

Progress toward elimination of onchocerciasis in the Americas

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The Onchocerciasis Elimination Program for the Americas (OEPA) is a regional initiative and international partnership that has made considerable progress toward its goal since it was launched in 1993. Its strategy is based on mass drug administration of ivermectin (Mectizan, donated by MSD, also known as Merck & Co., Inc., Kenilworth, NJ, USA), twice or four times per year, with at least 85% coverage of eligible populations. From 1989 to 2016, 11 741 276 ivermectin treatments have been given in the Americas, eliminating transmission in 11 of 13 foci. The OEPA's success has had a great influence on programs in Africa, especially Sudan and Uganda, which moved from a control to an elimination strategy in 2006 and 2007, respectively. The successes in the Americas have also greatly influenced WHO guidelines for onchocerciasis transmission elimination. With four of the six originally endemic American countries now WHO verified as having eliminated onchocerciasis transmission, and 95% of ivermectin treatments in the region halted, the regional focus is now on the remaining active transmission zone, called the Yanomami Area, on the border between Venezuela and Brazil. Both countries have difficult political climates that hinder the elimination task in this remote and relatively neglected region. As with other elimination efforts, 'the final inch' is often the most difficult task of all.

Keywords: Disease elimination, *Onchocerca volvulus*, Ov16, Post-treatment surveillance, Pool screen, River blindness

Introduction

The filarial disease onchocerciasis, also known as river blindness, is caused by the parasite *Onchocerca volvulus*. Transmission occurs when a person receives numerous bites from infected black flies of the genus *Simulium*. The flies transmit infective larvae that grow to adulthood and breed in subcutaneous nodules in the human host. Female adult worms produce microfilariae (mf), the pre-larval forms of the parasite, which cause various ailments including chronic skin disease, painful itching and eye disease that can culminate in blindness. The disease cycle begins anew when mf are picked up by biting black flies, where they develop into infective larvae. Worldwide, approximately half a million people are estimated to be blinded or suffer visual impairment as a result of onchocerciasis, and 187 million are at risk in 34 countries.^{1,2} Ivermectin (Mectizan, donated by MSD, also known as Merck & Co., Inc., Kenilworth, NJ, USA, is a safe and effective oral medicine that kills the mf and prevents skin and eye disease. It has been given in annual, semi-annual or quarterly mass drug administration (MDA) campaigns. In Africa, where 99% of the world's onchocerciasis cases occur, most MDAs are provided annually. The more frequent and higher the MDA coverage, the more quickly transmission can be interrupted and the parasite completely eliminated.^{3,4}

Onchocerciasis in the Americas and the history of the OEPA initiative

Estimates of the Americas' population at risk of onchocerciasis in the late 1980s was put at 5 million persons, but refinement mapping resulted in a 90% decrease of that number to about 500 000 in 13 geographically discrete transmission zones (foci) in six countries: Brazil, Colombia, Ecuador, Guatemala, Mexico and Venezuela (Figure 1). The three largest foci (the Central Zone in Guatemala, the South Chiapas in Mexico and the Northeast in Venezuela) contained about 60% of the regional at-risk population. By 1990, ivermectin MDA was active in three countries (Guatemala, Ecuador and Mexico), albeit with treatment coverage below what appeared necessary to interrupt transmission.^{5,6}

In 1991 the Pan American Health Organization (PAHO) was anxious to capitalize on recent disease elimination successes in the region of the Americas and identified the donation of ivermectin as an opportunity to organize a regional campaign to eliminate onchocerciasis. A PAHO resolution (CD35.R14) that year called for countries and partners to mobilize resources to use ivermectin MDAs to eliminate onchocerciasis-related eye disease (and where possible transmission) by 2007. The Onchocerciasis Elimination

