



annual highlights



2013



The accomplishments of the
Mectizan Donation Program in its 26th year

Message from the Director, Dr. Adrian Ho

2013 has been another momentous year for the development of the onchocerciasis (river blindness) and lymphatic filariasis (elephantiasis) elimination programs as well as for Neglected Tropical Diseases (NTDs) in general. Great strides have been made in some countries, new partnerships have been forged and the African Programme for Onchocerciasis Control has begun a major restructuring and the “new entity” (name still to be decided) will develop linkages between onchocerciasis and lymphatic filariasis in particular but will be working within the context of NTD control in general. New grants have been made for ongoing operational research to improve the output of the various programs and establish simpler methods for implementation, monitoring and evaluation.

The major news of the year has to be Colombia. This is the first country to be verified as free from Onchocerciasis by the World Health Organisation. Although the focus was

small, a well-coordinated effort was required to ensure that all individuals were treated twice yearly. This success has shown the rest of the world what can be done with a concerted effort. Many congratulations to the Ministry of Health in Colombia, its field workers and the Onchocerciasis Elimination programme for the Americas (OEPA) supported by the Carter Center. Ecuador is not far behind Colombia. The Ministry has prepared and submitted the paperwork for verification of elimination of transmission, which should happen early in 2014. Guatemala and Mexico are also close behind as they wrap up the post-treatment surveillance phase in 2014. They will likely apply for verification of elimination in 2015. This just leaves Venezuela and Brazil, a tiny focus on their common border inhabited by the Yanomami Indians. This area is very difficult terrain deep in the Amazon jungle.

Onchocerciasis in Africa is very different. The vectors are different species and the scale is much larger than that of the Americas. Despite the challenges facing onchocerciasis elimination in Africa, recent epidemiological evaluations have been showing great progress and a target date for elimination in most foci has been set for 2025.

Lymphatic filariasis (LF) elimination in Africa presents more of a mixed picture. Togo, which has stopped treatment, is maintaining very good and innovative surveillance and there does not seem to be any recurrence. The Islands of Zanzibar had stopped treatment but unfortunately some cases have been found recently. The significance of these new cases is yet to be determined but to ensure the success of elimination in Zanzibar, treatment has resumed. Epidemiological indicators in implementation units in some countries (e.g. Burkina Faso) where treatment has been ongoing for

some time have shown that treatment can be stopped provided surveillance is ongoing. Unfortunately, the cost of monitoring and evaluation, particularly the Transmission Assessment Surveys (TAS), are expensive therefore few TAS surveys are being conducted. Some countries continue to treat because they cannot afford to complete the assessment needed to determine whether it's time to stop!

The target for stopping treatment for LF elimination in Africa is 2020. According to the World Health Organization (WHO), endemic areas need 5-6 years of consistent treatment to eliminate transmission, which does not leave much time for countries that remain to be mapped. Additional funding is now available and AFRO are working hard with the NTD Support Center in Atlanta to complete all the basic mapping by the end of 2014.

So much of this work can only be done through partnerships. The Mectizan Donation Program's first responsibility is to get the Mectizan where it is needed, when it is needed for distribution in and by the community. This cannot be achieved without strong partnership: partnerships for implementation with Ministries of Health and Nongovernmental Development Organisations (NGDO), and partnerships for funding by governments of endemic countries, NGDOs and by the international donor community. A lot of this work is coordinated through the World Health organization either through their African Regional Office (WHO AFRO) in Brazzaville or through the African Programme for Onchocerciasis Control (APOC). APOC is a classic example of strong partnership between countries, WHO, the World Bank and NGDOs, all contributing to funding, implementation, monitoring and evaluation.



