseases such as trichuriasis and strongyloidiasis.
- The impact of semi-annual treatment on elimination of onchocerciasis is supported by data from programme practice, as mentioned; however, semi-annual MDA to eliminate lymphatic filariasis with the current two-drug regimen has not been applied broadly or been well-documented.
- The results of LYMFASIM modelling simulation are encouraging. Additional data from ongoing operational research studies conducted under the Bill & Melinda Gates sponsored Death to Onchocerciasis and Lymphatic Filariasis research grant will provide additional information in addition to the reported experience from Burkina Faso.
- A framework to help programme managers is needed to determine the epidemiological and programmatic conditions in which initiating semi-annual treatment would be most beneficial. The group considered that any endorsement from WHO should not limit the use of semi-annual treatment to certain conditions, especially when resources and political commitment were available.
- Vector control is a supplementary strategy to MDA for elimination of lymphatic filariasis. Use of long-lasting insecticidal nets in some settings has enabled programmes to reach elimination targets, demonstrating the positive impact of successful malaria control activities in many countries on transmission of filarial infection.

\(^{16}\) Progress towards eliminating onchocerciasis in the WHO Region of the Americas: verification of elimination of transmission in Mexico. Wkly Epidemiol Rec. 2015;90(43):577–81.
6. Delivery strategies and monitoring treatment coverage

Dr Afework Tekle summarized the history of APOC and the concept of the CDTI strategy. APOC started in 1995 as a partnership among endemic countries, donors, partners (nongovernmental development organizations) and Merck & Co., Inc. to provide sustained, community-level treatment for onchocerciasis.

CDTI was adopted in 1997 as a sustainable drug delivery strategy to allow long-term provision of health services in African countries where health systems were weak. The major principles include community empowerment; integration with and strengthening of the health system at the community level; partnership and coordination at global, national and community levels; and sustainability and flexibility according to local conditions. Monitoring activities include routine annual technical reports, independent participatory monitoring, community self-monitoring and treatment coverage surveys. Evaluation activities include sustainability evaluation, multi-country health impact assessment, epidemiological evaluation and entomological evaluation. Challenges include increasing demand for monetary incentives by community drug distributors, significant workload of community drug distributors, poorly-oriented health workers and reliance on donors for financial support.

Dr Jonathan King highlighted the two key MDA targets of the GPELF, which are 100% geographical coverage and 100% programme coverage in all endemic districts in all endemic countries within a limited timeframe. To achieve these targets, programmes should use any delivery strategy appropriate to local settings that maximizes compliance to MDA as well as geographical scale up. Most of the reasons for low compliance are those that the programme can control, such as not knowing the details of the distribution or the purpose of the MDA. Community involvement improves coverage and is the key concept of CDTI; and is necessary to plan and implement any MDA. Unlike CDTI, it is recommended that MDA for LF should occur as a short, time-limited intervention with distribution to all targeted areas over a few weeks to no more than 2 months. Such a delivery strategy is recommended according to the epidemiology of filarial transmission. The greatest impact will occur if the density of microfilaria among the pool of infected individuals in communities is reduced simultaneously, thereby blocking transmission to mosquitoes across the entire population. If MDA occurs throughout the year, there are likely to always be infected individuals spreading microfilaria to mosquitoes. Dr King referenced the key WHO recommendations on MDA strategies for lymphatic filariasis of relevance for both lymphatic filariasis and onchocerciasis elimination programmes.

Country experiences

Experiences with integrated implementation and monitoring of MDA for lymphatic filariasis and CDTI for onchocerciasis were presented by Dr Square Mkwanba (Malawi) and Mr Windtare Bougna (Burkina Faso).

In Malawi, MDA started with 8 districts in 2008 and scaled up to 26 districts in 2009 through integrated CDTI and MDA, without specific financial support from external partners. Treatment, supervision, advocacy and social mobilization for lymphatic filariasis, onchocerciasis and soil-transmitted helminthiases were fully integrated. Once treatment for all diseases was completed, the programme managers from all the districts were invited to the national programme review meeting. The programme managers who achieved high coverage were given incentives in kind.

References:

and also tasked to assist those with low coverage. The central team conducted supervisory visits in a few randomly selected districts, and organized a meeting on report-writing with all the district coordinators. Malawi has now passed the WHO recommended transmission assessment survey (TAS) in all endemic districts and stopped MDA. The results of epidemiological and entomological evaluations are awaited to determine whether transmission of onchocerciasis has also been interrupted. The programme is a success story for integrated preventive chemotherapy of neglected tropical diseases including delivery strategies and supervision.

Burkina Faso represents another success story. Neglected tropical disease control and elimination programmes that implement preventive chemotherapy are centralized. Preparation of requests for preventive chemotherapy medicines, provision of administrative documents to inform the regions and districts about the treatment period, production of dose polls and information, education and communication materials, transportation of medicines and supplies, advocacy, social mobilization and training were integrated for lymphatic filariasis and onchocerciasis in the co-endemic districts under the umbrella of the national programme. Integrated advocacy meetings were organized in all regions and districts before drug distribution. At the community level, both programmes employed the same personnel to integrate drug distribution, and both programmes shared logistics such as vehicles and motorcycles. However, operational research, and entomological and epidemiological surveys were not integrated.

Burkina Faso has implemented MDA in all districts endemic for lymphatic filariasis and onchocerciasis. In some problem districts, multiple rounds of MDA and CDTI have not reduced prevalences of infection in the community as expected, and semi-annual MDA is being implemented as an alternative strategy to achieve elimination targets in some of these areas. MDA for lymphatic filariasis is scaling down as districts complete TAS. Only one EU (four districts) in a rural area of central region failed TAS; two districts with good pre-TAS results are eligible for TAS but these border districts of very high endemicity at baseline have not yet stopped MDA.

6.1. Discussion

- The group agreed that CDTI is an effective strategy for long-term control of onchocerciasis. However, integration of CDTI with lymphatic filariasis programmes requires that traditional distribution strategies should be programmatically revised towards elimination, specifically after focused, time-limited MDA for the disease while maintaining community engagement during distribution. For the both programmes to maximize their impacts through integration, treatment schedules must be matched to accommodate the timing of any transmission peak of each disease.
- Timing the arrival of medicines in countries should be aligned with the planned treatment schedule too; better planning at national level and coordination at global level for distribution and shipment are essential. The group urged WHO and the pharmaceutical donors to improve coordination to ensure that the required medicines all arrive at the country in time for the drug distribution.
- The country representatives of Burkina Faso and Malawi urged WHO and APOC to harmonize and standardize the data capture tools for both diseases in order to reduce the burden of reporting of national programmes. With the closure of APOC in 2015, all reporting and requesting of medicines should now be done through the WHO Joint Application Package.19
- Currently, the protocols for coverage surveys differ for both diseases; however, new tools are being designed to support integrated monitoring of preventive chemotherapy such as guidelines on assessing the quality of data.

19 http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/en/
The group acknowledged the success of both programmes in Burkina Faso and Malawi, and commended their considerable achievements in terms of the scale of community health systems, health workers and population being reached at community level. It recommended that these achievements should be widely disseminated and recognized globally.

7. Coordinating impact evaluation

Dr Frank Richards presented the challenges of coordinating stop-treatment surveys and post-treatment surveillance between lymphatic filariasis and onchocerciasis programmes in areas where both diseases are co-endemic. He revisited the general concept of elimination when an intervention interrupts transmission and no recrudescence of infection is confirmed after a certain time period in the absence of continued intervention during the post-treatment surveillance phase.

With the interruption of transmission of onchocerciasis, the lifespan of the adult worms is believed to dictate the required duration of intervention once the transmission system is ‘closed’ (that is, annual transmission potential is suppressed to zero through intervention). The evidence suggests that the closed system needs to be maintained for around 14 years with annual treatments and vector control interventions and for more than 6 years even with semi-annual mass treatment using ivermectin until all the adult worms have died. Onchocerciasis programmes maintain more stringent criteria during stop treatment surveys and post-treatment surveillance than lymphatic filariasis programmes. An upper bound of the 95% confidence interval of less than 2% antigen positivity in children aged 6–7 years (n ~ 1700) is considered sufficient during TAS of lymphatic filariasis to stop MDA, whereas an antibody seroprevalence of less than 0.1% Ov16 in children aged under age 10 years is indicated in the new guidelines for the verification of elimination of onchocerciasis (n = 2000).

National onchocerciasis programmes are committed to entomological indices, which are often challenging because of the difficulty in collecting sufficient numbers of flies. Generally, it is more difficult to achieve the criteria to stop treatment for onchocerciasis than for lymphatic filariasis; this often leads to the situation where in a given co-endemic area MDA for lymphatic filariasis using ivermectin and albendazole has stopped but treatment for onchocerciasis with ivermectin alone must be continued (for example, in local government areas in Plateau and Nasarawa States of Nigeria). The opposite scenario occurs in some areas of Uganda. There, the National Onchocerciasis Elimination Expert Advisory Committee has decided to stop semi-annual treatment with ivermectin alone but to continue annual MDA with ivermectin and albendazole. In the Nigerian scenario, and in the absence of clear WHO guidance, the national programme is considering whether to segregate evaluation units (EUs) into co-endemic and non-co-endemic areas for onchocerciasis during TAS of post-treatment surveillance. Post-MDA surveillance TAS (TAS2 and TAS3) would continue in non-co-endemic EUs but be delayed in co-endemic EUs until treatment for onchocerciasis is stopped. In the Ugandan scenario, the national programme has postponed post-treatment surveillance for onchocerciasis until areas co-endemic for lymphatic filariasis pass TAS and MDA is stopped.