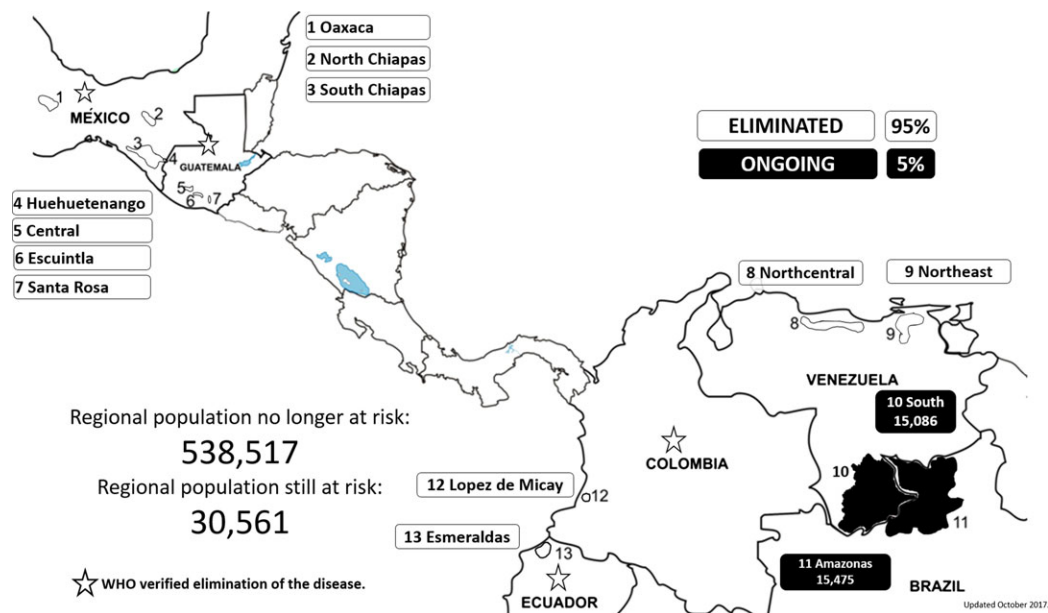


Figure 1. Distribution of onchocerciasis in the Americas in 2017.

Program for the Americas (OEPA) was launched in 1993 as the vanguard for fulfilling Resolution CD35.R14. With a grant from the River Blindness Foundation (RBF), an OEPA secretariat (consisting of a director, an epidemiologist, a social scientist, a data specialist and support staff) was established and based in Guatemala. In 1996 the Carter Center assumed the role of administratively supporting the OEPA secretariat when the RBF closed.⁷

The OEPA strategy is to break onchocerciasis transmission using ivermectin MDA twice or four times per year, with at least 85% coverage of the eligible at-risk population in all endemic communities. From 1986 to 2016, a total of 11 741 276 ivermectin treatments were distributed in the region, primarily by salaried Ministry of Health personnel, assisted in some countries by community volunteers. Over time, each focus passes through four distinct transmission phases (active, suppressed, interrupted and eliminated). When all foci in a country have reached eliminated transmission, the country can request national WHO verification.^{8,9}

Structure of the OEPA initiative

Figure 2 shows the structure of the OEPA initiative. The six countries are responsible for executing their MDA programs, monitoring that the requisite 85% coverage is reached and sustained, evaluating impact at least every 4 years within preselected (primarily hyperendemic) sentinel communities, conducting post-treatment surveillance and ultimately preparing their national elimination reports (‘dossiers’) to request WHO verification of elimination. From a regional perspective, the OEPA secretariat works with a steering committee called the Program Coordinating Committee (PCC), consisting of institutional representatives from the PAHO, the Centers for Disease Control and Prevention and the Carter Center; country representatives; and onchocerciasis (‘at large’) experts. Key donors attend the meeting as observers. The PCC meets twice a year: once midyear in Guatemala and the second

time in tandem with the larger annual InterAmerican Conference on Onchocerciasis (IACO), which is a meeting of all OEPA stakeholders. The OEPA secretariat, as well as the PCC and IACO meetings, focus on program review, special initiatives/operational research, technical assistance, coordination, laboratory assistance and quality control, advocacy, political will, supplemental financial assistance and resource mobilization. The PAHO plays a key role in the verification process and in maintaining political will through resolutions (CD48.R12, CD49.R19 and CD55.R9 in 2008, 2009 and 2016, respectively) that currently call for transmission interruption by 2022 throughout the region.^{9–11}