But APOC is evolving. At the the Joint Action Forum in 2011 there was general agreement to extend the life of APOC from 2015 to 2025 so that onchocerciasis could be eliminated from most countries before the end of the Program. The remaining countries will be those with specific problems such as post-conflict challenges, or the co-endemicity of another filarial parasite, Loa loa, which complicates Mectizan treatment. In 2013, APOC and its partners were tasked to develop a detailed concept paper and strategic plan of action and budget from 2015 to 2025. The need for this plan was reinforced during an NTD partners meeting hosted by WHO AFRO in Brazzaville in March. WHO AFRO's regional director, Dr. Luis Gomes Sambo, reiterated the need to develop linkages between the onchocerciasis and LF programs in Africa as the interventions are the same, Mectizan for onchocerciasis and co-administration of Mectizan and albendazole for LF distributed annually or twice annually. Improved integration has involved a lot of work particularly on the part of APOC management who took the opportunity in 2013 to consult with a wide variety of key stakeholders. The Joint Action Forum (JAF) approved the new strategy and now the real work begins to transform APOC into a new entity which will incorporate onchocerciasis in the whole of Africa together with elimination of LF. This has been an extraordinary example of partnership in action as each organisation brings an important component to the table. The programs for the two diseases have been organised in very different ways, but in Africa you cannot eliminate one disease and ignore the other where the diseases overlap. The improved integration of onchocerciasis and LF elimination is the next logical development and we look forward to participating in the creation of this new entity in 2016. In the meantime, however, there is still a lot of work to do to scale up -- particularly in



LF elimination in Africa as the program will need to hit the ground running at full speed if targets are to be met.

2013 brought other changes as NTDs activities scale up in many countries, requiring improved coordination. Most countries in Africa have developed five-year Master Plans for NTD control. WHO began rolling out a joint request form for preventive chemotherapy for NTDs. We hope in 2014 you will all make use of this form by completing it and sending a copy to WHO but also a copy to the Mectizan Donation Program at mectizan@taskforce.org for Mectizan and for albendazole in onchocerciasis co-endemic countries. Applications for Mectizan will be reviewed and approved through the Mectizan Donation Program for onchocerciasis and with WHO for LF, but we hope the use of the joint request will enable better coordination with other donations for NTDs.

We previously mentioned the importance of NTD mapping. We're delighted to announce that Dr. Kisito Ogoussan left MDP at the end of 2013 to work with the NTD Support Center coordinating a Bill and Melinda Gates Foundation funded project with WHO AFRO for NTD mapping. He did not move far from his former MDP office, just a few offices down the corridor. This is convenient given that during his six years with MDP he became a very active partner with APOC and country partners. Although he's not with MDP anymore I think we will be consulting him from time to time! As part of this change, we decided to slightly alter the application approval process. Applications should be sent to the Mectizan address above. Initial review

will be done by MDP's new Senior Program Associate, Helen Lim, who has already been working with MDP for some time on data management. Helen will settle any administrative issues related to the applications and will then send them to Dr. Yao Sodahlon, MDP's Senior Associate Director, who will conduct the final review and approval of both onchocerciasis and LF applications. As many applications received by MDP are joint applications, our hope is that this will fit in with the new WHO system and will not create a burden at the country level.

Work on overhauling data management for MDP is ongoing with the design of a new database, which we hope will be fully functional and compatible with the WHO databases in Geneva and Brazzaville by the end of 2014. As programs scale up, and the demand for drugs increase, it is vital that we ensure accurate forecasting for drug needs. To this end, we are also working on a tool to help with accurate long term forecasting. We are also working with countries to determine the ideal time for drug shipments to arrive to ensure they are available well before the peak-transmission season. This may mean shortening the treatment cycle by a couple of months in 2014 or 2015 but we hope eventually it will be much more beneficial to all programs.

We expect a number of changes in 2014 that we hope will improve coordination and efficiency. Our goal is to ensure that sufficient medicines are provided when they are needed. We will all need to work together if we are to scale up effectively and reach those 2020 and 2025 targets.

Onchocerciasis Achievements

In 2013, MDP approved 167,984,016 Mectizan treatments to be administered in Africa, Latin America, and Yemen for onchocerciasis control and elimination. Of these treatments, 24% (40,346,810) were approved for areas where onchocerciasis and LF are co-endemic. For LF, Mectizan is co-administered with albendazole. MDP received a total of 54 applications, 13 of which were joint applications for both LF and onchocerciasis.