Dr Richards concluded that coordinated assessment between both programmes on whether to stop treatment and implement post-treatment surveillance between lymphatic filariasis and onchocerciasis programmes would require harmonization of the target age group and the thresholds for decision-making of the surveys. He also emphasized the need for clear messaging to

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the national programmes about when transmission of lymphatic filariasis is eliminated in the presence of continuing treatment for onchocerciasis.

Dr Vitaliano Cama presented the progress that has been made to assess, validate and develop potential tools for integrated surveys for both diseases, specifically a multiplex bead antibody assay to detect multiple analytes simultaneously in the same sample. The Ov-16 assay has excellent sensitivity and specificity in this format, even when *Wuchereria* infections are present. The Wb123 or other antibody or antigen for lymphatic filariasis could easily be added. Data demonstrating the low sensitivity of skin snips, particularly when microfilarial loads are low, were also presented, as were schematics to indicate the timing of and tools for surveillance of *Onchocerca volvulus*.

Dr Daniel Boakwe presented the updates of operational research on potential methods of vector surveillance to eliminate both diseases. In onchocerciasis programmes, entomological surveillance aims to determine whether transmission is continuing (in order to stop treatment) and where the infection could be reintroduced as vectors migrate (during post-treatment surveillance). Entomological surveillance involves assessment of transmission by screening pools of adult vectors and delineating transmission zones by cytotaxonomy of larvae. Although not recommended by the GPELF, entomological surveillance is a potential tool to measure the presence of infection in communities after MDA has been stopped. However, entomological indicators for lymphatic filariasis remain to be defined. Once indicators are determined, integrated entomological surveillance may be possible where community-based sampling during the high transmission seasons of both targeted vectors is conducted. It should be noted that the transmission characteristics of mosquitoes and flies are different. Transmission is focal near vector breeding sites and, even in co-endemic communities, the vectors of both diseases cannot necessarily be found at the same time. There is also limited information on the major vector species of lymphatic filariasis in affected African countries.

### 7.1. Discussion

- Currently there is no guidance from WHO on the timing of TAS or of epidemiological and entomological surveys for onchocerciasis in areas co-endemic for both diseases where preventive chemotherapy is ongoing for at least one disease.
- Impact surveys should be coordinated. To do so, programmes must accept either to: (i) defer conducting the recommended surveys or continue interventions until both assessments can be done simultaneously; or (ii) conduct the surveys but defer decisions on elimination until assessments can be done at the recommended time after stopping mass treatment for co-endemic diseases.
- The results of ongoing operational research indicate that Ov16 is a more sensitive diagnostic than detection of microfilaria in skin snips in indicating transmission of onchocerciasis, especially in settings after many rounds of mass treatment with ivermectin.
- There is a need to develop a protocol for integrated assessment of Ov16 during TAS.
- There is further need to develop standardized sampling methodologies in xenomonitoring surveys for lymphatic filariasis and standardized interpretation of results before recommending their use in the GPELF.
8. Conclusions

The meeting agreed the following conclusions for consideration and further discussion by the Working Group on Monitoring and Evaluation of the Strategic and Technical Advisory Group on Neglected Tropical Diseases. Many of the conclusions presented here simply reinforce existing guidance to programmes.

8.1. New considerations

8.1.1 Defining an implementation unit

- An IU is defined as the administrative unit in a country that is used as the basis for making decisions about treatment (that is, where MDA is required) as follows:
  - in areas where lymphatic filariasis is endemic the IU is the DISTRICT (or equivalent);
  - in areas where lymphatic filariasis and onchocerciasis are co-endemic the IU is the DISTRICT;
  - in areas where onchocerciasis is endemic the IU is the COMMUNITY.

8.1.2 Harmonizing the interpretation of coverage indicators between lymphatic filariasis and onchocerciasis elimination programmes

- The population requiring preventive chemotherapy for lymphatic filariasis and onchocerciasis is equally defined as the total population living in areas where the intervention is required according to the following treatment thresholds:
  - for lymphatic filariasis, where the prevalence of infection is equal to or greater than 1%;
  - for onchocerciasis, where the prevalence of infection is greater than 0.1% by skin snip or serology.

- The key coverage indicators are defined for both diseases as follows:
  i. Geographical coverage = \[
  \frac{\text{Number of IUs where PC is implemented}}{\text{Total number of IUs where PC is required}}
  \]
  ii. National coverage = \[
  \frac{\text{Number of individuals ingesting the PC medicine for a specific disease in an endemic country}}{\text{Number of individuals at the national level requiring PC for a specific disease in an endemic country}}
  \]
  iii. Therapeutic or epidemiological coverage = \[
  \frac{\text{Number of individuals ingesting the PC medicines at IU level for a specific disease}}{\text{Total population of the IU}}
  \]
  iv. Programme coverage = \[
  \frac{\text{Number of individuals in the target population ingesting the PC medicines in the (designated) endemic area}}{\text{All the individuals targeted for treatment in the (designated) endemic area}}
  \]

The ‘target’ population should be understood by both programmes as the ‘eligible’ population ‘targeted’ by a given package of preventive chemotherapy; for example, school-aged children and adults in countries co-endemic for onchocerciasis (in lymphatic filariasis and onchocerciasis elimination programmes), individuals aged 2 years old or older in countries where onchocerciasis is not co-endemic (in lymphatic filariasis elimination programmes), and preschool-aged children and school-aged children (in school-based soil-transmitted helminthiasis control programmes).
8.1.3 Harmonizing reporting between lymphatic filariasis and onchocerciasis elimination programmes

- WHO and APOC should harmonize the existing data reporting forms to one standardized tool.
- WHO’s Joint Request for Selected Preventive Chemotherapy Medicines and Joint Reporting Form should be adapted to account for the targeted population requiring preventive chemotherapy for different diseases and for the calculations of coverage.

8.1.4 Timing of integrated preventive chemotherapy between lymphatic filariasis and onchocerciasis elimination programmes

- Countries should ensure that each planned round of preventive chemotherapy is distributed. To maximize the impact of the intervention, countries should plan distribution in line with the epidemiology of both diseases and encourage communities to distribute preferably:
  i. as a focused, time-limited distribution within 2 months;
  ii. at a time before the peak transmission seasons.

8.1.5 Eliminating lymphatic filariasis in districts where *Loa loa* is present

- In districts where lymphatic filariasis is endemic, where there is any evidence of *Loa loa* (that is, where RAPLOA exceeds 0%), and MDA has not started, countries should implement district-wide the recommended strategy of preferably twice-yearly treatment with albendazole and coordinated, integrated vector control for lymphatic filariasis. Vector control activities should be incorporated within existing malaria programme efforts.
- In districts where lymphatic filariasis and onchocerciasis are (hypo) co-endemic, where there is any evidence of *Loa loa* and CDTI has not started, countries should implement treatment district-wide with preferably twice-yearly albendazole and coordinated vector control. Vector control activities should be incorporated within existing malaria programme efforts.

8.1.6 Implementing semi-annual preventive chemotherapy to eliminate onchocerciasis

- Where countries are committed to the elimination objective and resources are available, programmes may implement semi-annual preventive chemotherapy with ivermectin to hasten elimination of onchocerciasis. Areas that are not on track to achieve elimination by the target date should be prioritized for semi-annual treatment. Efforts should be made to evaluate and improve programme performance.

8.1.7 Monitoring and evaluation

- Where feasible, national programmes should try to align the timing of impact assessments (TAS and epidemiological or entomological evaluations) to coordinate decisions about stopping treatment. Integrated assessments are possible. However, modified sampling strategies will be needed.
8.2. Reinforcing existing guidance

8.2.1 Distribution strategies

- Programme managers should plan strategies to deliver medicines that are appropriate for local conditions. Communities must be involved in decisions about the timing of distribution at local levels under the guidance of health workers. A number of approaches may be adopted, such as house-to-house distribution, booth distribution and distribution in areas of community gathering.
- The ingestion of the medicine should always be supervised by the person administering it (that is, directly observed therapy).

8.2.2 Training and supervision

- Countries should reinforce supervision of preventive chemotherapy activities to maximize coverage, compliance and reporting.
- Programme capacity and WHO staff are needed at all levels to plan and manage programmes, specifically to ensure that the WHO Joint Application Package is submitted to WHO by the requested due date.

8.2.3 Coordinated support

- Countries, WHO, pharmaceutical companies and donors should improve communication and coordination to ensure timely release of resources and arrival of necessary medicines at national and sub-national levels.

8.2.4 Monitoring and evaluation

- Each programme should continue to follow the recommended disease-specific guidance to determine when to stop MDA and conduct post-treatment surveillance as contained in the following documents:

8.3. Urgent needs for operational research

8.3.1 Onchocerciasis

Operational research is needed to determine:

- the serological threshold at which preventive chemotherapy is warranted in hypo-endemic areas (this will likely require a combination of serology, skin snip and vector data);
- the serological threshold (or data-based adjustment) below which preventive chemotherapy can be stopped in endemic areas;
- the prevalence of Ov16 in children that indicates sustained interruption of transmission;
- the epidemiological threshold that indicates a need for increased frequency of ivermectin to achieve elimination; and
- the most feasible, cost–effective and safe public health strategy for elimination in areas where onchocerciasis is hypo-endemic, loiasis is endemic and the population is naive to ivermectin.
8.3.2 Lymphatic filariasis

Operational research is called for to:

- develop new monitoring and evaluation strategies to evaluate filarial infection after MDA with albendazole only in areas endemic for loiasis (what tools and when);
- model the results of current operational research to determine the number of rounds and frequency of MDA with albendazole alone at 65% coverage required to achieve the elimination targets;
- determine the reasons for and programmatic implications of focal endemicity;
- design cost–effective diagnostic tools to map lymphatic filariasis in districts where loiasis is endemic;
- establish the specificity of Wb123 to measure transmission of lymphatic filariasis in *Loa loa* areas; and
- because entomological evaluation is an essential component of surveillance of onchocerciasis after treatment and a promising tool for indicating infection in the community, the correlation between rates of infection in mosquitoes and prevalence of antigen or antibody in humans and from such, the rate that indicates interruption of transmission.

8.3.3 Integrated needs

For both diseases there is a need to:

- develop a standardized survey protocol to integrate assessments of filarial and onchocercal infections and determine when to stop MDA;
- design an algorithm to determine when modified sampling is needed during a TAS for an integrated impact assessment when the IU for lymphatic filariasis does not overlap completely with that for onchocerciasis (for example, when less than 50% of an IU for lymphatic filariasis is endemic for onchocerciasis);
- assess the acceptability of test and not treat strategies in communities; specifically, to examine the impact on coverage among those found to be eligible and the stigmatization of those who refused treatment;
- design a micro-mapping and micro-treatment strategy for areas where loiasis is co-endemic but RAPLOA is less than 40%.
### Annex 1. Meeting agenda

#### 7 February 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00–09:30</td>
<td>Opening remarks and administrative arrangements</td>
<td>Dr Biswas</td>
</tr>
<tr>
<td></td>
<td>Introductions</td>
<td>Dr King</td>
</tr>
<tr>
<td></td>
<td>Clarification of objectives and process</td>
<td></td>
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<tr>
<td>09:30–10:30</td>
<td><strong>Defining the implementation unit (IU) and reporting</strong></td>
<td></td>
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<tr>
<td></td>
<td>- Delineation of oncho treatment zones and population requiring treatment</td>
<td>Mr Zouré</td>
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<tr>
<td></td>
<td>- Should the IU of oncho be switched to the district?</td>
<td>Dr Sodahlon</td>
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<td></td>
<td>- How should coverage be reported?</td>
<td>Mr Mikhailov</td>
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<tr>
<td>10:30–11:00</td>
<td>Discussion</td>
<td>Chair</td>
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<tr>
<td>11:30–13:00</td>
<td><strong>Defining the landscape “LF, oncho, Loa” endemicity of districts and clarifying intervention strategies</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- District classification and at-risk population</td>
<td>Dr King</td>
</tr>
<tr>
<td></td>
<td>- Elimination in the presence of Loiasis</td>
<td>Dr Boussinesq</td>
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<tr>
<td>14:00–15:00</td>
<td>Discussion and clarified positions on intervention strategies</td>
<td>Chair</td>
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<tr>
<td>15:30–16:30</td>
<td><strong>Intervention strategy</strong></td>
<td>Dr Stolk</td>
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<td>- Single vs twice-yearly preventive chemotherapy for oncho in the context of integration with LF</td>
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<td>16:30–17:30</td>
<td>Discussion</td>
<td>Chair</td>
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#### 8 February 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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</thead>
<tbody>
<tr>
<td>09:00–10:30</td>
<td><strong>Delivery strategies and monitoring treatment coverage</strong></td>
<td>Dr Tekle</td>
</tr>
<tr>
<td></td>
<td>CDTI and MDA: concept and practice</td>
<td>Dr King</td>
</tr>
<tr>
<td></td>
<td>- Malawi experience</td>
<td>Dr Mkwanda</td>
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<td></td>
<td>- Burkina Faso experience</td>
<td>Dr Bougma</td>
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<tr>
<td>11:00–11:30</td>
<td>Discussion</td>
<td>Chair</td>
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<tr>
<td>11:30–12:30</td>
<td><strong>Impact evaluation</strong></td>
<td>Dr Richards</td>
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<tr>
<td></td>
<td>How should national programmes coordinate stop-treatment surveys in co-endemic areas?</td>
<td></td>
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<tr>
<td></td>
<td>Discussion</td>
<td>Chair</td>
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<tr>
<td>13:30–14:30</td>
<td><strong>Impact evaluation (cont)</strong></td>
<td>Dr Cama</td>
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<td></td>
<td>Tools and potential for integrated surveys</td>
<td>Dr Lammie</td>
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<tr>
<td></td>
<td>Can vector surveillance activities be coordinated?</td>
<td>Professor Bockerie</td>
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<tr>
<td></td>
<td></td>
<td>Dr Boakye</td>
</tr>
<tr>
<td>14:30–15:00</td>
<td>Discussion</td>
<td>Chair</td>
</tr>
<tr>
<td>15:30–17:00</td>
<td>Conclusions and Recommendations for the M&amp;E Working-Group of STAG</td>
<td>Chair</td>
</tr>
<tr>
<td>17:00–17:30</td>
<td>Closure of the meeting</td>
<td>Dr Biswas</td>
</tr>
</tbody>
</table>
### Annex 2. List of participants

<table>
<thead>
<tr>
<th>EXPERTS</th>
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</thead>
<tbody>
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### Annex 3. WHO-recommended intervention actions against lymphatic filariasis, and onchocerciasis by co-endemic setting with loiasis

<table>
<thead>
<tr>
<th>Endemic setting</th>
<th>Estimated scope Population (districts)*</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphatic filariasis and loiasis</td>
<td>MDA not started</td>
<td>Administer ALB monotherapy once, preferably twice, a year plus vector control for lymphatic filariasis</td>
</tr>
<tr>
<td>Onchocerciasis and loiasis</td>
<td>CDTI ongoing</td>
<td>Continue CDTI</td>
</tr>
<tr>
<td></td>
<td>CDTI not started</td>
<td>No WHO recommendation. Alternative treatment strategies needed</td>
</tr>
<tr>
<td>Lymphatic filariasis, onchocerciasis and loiasis</td>
<td>MDA/CDTI at district level</td>
<td>Continue MDA/CDTI</td>
</tr>
<tr>
<td></td>
<td>MDA/CDTI at community level</td>
<td>Continue MDA/CDTI, ALB plus vector control in communities naive to IVM; no WHO recommendation for onchocerciasis; alternative treatment strategies for IVM-naive communities</td>
</tr>
<tr>
<td></td>
<td>MDA/CDTI not started</td>
<td>ALB plus vector control for lymphatic filariasis; assess for onchocerciasis and loiasis; no WHO recommendation for onchocerciasis; alternative treatment strategies</td>
</tr>
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</table>

ALB, albendazole; CDTI, community-directed treatment with ivermectin; IVM, ivermectin; MDA, mass drug administration

* According to data on the status of endemicity available to WHO (African Programme for Onchocerciasis Control, WHO Regional Office for Africa, WHO headquarters) as of December 2014.
Annex 4. Definitions of coverage-related indicators and terminology in APOC and WHO guidelines

APOC definitions

(i) **Total population**: the total population living in meso/hyper-endemic communities within the project area (based on REMO and census taking).

(ii) **Eligible population**: calculated as 84% of the total population in meso/hyper-endemic communities in the project area.

(iii) **Annual Treatment Objective** (ATO): the estimated number of persons living in meso/hyper-endemic areas that a CDTI project intends to treat with ivermectin in a given year.

(iv) **Ultimate Treatment Goal** (UTG): calculated as the maximum number of people to be treated annually in meso/hyper-endemic areas within the project area, ultimately to be reached when the project has reached full geographic coverage (normally the project should be expected to reach the UTG at the end of the 3rd year of the project).

(v) **Therapeutic coverage**: number of people treated in a given year over the total population (this should be expressed as a percentage).

(vi) **Geographical coverage**: number of communities treated in a given year over the total number of meso/hyper-endemic communities as identified by REMO in the project area (this should be expressed as a percentage).