Most of the applications came from Africa and one application from Yemen. In Africa region, Ethiopia was approved for 2013 & 2014 MDA as well as 6 out of 22 projects from DRC enhancing further the increase in the number of treatments approved.

In the Latin American region, only Brazil submitted a request for Mectizan in 2013. Thus Venezuela and Brazil will be the only countries from the region to implement MDA.

From the inception of the program in 1987 to December 2013, a total of 1,322,829,539 cumulative treatments have been approved for the control and elimination of onchocerciasis.

Colombian President Juan Manuel Santos congratulates his country on its success as the first country in the world to eliminate onchocerciasis. At the table (L-R) Dr. Mauricio Sauerbrey, OEPA, Mr. Jimmy Carter, The Carter Center, Dr. Alejandro Gaviria Uribe, Minister of Health, Dr. Jose R. Teruel, PAHO.



Colombia becomes the first country to receive verification of elimination of river blindness from WHO.

In July 2013, the Mectizan Donation Program congratulated President Juan Manuel Santos, the Colombian Ministry of Health and Social Protection, The Carter Center, the Onchocerciasis Elimination Program for the Americas, and the Pan American Health Organization on the formal verification of elimination of the transmission of river blindness from Colombia – the first country in the world to achieve this milestone.

Dr. Adrian Hopkins traveled to Colombia in July to join the celebra-

tion led by President Santos as well as Colombia's Minister of Health and Social Protection, Dr. Alejandro Gaviria Uribe, and other dignitaries including former US President Jimmy Carter and former First Lady Rosalynn Carter, and representatives of: the Colombian government, the Carter Center's River Blindness Elimination Program and Onchocerciasis Elimination Program for the Americas, the Pan American Health Organization (PAHO), Merck/MSD, the Lions Clubs International Foundation, and the Bill & Melinda Gates Foundation.

The success in Colombia is attributed to the commitment of the government and to the inter-disciplinary public-private partnership that provided treatment with Mectizan and the necessary health education and community mobilization, which was sustained for more than 15 years.

“We are so proud of this is a remarkable achievement. It is tremendously rewarding to see that the MECTIZAN Donation Program and its partners have achieved this long held goal of making river blindness a disease of the past in Colombia,” said Kenneth C. Frazier, chairman and chief executive officer of Merck. “We are humbled by the great work of the alliance of partners to protect future generations from a disease that carries devastating implications for people, families, healthcare systems and local economies.”



Lymphatic Filariasis Achievements

Twenty-eight countries in Africa and Yemen are eligible to co-administer Mectizan and albendazole for mass drug administration (MDA) to interrupt the transmission of lymphatic filariasis (LF). Since the beginning of the LF Elimination Program in 2000, more than 982.6 million Mectizan and albendazole treatments have been approved in 22 African countries and in Yemen. The number of treatments approved continues to increase every year as new countries launch their LF elimination (LFE) programs and others expand into new implementation units (IUs).

In 2013, 167 million treatments were approved for LFE in 17 countries. Among the applications approved, two initial applications were approved to start LF programs in the Congo and Guinea. To comply with safety guidelines and avoid adverse experiences, Mectizan and albendazole were only approved for LFE in loiasis co-endemic areas in Congo where community distribution of ivermectin (CDTI) has been ongoing.

Ten re-applications were approved for the continuation of LFE in existing program areas in Burkina Faso, Cameroon, Ghana, Guinea Bissau, Liberia, Malawi, Mali, Niger, Sierra Leone and, Uganda. Six re-applications were approved for program expansion in Benin, Ethiopia, Mozambique, Nigeria, and Tanzania where an additional application was approved to resume mass treatment in some areas of Zanzibar.

For all 18 approved re-applications, 24% of the treatments will be distributed in areas co-endemic with onchocerciasis. In Nigeria, an additional 7,258,000 albendazole treatments were approved for 3 south-eastern states (Anambra, Ebonyi and Imo) for distribution in areas where loiasis is co-endemic but not eligible for Mectizan. As recently recommended by WHO¹, only albendazole will be used in these areas along with integrated vector management.