---

WHO definitions\textsuperscript{22,23,24}

(i) **Targeted population:** The population (or its sub-set) in eligible age groups that are targeted by a given PC package

### WHO-recommended age groups targeted for PC

<table>
<thead>
<tr>
<th>Neglected tropical disease</th>
<th>Medicine</th>
<th>Pre-SAC (aged 2–5 years)</th>
<th>SAC (aged 5–14 years)</th>
<th>Adults (aged &gt; 15 years)</th>
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</thead>
<tbody>
<tr>
<td>Lymphatic filariasis</td>
<td>DEC + ALB</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>IVM + ALB</td>
<td>X</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Onchocerciasis</td>
<td>IVM</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Soil-transmitted helminthiases</td>
<td>ALB or MBD</td>
<td>X</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Schistosomiasis</td>
<td>PZQ</td>
<td>X</td>
<td>x</td>
<td>X (only at-risk adults)</td>
</tr>
<tr>
<td>Trachoma</td>
<td>AZT</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>

ALB, albendazole; AZT, azithromycin; DEC, diethylcarbamazine; IVM, ivermectin; MBD, mebendazole; PZQ, praziquantel

(ii) **Geographical coverage** = \[
\frac{\text{Number of endemic administrative units where PC is implemented}}{\text{Total number of endemic administrative units where PC is required}}\]

(iii) **National coverage** = \[
\frac{\text{Number of individuals ingesting PC drug for a specific disease in an endemic country}}{\text{Number of individuals at the national level requiring PC for a specific disease in an endemic country}}\]

(iv) **Programme coverage** = \[
\frac{\text{Number of individuals in the target population ingesting the PC drugs in (designated) endemic area}}{\text{All the individuals targeted for treatment in the (designated) endemic area}}\]


Integrating national programmes to eliminate lymphatic filariasis and onchocerciasis

Strategic and technical advisory group for neglected tropical diseases
subgroup on disease-specific indicators

7–8 February 2015
World Health Organization, Geneva
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1. Background and opening session

Lymphatic filariasis and onchocerciasis are co-endemic in 28 countries of the World Health Organization (WHO) African Region. Both diseases are targeted for elimination and share the same strategy of preventive chemotherapy to interrupt transmission using ivermectin alone or in combination with albendazole. While many countries are progressively scaling up preventive chemotherapy interventions for either one or both of the diseases, there remain countries that are not on track to meet the elimination targets for each disease. Co-endemicity of loiasis with lymphatic filariasis and/or onchocerciasis is particularly challenging in affected African countries due to the risk of severe adverse events following mass treatment and the observed cross-reactivity of the immunochromatographic test (ICT).

Dr Gautam Biswas, Coordinator, Preventive Chemotherapy and Transmission Control, WHO Department of Control of Neglected Tropical Disease, opened the meeting. Dr Patrick Lammie was elected as the chair and Dr Tony Ukety and Dr Aya Yajima as the rapporteurs. All the invited experts completed a declaration of interests form for WHO experts, which was submitted to and assessed by the WHO Secretariat before the meeting. WHO concluded that all participants could contribute to the discussions of all technical sessions. Annex 1 contains the meeting agenda and Annex 2 the list of participants.

2. Purpose and objectives

Dr Jonathan King explained the need for clear procedures on how best to integrate and coordinate the activities recommended by WHO, including drug distribution, data reporting, and monitoring and evaluation, between lymphatic filariasis and onchocerciasis programmes to accelerate elimination. The specific objectives of the meeting were:

- to define the implementation units (IU) of mass treatment for lymphatic filariasis and onchocerciasis and harmonize the methods of coverage estimation in both programmes to facilitate coordinated and integrated reporting;
- to define the status of co-endemicity of lymphatic filariasis, onchocerciasis and loiasis at the district level and clarify the recommended intervention strategies for each situation;
- to discuss how best to integrate and coordinate drug distribution and reporting of treatment data between the two programmes; and
- to review the progress of operational research and the available evidence supporting integrated surveys and vector surveillance.

3. Harmonizing the interpretation of implementation units, coverage indicators and reporting processes between lymphatic filariasis and onchocerciasis elimination programmes

Mr Honorat Zouré presented the proposed methodology of the African Programme for Onchocerciasis Control (APOCH) for revising the boundaries of treatment with ivermectin within the context of elimination and clarified how different reporting indicators are defined in APOCH’s annual reporting formats. The original guidance classifies areas as hypo-endemic or non-endemic for onchocerciasis where the prevalence of nodules is less than 20% and mass treatment is not required. The revised methodology considers a nodule prevalence of 5% as a threshold below which it is assumed unlikely that local transmission can sustain itself and thus the area is considered non-endemic for onchocerciasis. It also aims to identify the remaining untreated hypo-endemic areas where local transmission might be sustaining itself.
Dr Yao Sodahlon presented differences and commonalities in definitions of IU, and the intervention goals and strategies of the Global Programme to Eliminate Lymphatic Filariasis (GPELF) and APOC. He questioned whether the IU defined for treatment of onchocerciasis should be changed from communities to districts. Although the methods of mapping both diseases differ, both programmes define an IU as the smallest (or lowest level) administrative unit responsible for implementing mass treatment within which all the eligible population is treated irrespective of individual infection status.

Where the entire population living in a given district is defined as the target population of community-directed treatment with ivermectin (CDTI) by mapping carried out by APOC, changing the IU from communities to districts is feasible. However, in Cameroon and Uganda, such a change would result in significant, unnecessary distribution of ivermectin. Additionally, in areas where lymphatic filariasis and onchocerciasis are co-endemic for loiasis, expanding the IU from communities to districts is considered contraindicated by the Mectizan Expert Committee owing to the risk of severe adverse events occurring in populations infected with *Loa loa* who are naive to treatment with ivermectin.

Mr Alexei Mikhailov summarized the current mechanism of drug application, review and data reporting of preventive chemotherapy medicines to WHO as well as the WHO definitions of the three main coverage indicators: geographical coverage, national coverage, and programme coverage. He presented also an example of a well-integrated, coordinated data reporting form submitted by Burkina Faso for treatment of lymphatic filariasis and onchocerciasis. Annex 3 lists the definitions of coverage indicators used by APOC and those recommended by WHO to monitor preventive chemotherapy.

### 3.1 Discussion

#### Treatment boundaries

- Where the entire population living in a given district is defined as the population targeted for CDTI by APOC mapping, the district should be defined as the IU. The main concern is defining the IU where onchocerciasis is present only in part of the district. Transmission of onchocercal infection is closely associated with the location of vector breeding sites and the human behaviour of communities in river basin areas; typically, a transmission zone does not correspond with the administrative boundary of a district. Changing the IU from a transmission zone to a district might therefore have resource implications. Where only a part of a district is defined as a transmission zone and preventive chemotherapy is thus required, extending an IU to a district was considered unwarranted and subject to a case-by-case decision.

- Thresholds for treatment decisions should be based on the scientific evidence. Currently, the thresholds proposed for prevalence of nodules and microfilaria are based mostly on the results of modelling in hyper-endemic and meso-endemic settings; data are scant from settings of low endemicity.

- Operational research is ongoing to determine whether a small focal breeding site is indeed capable of sustaining prevalence of local transmission in isolated foci and at the end of transmission zones.

- The group recalled that at the inception of APOC, treatment focused on highly endemic areas in river basin areas because of resource constraints and a control-only

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programme target, whereas the GPELF decided to cover the entire district even if this required more resources to achieve elimination.

**Implementation unit and reporting**

- The group agreed that the population requiring preventive chemotherapy for lymphatic filariasis and onchocerciasis is defined as the ‘total population living in areas where PC is required.’ The definitions of geographical, national and therapeutic (or epidemiological) coverage were agreed between APOC and WHO. The main cause of confusion was the definition of ‘targeted’ population, which is used as a denominator of programme coverage. The ‘targeted’ population should be understood by both programmes as ‘the eligible population targeted by a given PC package’.
- Country representatives urged APOC and WHO to harmonize the reporting tools to reduce the reporting burdens at national level.
- The importance of thorough review of the request for preventive chemotherapy medicines at WHO regional and global levels was emphasized after a point was raised that often national programme managers do not review the data auto-generated by embedded formulas in the Joint Application Package forms before submitting them to WHO; specifically, this was noted as an issue in the Joint Request for Selected Preventive Chemotherapy Medicines and Joint Reporting Form. For onchocerciasis, manual entry of data might be required in some cells (for example, in case the targeted population is villages instead of districts).

4. **Defining the endemicity of lymphatic filariasis, onchocerciasis and loiasis in districts and clarifying intervention strategies**

Dr Jonathan King summarized the treatment strategies recommended in different settings of co-endemicity for lymphatic filariasis, onchocerciasis and loiasis from the following WHO documents and other published literature (see also Annex 4):

- **Provisional strategy for interrupting lymphatic filariasis transmission in loiasis-endemic countries** (WHO, 2012);
- **Meeting of the Neglected Tropical Diseases Strategic and Technical Advisory Group’s Monitoring and Evaluation Subgroup on Disease-specific Indicators** (WHO, 2014);
- **Recommendations for the treatment of Oncho with Mectizan® in areas co-endemic for Oncho and Loiasis** (Mectizan Expert Committee and Technical Consultative Committee, 2004); and
- **Loa loa Scientific Working Group Meeting** (Bill & Melinda Gates Foundation, 2014).

Dr Michel Boussinesq presented the categorization of adverse events following mass treatment for onchocerciasis with ivermectin in areas co-endemic for loiasis, the threshold density of *L. loa* microfilaria before treatment in daytime blood smears and the prevalence of *L. loa* microfilaria at community level above which the risk of adverse events is likely to

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2 WHO defines an adverse event as a medical incident that takes place after a preventive chemotherapy intervention and is suspected to be caused by the medicines used in the intervention. A serious adverse event is defined as any untoward medical occurrence that at any dose results in death, requires hospitalization or prolongation of existing hospital stay, results in persistent or significant disability/incapacity, or is life threatening. (See also: *Assuring the safety of preventive chemotherapy interventions for the control of neglected tropical diseases*. Geneva: World Health Organization; 2011).
The severity of adverse events after treatment with ivermectin correlates with the density of *L. loa* microfilaria in treated individuals. Adverse events following treatment with ivermectin for onchocerciasis occurring in individuals infected with *L. loa* are classified into mild reactions, marked reactions (functional impairment), and serious neurological events (coma and death) that are considered severe (or serious) adverse events. A density of *L. loa* above 30,000 microfilaria/ml is considered to be high risk for serious adverse events after CDTI. A risk of functional impairment occurs when the density of *L. loa* exceeds 8000 microfilaria/ml. However, there is currently no absolute threshold at which there is no risk of marked or serious adverse events.

The Mectizan Expert Committee and the Technical Consultative Committee currently recommends that CDTI should be avoided in areas where the prevalence of *L. loa* microfilaria exceeds 20% or the prevalence of eye-worm history is equal to or greater than 40% at the community level. The density of *L. loa* microfilaria can be assessed using a mobile, phone-based microscope to determine from small quantities of blood which patients to exclude from treatment with ivermectin. Dr Boussinesq raised operational research questions about the cost–effectiveness of various potential test and treat or not-treat strategies in areas endemic for onchocerciasis and loiasis, which would depend on various factors such as the size of the target population, the availability of potential medicines including doxycycline and the frequency of treatment. Research is ongoing to determine whether such technology and test and treat approaches are feasible for implementation in public health programmes.


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Dr Maria Rebollo presented an algorithm proposed for helping national programmes to review the status of co-endemicity of lymphatic filariasis, onchocerciasis and loiasis at subnational level and determine which treatment strategies are warranted according to WHO guidelines and other referenced documents. An effort was made to work with APOC to review the status of endemicity by district in all the 10 countries where loiasis is endemic. Where the status of endemicity is unknown, the recommended action would be to complete mapping, or to list possible options for eliminating onchocerciasis in areas with *L. loa*. The intention is to produce a tool for programme managers to enter data on endemicity and generate a report listing the recommended strategy.

### 4.1 Discussion

- There is no WHO recommendation on treatment strategies using ivermectin to eliminate onchocerciasis in hypo-endemic settings where *L. loa* is present; treatment for low-prevalence onchocercal infection in areas endemic for loiasis requires careful assessment of benefit to harm.
- The participants reinforced the importance of provision of specific training at the field level on identifying and managing serious adverse events in areas endemic for loiasis where CDTI or MDA is being implemented.
- The proposed test and treat strategies are assumed to be resource intensive and need to be validated.
- Applying a community-level prevalence threshold of *L. loa* that minimizes the risk of serious adverse events may be more feasible than test and treat, but may require surveys in every community in which co-endemicity for the diseases is suspected.
- Given the recently identified correlation of ICT-positivity and *L. loa* microfilaraemia, an additional diagnostic is warranted to confirm filarial infection when mapping, monitoring or evaluating infection in areas endemic for loiasis (as discussed during a previous meeting of the Subgroup). The available options are limited and include assessment of Wb123 or microfilaria and/or polymerase chain reaction of night blood. Night blood assays detect microfilaria. The Alere Filariasis Test Strip (FTS) is expected to have the same cross-reactivity as the ICT when circulating loads of *L. loa* microfilaraemia are high. The FTS should still be used to evaluate lymphatic filariasis in areas of *L. loa* as a negative test indicates absence of infection. However, additional assays will be needed to confirm positive results for *W. bancrofti*.
- Dr Boussinesq noted that lymphatic filariasis seems to be highly focal in central Africa where loiasis is co-endemic (e.g. Congo and Central African Republic). Dr Moses Bockarie explained that lymphatic filariasis is focal only in those areas where the infection is transmitted by *Anopheles* mosquitoes and thus the GPELF should continue to use districts as the IU for MDA.

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5. **Intervention strategy: single versus semi-annual preventive chemotherapy for onchocerciasis in the context of integration with lymphatic filariasis programmes**

Dr Wilma Stolk presented the outcome of mathematical modelling of annual and semi-annual mass treatment to accelerate elimination of lymphatic filariasis and onchocerciasis.

She compared the results of two different modelling approaches to estimate the impact of semi-annual treatment with ivermectin; one using ONCHOSIM the other EpiOncho, the results of which have been published.\(^{11,12}\) Based on these models, 6-monthly treatment with ivermectin for onchocerciasis reduces the duration of the elimination programme by about 35% but increases the number of treatment rounds required for elimination, provided that treatment coverage is sustained. The models indicate that improving coverage alone during annual preventive chemotherapy with ivermectin also decreases the total number of estimated treatment rounds required to interrupt transmission. Twice yearly treatment with improved coverage is therefore a way to reduce duration to elimination. In terms of cost, semi-annual treatment is estimated to increase annual cost of drug distribution by 60% but reduces cost per treatment round by 20%. The benefits of semi-annual versus annual treatment are estimated to be greater in settings where pretreatment prevalence is highest. Semi-annual treatment applied in such settings and late-starting areas may have long-term programmatic cost savings.

The areas Dr Stolk suggested for changing the frequency of treatment from once to twice a year would be those areas with high levels of endemicity or vector competency before control interventions, late starter countries and countries with operational issues (for example, low coverage, atypical response to treatment). The models rely on assumptions around coverage. Systematic non-compliance is assumed to be the critical factor in the overall success of any preventive chemotherapy intervention. The pattern of non-compliance to MDA or CDTI in a population differs by country and could be totally random or systematic. She emphasized that the model assumed that a randomly selected small portion of the population is non-compliant during each round of treatment.

Based on the LYMFASIM model, changing from annual to semi-annual treatment would halve the duration in years required for elimination.\(^{13}\) In contrast to the model simulations for onchocerciasis, the model for lymphatic filariasis suggests that the total number of treatment rounds required to achieve elimination targets with semi-annual MDA remains the same as annual MDA. As a result of the efficiency gain, the total programme cost required to eliminate the disease is expected to be reduced. Dr Stolk suggested areas for changing treatment frequency from once to twice a year as those that have not started MDA or scaled up fully and those with pockets of high prevalence of microfilaria. However, the model needs to be validated against longitudinal data from treatment programmes. Additional data are needed to validate the model.


5.1 Discussion

- It was noted that Member States are committed to eliminating onchocerciasis and lymphatic filariasis by the target dates in accordance with resolutions of the World Health Assembly and regional committees. Partners and donors have made additional commitments to support programmes achieve elimination by the set target dates.
- The group generally encouraged strategies that would decrease the time required to achieve elimination and would further support meeting elimination of both diseases by the set dates.
- Semi-annual treatment for elimination of onchocerciasis is not a new strategy. The Onchocerciasis Elimination Program for the Americas (OEPA) has regional resolutions to recommend semi-annual treatment for elimination in the WHO Region of the Americas. Eligible populations in countries endemic for the disease in this region have been treated twice or more per year. Onchocerciasis has been eliminated from Colombia, Ecuador, Mexico and likely now Guatemala under these strategies. Burkina Faso, Ethiopia, Sudan and Uganda have implemented semi-annual treatment programmatically.
- In Burkina Faso, semi-annual treatment for onchocerciasis and lymphatic filariasis since 2010 in four co-endemic districts of the south-west region has significantly reduced the prevalences of onchocercal and filarial infections. As a result, the country has been exploring the possibility of harmonizing semi-annual treatment between the two programmes in co-endemic areas to accelerate elimination of both diseases.
- In Uganda, semi-annual treatment of onchocerciasis with ivermectin alone and annual deworming against soil-transmitted helminthiases with albendazole alone is ongoing. Adding one more distribution of albendazole to achieve semi-annual treatment for lymphatic filariasis is operationally feasible. In many districts where semi-annual deworming is ongoing, it can serve as an entry point for semi-annual treatment for lymphatic filariasis by adding ivermectin and expanding the target population to adults.
- Expanding distribution of ivermectin has ancillary impacts on other parasitic diseases such as trichuriasis and strongyloidiasis.
- The impact of semi-annual treatment on elimination of onchocerciasis is supported by data from programme practice, as mentioned; however, semi-annual MDA to eliminate lymphatic filariasis with the current two-drug regimen has not been applied broadly or been well-documented.
- The results of LYMFASIM modelling simulation are encouraging. Additional data from ongoing operational research studies conducted under the Bill & Melinda Gates sponsored Death to Onchocerciasis and Lymphatic Filariasis research grant will provide additional information in addition to the reported experience from Burkina Faso.
- A framework to help programme managers is needed to determine the epidemiological and programmatic conditions in which initiating semi-annual treatment would be most beneficial. The group considered that any endorsement from WHO should not limit the use of semi-annual treatment to certain conditions, especially when resources and political commitment were available.
- Vector control is a supplementary strategy to MDA for elimination of lymphatic filariasis. Use of long-lasting insecticidal nets in some settings has enabled programmes to reach elimination targets, demonstrating the positive impact of successful malaria control activities in many countries on transmission of filarial infection.