¹ <http://www.filariasis.org/documents/ReportofthemeetingonLFmalariaandIVM59March2012.pdf>



Stopping MDA and Post Treatment Surveillance

Benin

Treatment stopped in 23 IUs

Burkina Faso

Treatment stopped in 6 IUs

Ghana

Treatment stopped in 4 IUs:

Mali

Treatment stopped in 2 IUs

Nigeria

Treatment stopped in 30 IUs in Plateau and Nasarawa states

Tanzania

Treatment stopped in 1 IU

Togo

Post MDA activities continue: the second Transmission Assessment Survey (TAS) was successfully conducted in 2012; a third TAS is planned for 2015.

Yemen

Post MDA activities continue.



2013 Highlights

The role of the MEC continues to evolve following MDP's 2012 strategic planning exercise. The updated detailed 5-year strategic plan will be presented to the MEC during the Spring 2013 meeting. Now that few new applications are received each year, the MEC no longer spends most of its time reviewing applications. In 2013, the MEC convened to discuss important issues around the elimination of onchocerciasis and lymphatic filariasis.

The Spring 2013 MEC meeting was held in Accra, Ghana following a meeting of experts convened to address atypical responses to Mectizan. During this meeting it was agreed that atypical responses observed in isolated communities in Ghana were likely due to low coverage with Mectizan. The MEC, together with partners, will continue to monitor Mectizan efficacy.

In 2013, some of the MEC key recommendations included:

- The MEC approved the use of Mectizan in onchocerciasis hypoendemic areas where:
 - The area is part of a transmission zone
 - Epidemiological data are no more than 5 years old
 - Treatment is planned using the health district as the implementation unit
- The MEC does not approve the use of Mectizan in onchocerciasis hypoendemic areas where loiasis has a prevalence of greater than 20% as measured by the rapid assessment procedure for loiasis (RAPLOA).

Chad

The MEC approved Chad's application for extension to treat in hypoendemic areas provided prevalence studies were updated. Areas co-endemic for loiasis in Chad are not eligible for treatment.

Ethiopia

The MEC approved the request for Mectizan for two newly defined APOC projects and extension areas.

Togo

The MEC approved twice yearly treatment in Togo; however, there was concern about the validity of the skin snip data. The MEC requested that APOC review the data and initiate rigorous coverage surveys.

The MEC noted APOC's epidemiological work to create new elimination strategies and requested that information on expanded geographic areas or treatment frequency be shared as early as possible to facilitate Mectizan forecasting.

To address the possibility for atypical response to Mectizan, the MEC recommended a clear definition for "typical" response. The MEC requested that a review of the data from the recent Moxidectin trials be undertaken to provide an overview of clinical and parasitological changes following ivermectin treatment. Furthermore, descriptions of the relationship between levels of microfilariae in the skin and itching are needed.

MEC further recommended that APOC take urgent action to prevent the development of resistance in areas where progress was poor by ensuring that coverage is improved, encouraging treatment just before the peak transmission season and treating twice yearly where appropriate.

With regard to the role of APOC evolving into LF elimination, the MEC recommended that MDP and Merck remain engaged in the evolution of the program. The new entity should emphasize developing capacity to ensure that programs are sustainable.

The ongoing work between AFRO and APOC to define implementation units should be completed as soon as possible and be made available to partners.

Nigeria

Dr. Yao Sodahlon visited Nigeria twice in 2013 to provide technical assistance. Though baseline data had been collected, MDA for LF was confined to areas co-endemic for onchocerciasis and did not cover the entire IU. The MEC approved ongoing technical support to Nigeria to ensure the successful scale up of MDA for LF.

The MEC agreed that MDP should work with partners to add onchocerciasis and LF data to the NTD mapping tool that was launched in 2013.



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Through the Mectizan Donation Program, Merck donates Mectizan for the elimination of onchocerciasis as a public health problem in Africa, Latin America, and Yemen. For the elimination of lymphatic filariasis in Africa and Yemen where onchocerciasis is co-endemic, Mectizan is co-administered with albendazole, which is donated by GlaxoSmithKline.

Mectizan is not approved for use in the United States.