6. Delivery strategies and monitoring treatment coverage

Dr Afework Tekle summarized the history of APOC and the concept of the CDTI strategy. APOC started in 1995 as a partnership among endemic countries, donors, partners (nongovernmental development organizations) and Merck & Co., Inc. to provide sustained, community-level treatment for onchocerciasis.

CDTI was adopted in 1997 as a sustainable drug delivery strategy to allow long-term provision of health services in African countries where health systems were weak. The major principles include community empowerment; integration with and strengthening of the health system at the community level; partnership and coordination at global, national and community levels; and sustainability and flexibility according to local conditions\(^\text{18}\). Monitoring activities include routine annual technical reports, independent participatory monitoring, community self-monitoring and treatment coverage surveys. Evaluation activities include sustainability evaluation, multi-country health impact assessment, epidemiological evaluation and entomological evaluation. Challenges include increasing demand for monetary incentives by community drug distributors, significant workload of community drug distributors, poorly-oriented health workers and reliance on donors for financial support.

Dr Jonathan King highlighted the two key MDA targets of the GPELF, which are 100% geographical coverage and 100% programme coverage in all endemic districts in all endemic countries within a limited timeframe. To achieve these targets, programmes should use any delivery strategy appropriate to local settings that maximizes compliance to MDA as well as geographical scale up. Most of the reasons for low compliance are those that the programme can control, such as not knowing the details of the distribution or the purpose of the MDA. Community involvement improves coverage and is the key concept of CDTI\(^\text{17}\); and is necessary to plan and implement any MDA. Unlike CDTI, it is recommended that MDA for LF should occur as a short, time-limited intervention with distribution to all targeted areas over a few weeks to no more than 2 months. Such a delivery strategy is recommended according to the epidemiology of filarial transmission. The greatest impact will occur if the density of microfilaria among the pool of infected individuals in communities is reduced simultaneously, thereby blocking transmission to mosquitoes across the entire population. If MDA occurs throughout the year, there are likely to always be infected individuals spreading microfilaria to mosquitoes. Dr King referenced the key WHO recommendations on MDA strategies for lymphatic filariasis of relevance for both lymphatic filariasis and onchocerciasis elimination programmes\(^\text{18}\).

**Country experiences**

Experiences with integrated implementation and monitoring of MDA for lymphatic filariasis and CDTI for onchocerciasis were presented by Dr Square Mkwanda (Malawi) and Mr Windtare Bougna (Burkina Faso).

In Malawi, MDA started with 8 districts in 2008 and scaled up to 26 districts in 2009 through integrated CDTI and MDA, without specific financial support from external partners. Treatment, supervision, advocacy and social mobilization for lymphatic filariasis, onchocerciasis and soil-transmitted helminthiases were fully integrated. Once treatment for all diseases was completed, the programme managers from all the districts were invited to the national programme review meeting. The programme managers who achieved high coverage were given incentives in kind.


and also tasked to assist those with low coverage. The central team conducted supervisory visits in a few randomly selected districts, and organized a meeting on report-writing with all the district coordinators. Malawi has now passed the WHO recommended transmission assessment survey (TAS) in all endemic districts and stopped MDA. The results of epidemiological and entomological evaluations are awaited to determine whether transmission of onchocerciasis has also been interrupted. The programme is a success story for integrated preventive chemotherapy of neglected tropical diseases including delivery strategies and supervision.

Burkina Faso represents another success story. Neglected tropical disease control and elimination programmes that implement preventive chemotherapy are centralized. Preparation of requests for preventive chemotherapy medicines, provision of administrative documents to inform the regions and districts about the treatment period, production of dose polls and information, education and communication materials, transportation of medicines and supplies, advocacy, social mobilization and training were integrated for lymphatic filariasis and onchocerciasis in the co-endemic districts under the umbrella of the national programme. Integrated advocacy meetings were organized in all regions and districts before drug distribution. At the community level, both programmes employed the same personnel to integrate drug distribution, and both programmes shared logistics such as vehicles and motorcycles. However, operational research, and entomological and epidemiological surveys were not integrated.

Burkina Faso has implemented MDA in all districts endemic for lymphatic filariasis and onchocerciasis. In some problem districts, multiple rounds of MDA and CDTI have not reduced prevalences of infection in the community as expected, and semi-annual MDA is being implemented as an alternative strategy to achieve elimination targets in some of these areas. MDA for lymphatic filariasis is scaling down as districts complete TAS. Only one EU (four districts) in a rural area of central region failed TAS; two districts with good pre-TAS results are eligible for TAS but these border districts of very high endemicity at baseline have not yet stopped MDA.

6.1. Discussion

- The group agreed that CDTI is an effective strategy for long-term control of onchocerciasis. However, integration of CDTI with lymphatic filariasis programmes requires that traditional distribution strategies should be programmatically revised towards elimination, specifically after focused, time-limited MDA for the disease while maintaining community engagement during distribution. For the both programmes to maximize their impacts through integration, treatment schedules must be matched to accommodate the timing of any transmission peak of each disease.
- Timing the arrival of medicines in countries should be aligned with the planned treatment schedule too; better planning at national level and coordination at global level for distribution and shipment are essential. The group urged WHO and the pharmaceutical donors to improve coordination to ensure that the required medicines all arrive at the country in time for the drug distribution.
- The country representatives of Burkina Faso and Malawi urged WHO and APOC to harmonize and standardize the data capture tools for both diseases in order to reduce the burden of reporting of national programmes. With the closure of APOC in 2015, all reporting and requesting of medicines should now be done through the WHO Joint Application Package.\(^\text{19}\)
- Currently, the protocols for coverage surveys differ for both diseases; however, new tools are being designed to support integrated monitoring of preventive chemotherapy such as guidelines on assessing the quality of data.

\(^{19}\)http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/en/
The group acknowledged the success of both programmes in Burkina Faso and Malawi, and commended their considerable achievements in terms of the scale of community health systems, health workers and population being reaching at community level. It recommended that these achievements should be widely disseminated and recognized globally.

7. Coordinating impact evaluation

Dr Frank Richards presented the challenges of coordinating stop-treatment surveys and post-treatment surveillance between lymphatic filariasis and onchocerciasis programmes in areas where both diseases are co-endemic. He revisited the general concept of elimination when an intervention interrupts transmission and no recrudescence of infection is confirmed after a certain time period in the absence of continued intervention during the post-treatment surveillance phase.

With the interruption of transmission of onchocerciasis, the lifespan of the adult worms is believed to dictate the required duration of intervention once the transmission system is ‘closed’ (that is, annual transmission potential is suppressed to zero through intervention). The evidence suggests that the closed system needs to be maintained for around 14 years with annual treatments and vector control interventions and for more than 6 years even with semi-annual mass treatment using ivermectin until all the adult worms have died. Onchocerciasis programmes maintain more stringent criteria during stop treatment surveys and post-treatment surveillance than lymphatic filariasis programmes. An upper bound of the 95% confidence interval of less than 2% antigen positivity in children aged 6–7 years (n ~ 1700) is considered sufficient during TAS of lymphatic filariasis to stop MDA, whereas an antibody seroprevalence of less than 0.1% Ov16 in children aged under age 10 years is indicated in the new guidelines for the verification of elimination of onchocerciasis (n = 2000).

National onchocerciasis programmes are committed to entomological indices, which are often challenging because of the difficulty in collecting sufficient numbers of flies. Generally, it is more difficult to achieve the criteria to stop treatment for onchocerciasis than for lymphatic filariasis; this often leads to the situation where in a given co-endemic area MDA for lymphatic filariasis using ivermectin and albendazole has stopped but treatment for onchocerciasis with ivermectin alone must be continued (for example, in local government areas in Plateau and Nasarawa States of Nigeria). The opposite scenario occurs in some areas of Uganda. There, the national Onchocerciasis Elimination Expert Advisory Committee has decided to stop semi-annual treatment with ivermectin alone but to continue annual MDA with ivermectin and albendazole. In the Nigerian scenario, and in the absence of clear WHO guidance, the national programme is considering whether to segregate evaluation units (EUs) into co-endemic and non-co-endemic areas for onchocerciasis during TAS of post-treatment surveillance. Post-MDA surveillance TAS (TAS2 and TAS3) would continue in non-co-endemic EUs but be delayed in co-endemic EUs until treatment for onchocerciasis is stopped. In the Ugandan scenario, the national programme has postponed post-treatment surveillance for onchocerciasis until areas co-endemic for lymphatic filariasis pass TAS and MDA is stopped.

Dr Richards concluded that coordinated assessment between both programmes on whether to stop treatment and implement post-treatment surveillance between lymphatic filariasis and onchocerciasis programmes would require harmonization of the target age group and the thresholds for decision-making of the surveys. He also emphasized the need for clear messaging to

the national programmes about when transmission of lymphatic filariasis is eliminated in the presence of continuing treatment for onchocerciasis.

Dr Vitaliano Cama presented the progress that has been made to assess, validate and develop potential tools for integrated surveys for both diseases, specifically a multiplex bead antibody assay to detect multiple analytes simultaneously in the same sample. The Ov-16 assay has excellent sensitivity and specificity in this format, even when *Wuchereria* infections are present. The Wb123 or other antibody or antigen for lymphatic filariasis could easily be added. Data demonstrating the low sensitivity of skin snips, particularly when microfilarial loads are low, were also presented, as were schematics to indicate the timing of and tools for surveillance of *Onchocerca volvulus*.

Dr Daniel Boakwe presented the updates of operational research on potential methods of vector surveillance to eliminate both diseases. In onchocerciasis programmes, entomological surveillance aims to determine whether transmission is continuing (in order to stop treatment) and where the infection could be reintroduced as vectors migrate (during post-treatment surveillance). Entomological surveillance involves assessment of transmission by screening pools of adult vectors and delineating transmission zones by cytotaxonomy of larvae. Although not recommended by the GPELF, entomological surveillance is a potential tool to measure the presence of infection in communities after MDA has been stopped. However, entomological indicators for lymphatic filariasis remain to be defined. Once indicators are determined, integrated entomological surveillance may be possible where community-based sampling during the high transmission seasons of both targeted vectors is conducted. It should be noted that the transmission characteristics of mosquitoes and flies are different. Transmission is focal near vector breeding sites and, even in co-endemic communities, the vectors of both diseases cannot necessarily be found at the same time. There is also limited information on the major vector species of lymphatic filariasis in affected African countries.

### 7.1. Discussion

- Currently there is no guidance from WHO on the timing of TAS or of epidemiological and entomological surveys for onchocerciasis in areas co-endemic for both diseases where preventive chemotherapy is ongoing for at least one disease.
- Impact surveys should be coordinated. To do so, programmes must accept either to: (i) defer conducting the recommended surveys or continue interventions until both assessments can be done simultaneously; or (ii) conduct the surveys but defer decisions on elimination until assessments can be done at the recommended time after stopping mass treatment for co-endemic diseases.
- The results of ongoing operational research indicate that Ov16 is a more sensitive diagnostic than detection of microfilaria in skin snips in indicating transmission of onchocerciasis, especially in settings after many rounds of mass treatment with ivermectin.
- There is a need to develop a protocol for integrated assessment of Ov16 during TAS.
- There is further need to develop standardized sampling methodologies in xenomonitoring surveys for lymphatic filariasis and standardized interpretation of results before recommending their use in the GPELF.
8. Conclusions

The meeting agreed the following conclusions for consideration and further discussion by the Working Group on Monitoring and Evaluation of the Strategic and Technical Advisory Group on Neglected Tropical Diseases. Many of the conclusions presented here simply reinforce existing guidance to programmes.

8.1. New considerations

8.1.1 Defining an implementation unit

- An IU is defined as the administrative unit in a country that is used as the basis for making decisions about treatment (that is, where MDA is required) as follows:
  - in areas where lymphatic filariasis is endemic the IU is the DISTRICT (or equivalent);
  - in areas where lymphatic filariasis and onchocerciasis are co-endemic the IU is the DISTRICT;
  - in areas where onchocerciasis is endemic the IU is the COMMUNITY.

8.1.2 Harmonizing the interpretation of coverage indicators between lymphatic filariasis and onchocerciasis elimination programmes

- The population requiring preventive chemotherapy for lymphatic filariasis and onchocerciasis is equally defined as the total population living in areas where the intervention is required according to the following treatment thresholds:
  - for lymphatic filariasis, where the prevalence of infection is equal to or greater than 1%;
  - for onchocerciasis, where the prevalence of infection is greater than 0.1% by skin snip or serology.

- The key coverage indicators are defined for both diseases as follows:

  i. Geographical coverage = \( \frac{\text{Number of IUs where PC is implemented}}{\text{Total number of IUs where PC is required}} \)

  ii. National coverage = \( \frac{\text{Number of individuals ingesting the PC medicine for a specific disease in an endemic country}}{\text{Number of individuals at the national level requiring PC for a specific disease in an endemic country}} \)

  iii. Therapeutic or epidemiological coverage = \( \frac{\text{Number of individuals ingesting the PC medicines at IU level for a specific disease}}{\text{Total population of the IU}} \)

  iv. Programme coverage = \( \frac{\text{Number of individuals in the target population ingesting the PC medicines in the (designated) endemic area}}{\text{All the individuals targeted for treatment in the (designated) endemic area}} \)

The ‘target’ population should be understood by both programmes as the ‘eligible’ population ‘targeted’ by a given package of preventive chemotherapy; for example, school-aged children and adults in countries co-endemic for onchocerciasis (in lymphatic filariasis and onchocerciasis elimination programmes), individuals aged 2 years old or older in countries where onchocerciasis is not co-endemic (in lymphatic filariasis elimination programmes), and preschool-aged children and school-aged children (in school-based soil-transmitted helminthiases control programmes).
8.1.3 Harmonizing reporting between lymphatic filariasis and onchocerciasis elimination programmes

- WHO and APOC should harmonize the existing data reporting forms to one standardized tool.
- WHO’s Joint Request for Selected Preventive Chemotherapy Medicines and Joint Reporting Form should be adapted to account for the targeted population requiring preventive chemotherapy for different diseases and for the calculations of coverage.

8.1.4 Timing of integrated preventive chemotherapy between lymphatic filariasis and onchocerciasis elimination programmes

- Countries should ensure that each planned round of preventive chemotherapy is distributed. To maximize the impact of the intervention, countries should plan distribution in line with the epidemiology of both diseases and encourage communities to distribute preferably:
  i. as a focused, time-limited distribution within 2 months;
  ii. at a time before the peak transmission seasons.

8.1.5 Eliminating lymphatic filariasis in districts where Loa loa is present

- In districts where lymphatic filariasis is endemic, where there is any evidence of Loa loa (that is, where RAPLOA exceeds 0%), and MDA has not started, countries should implement district-wide the recommended strategy of preferably twice-yearly treatment with albendazole and coordinated, integrated vector control for lymphatic filariasis. Vector control activities should be incorporated within existing malaria programme efforts.
- In districts where lymphatic filariasis and onchocerciasis are (hypo) co-endemic, where there is any evidence of Loa loa and CDTI has not started, countries should implement treatment district-wide with preferably twice-yearly albendazole and coordinated vector control. Vector control activities should be incorporated within existing malaria programme efforts.

8.1.6 Implementing semi-annual preventive chemotherapy to eliminate onchocerciasis

- Where countries are committed to the elimination objective and resources are available, programmes may implement semi-annual preventive chemotherapy with ivermectin to hasten elimination of onchocerciasis. Areas that are not on track to achieve elimination by the target date should be prioritized for semi-annual treatment. Efforts should be made to evaluate and improve programme performance.

8.1.7 Monitoring and evaluation

- Where feasible, national programmes should try to align the timing of impact assessments (TAS and epidemiological or entomological evaluations) to coordinate decisions about stopping treatment. Integrated assessments are possible. However, modified sampling strategies will be needed.
8.2. Reinforcing existing guidance

8.2.1 Distribution strategies

- Programme managers should plan strategies to deliver medicines that are appropriate for local conditions. Communities must be involved in decisions about the timing of distribution at local levels under the guidance of health workers. A number of approaches may be adopted, such as house-to-house distribution, booth distribution and distribution in areas of community gathering.
- The ingestion of the medicine should always be supervised by the person administering it (that is, directly observed therapy).

8.2.2 Training and supervision

- Countries should reinforce supervision of preventive chemotherapy activities to maximize coverage, compliance and reporting.
- Programme capacity and WHO staff are needed at all levels to plan and manage programmes, specifically to ensure that the WHO Joint Application Package is submitted to WHO by the requested due date.

8.2.3 Coordinated support

- Countries, WHO, pharmaceutical companies and donors should improve communication and coordination to ensure timely release of resources and arrival of necessary medicines at national and sub-national levels.

8.2.4 Monitoring and evaluation

- Each programme should continue to follow the recommended disease-specific guidance to determine when to stop MDA and conduct post-treatment surveillance as contained in the following documents:

8.3. Urgent needs for operational research

8.3.1 Onchocerciasis

Operational research is needed to determine:

- the serological threshold at which preventive chemotherapy is warranted in hypo-endemic areas (this will likely require a combination of serology, skin snip and vector data);
- the serological threshold (or data-based adjustment) below which preventive chemotherapy can be stopped in endemic areas;
- the prevalence of Ov16 in children that indicates sustained interruption of transmission;
- the epidemiological threshold that indicates a need for increased frequency of ivermectin to achieve elimination; and
- the most feasible, cost–effective and safe public health strategy for elimination in areas where onchocerciasis is hypo-endemic, loiasis is endemic and the population is naive to ivermectin.
8.3.2 Lymphatic filariasis

Operational research is called for to:

- develop new monitoring and evaluation strategies to evaluate filarial infection after MDA with albendazole only in areas endemic for loiasis (what tools and when);
- model the results of current operational research to determine the number of rounds and frequency of MDA with albendazole alone at 65% coverage required to achieve the elimination targets;
- determine the reasons for and programmatic implications of focal endemicity;
- design cost–effective diagnostic tools to map lymphatic filariasis in districts where loiasis is endemic;
- establish the specificity of Wb123 to measure transmission of lymphatic filariasis in Loa loa areas; and
- because entomological evaluation is an essential component of surveillance of onchocerciasis after treatment and a promising tool for indicating infection in the community, the correlation between rates of infection in mosquitoes and prevalence of antigen or antibody in humans and from such, the rate that indicates interruption of transmission.

8.3.3 Integrated needs

For both diseases there is a need to:

- develop a standardized survey protocol to integrate assessments of filarial and onchocercal infections and determine when to stop MDA;
- design an algorithm to determine when modified sampling is needed during a TAS for an integrated impact assessment when the IU for lymphatic filariasis does not overlap completely with that for onchocerciasis (for example, when less than 50% of an IU for lymphatic filariasis is endemic for onchocerciasis);
- assess the acceptability of test and not treat strategies in communities; specifically, to examine the impact on coverage among those found to be eligible and the stigmatization of those who refused treatment;
- design a micro-mapping and micro-treatment strategy for areas where loiasis is co-endemic but RAPLOA is less than 40%.
**Annex 1. Meeting agenda**

### 7 February 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenters</th>
</tr>
</thead>
</table>
| 09:00-09:30 | Opening remarks and administrative arrangements  
|         | Introductions  
|         | Clarification of objectives and process | Dr Biswas  
|         | Dr King       |
| 09:30-10:30 | **Defining the implementation unit (IU) and reporting**  
|         | - Delineation of oncho treatment zones and population requiring treatment | Mr Zouré  
|         | - Should the IU of oncho be switched to the district?  
|         | - How should coverage be reported? | Dr Sodahlon  
|         | Dr Mikhailov |
| 10:30-11:00 | - Discussion | Chair |
| 11:30-13:00 | **Defining the landscape “LF, oncho, Loa” endemicity of districts and clarifying intervention strategies**  
|         | - District classification and at-risk population | Dr King  
|         | - Elimination in the presence of Loiasis | Dr Boussinesq |
| 14:00-15:00 | Discussion and clarified positions on intervention strategies | Chair |
| 15:30-16:30 | **Intervention strategy**  
|         | - Single vs twice-yearly preventive chemotherapy for oncho in the context of integration with LF | Dr Stolk |
| 16:30-17:30 | Discussion | Chair |

### 8 February 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenters</th>
</tr>
</thead>
</table>
| 09:00-10:30 | **Delivery strategies and monitoring treatment coverage**  
|         | CDTI and MDA: concept and practice  
|         | - Malawi experience  
|         | - Burkina Faso experience | Dr Tekle  
|         | Dr King  
|         | Dr Mkwanda  
|         | Dr Bougma       |
| 11:00-11:30 | Discussion | Chair |
| 11:30-12:30 | **Impact evaluation**  
|         | How should national programmes coordinate stop-treatment surveys in co-endemic areas? | Dr Richards |
|         | Discussion | Chair |
| 13:30-14:30 | **Impact evaluation (cont)**  
|         | Tools and potential for integrated surveys | Dr Cama  
|         | Dr Lammie  
|         | Professor Bockerie  
|         | Dr Boakye |
| 14:30-15:00 | Discussion | Chair |
| 15:30-17:00 | Conclusions and Recommendations for the M&E Working-Group of STAG | Chair |
| 17:00-17:30 | Closure of the meeting | Dr Biswas |
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|-----------------|-----------------|
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Annex 3. WHO-recommended intervention actions against lymphatic filariasis, and onchocerciasis by co-endemic setting with loiasis

<table>
<thead>
<tr>
<th>Endemic setting</th>
<th>Estimated scope Population (districts)*</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphatic filariasis and loiasis</td>
<td>MDA not started</td>
<td>Administer ALB monotherapy once, preferably twice, a year plus vector control for lymphatic filariasis</td>
</tr>
<tr>
<td>Onchocerciasis and loiasis</td>
<td>CDTI ongoing</td>
<td>Continue CDTI</td>
</tr>
<tr>
<td></td>
<td>CDTI not started</td>
<td>No WHO recommendation. Alternative treatment strategies needed</td>
</tr>
<tr>
<td>Lymphatic filariasis, onchocerciasis and loiasis</td>
<td>MDA/CDTI at district level</td>
<td>Continue MDA/CDTI</td>
</tr>
<tr>
<td></td>
<td>MDA/CDTI at community level</td>
<td>Continue MDA/CDTI, ALB plus vector control in communities naive to IVM; no WHO recommendation for onchocerciasis; alternative treatment strategies for IVM-naive communities</td>
</tr>
<tr>
<td></td>
<td>MDA/CDTI not started</td>
<td>ALB plus vector control for lymphatic filariasis; assess for onchocerciasis and loiasis; no WHO recommendation for onchocerciasis; alternative treatment strategies</td>
</tr>
</tbody>
</table>

ALB, albendazole; CDTI, community-directed treatment with ivermectin; IVM, ivermectin; MDA, mass drug administration

* According to data on the status of endemicity available to WHO (African Programme for Onchocerciasis Control, WHO Regional Office for Africa, WHO headquarters) as of December 2014.
Annex 4. Definitions of coverage-related indicators and terminology in APOC and WHO guidelines

APOC definitions

(i) **Total population**: the total population living in meso/hyper-endemic communities within the project area (based on REMO and census taking).

(ii) **Eligible population**: calculated as 84% of the total population in meso/hyper-endemic communities in the project area.

(iii) **Annual Treatment Objective (ATO)**: the estimated number of persons living in meso/hyper-endemic areas that a CDTI project intends to treat with ivermectin in a given year.

(iv) **Ultimate Treatment Goal (UTG)**: calculated as the maximum number of people to be treated annually in meso/hyper-endemic areas within the project area, ultimately to be reached when the project has reached full geographic coverage (normally the project should be expected to reach the UTG at the end of the 3rd year of the project).

(v) **Therapeutic coverage**: number of people treated in a given year over the total population (this should be expressed as a percentage).

(vi) **Geographical coverage**: number of communities treated in a given year over the total number of meso/hyper-endemic communities as identified by REMO in the project area (this should be expressed as a percentage).

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**WHO definitions**

(i) **Targeted population**: The population (or its sub-set) in eligible age groups that are targeted by a given PC package

<table>
<thead>
<tr>
<th>Neglected tropical disease</th>
<th>Medicine</th>
<th>Pre-SAC (aged 2–5 years)</th>
<th>SAC (aged 5–14 years)</th>
<th>Adults (aged &gt; 15 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphatic filariasis</td>
<td>DEC + ALB</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Onchocerciasis</td>
<td>IVM + ALB</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Soil-transmitted helminthiases</td>
<td>ALB or MBD</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Schistosomiasis</td>
<td>PZQ</td>
<td>X</td>
<td>X</td>
<td>X (only at-risk adults)</td>
</tr>
<tr>
<td>Trachoma</td>
<td>AZT</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

ALB, albendazole; AZT, azithromycin; DEC, diethylcarbamazine; IVM, ivermectin; MBD, mebendazole; PZQ, praziquantel

(ii) **Geographical coverage** =  

\[
\text{Number of endemic administrative units where PC is implemented} \div \text{Total number of endemic administrative units where PC is required}
\]

(iii) **National coverage** =  

\[
\text{Number of individuals ingesting PC drug for a specific disease in an endemic country} \div \text{Number of individuals at the national level requiring PC for a specific disease in an endemic country}
\]

(iv) **Programme coverage** =  

\[
\text{Number of individuals in the target population ingesting the PC drugs in (designated) endemic area} \div \text{All the individuals targeted for treatment in the (designated) endemic area}
\]

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INTEGRATING NATIONAL PROGRAMMES TO ELIMINATE LYMPHATIC FILARIASIS AND ONCHOCERCIASIS

STRATEGIC AND TECHNICAL ADVISORY GROUP FOR NEGLECTED TROPICAL DISEASES
SUBGROUP ON DISEASE-SPECIFIC INDICATORS

7–8 FEBRUARY 2016
WORLD HEALTH ORGANIZATION, GENEVA