The roadmap to elimination

The OEPA’s strategy is for the elimination of onchocerciasis transmission solely through ivermectin MDA twice or four times per year to cover at least 85% of all individuals eligible to take the medicine in all endemic communities. Following a 1999 recommendation by the IACO, the OEPA developed draft guidelines for certifying elimination of onchocerciasis (including a discussion of critical issues and a flow chart of activities)¹² for the WHO’s Department of Control and Elimination of Diseases. In response, the department convened a large group of onchocerciasis experts in Geneva to review and discuss the OEPA’s draft. The first set of guidelines, published by the WHO in 2001,¹³ drew heavily on this OEPA document. The 2001 guidelines were operationalized by Lindblade and colleagues¹⁴ in Guatemala to stop MDA in the first of the 13 foci in the Americas (Santa Rosa) in 2004. The 2001 guidelines were eventually used (substituting the term ‘verification,’ which is now preferred by the WHO Neglected Tropical Diseases [NTD] program, for the 2001 term ‘certification’) by the WHO’s International Verification Teams (IVTs) that visited Colombia, Ecuador and Mexico to verify elimination of transmission of *O. volvulus* (in 2013, 2014 and 2015,

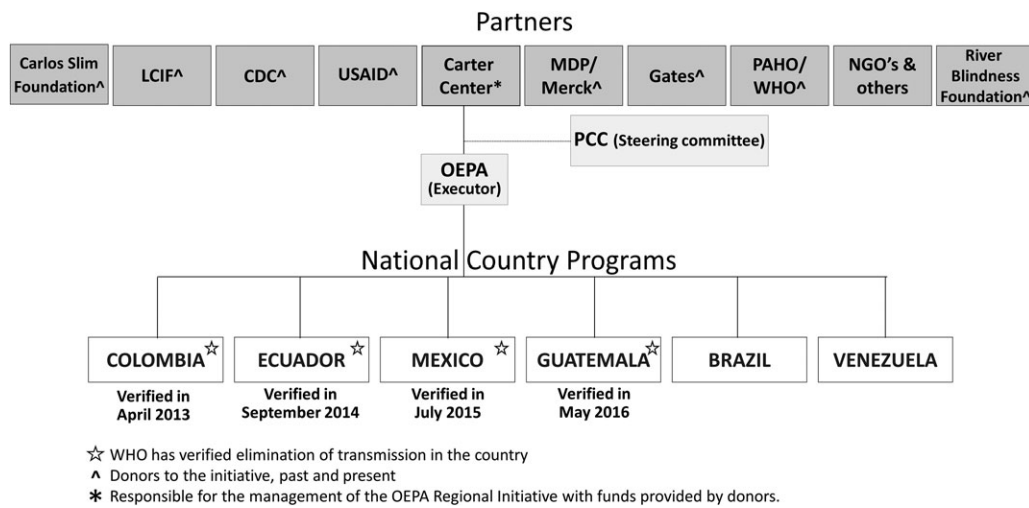


Figure 2. Onchocerciasis Elimination Program for the Americas regional initiative organization chart.

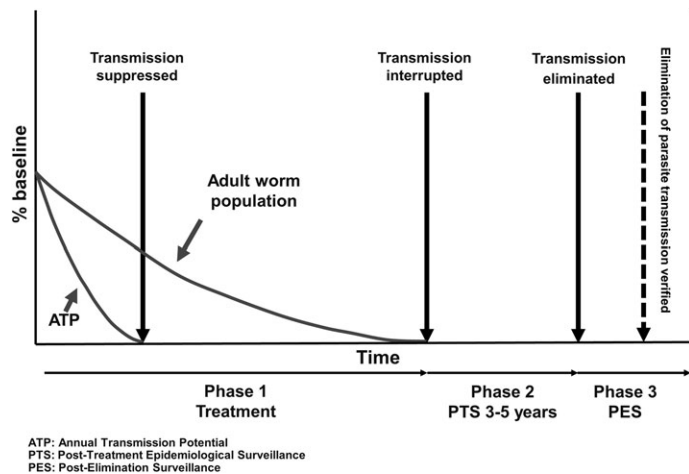


Figure 3. WHO guidelines 2016: phases of elimination of human onchocerciasis.

respectively). Revised 2016 guidelines were used for verification in Guatemala in 2016.

The steps in the roadmap are common in both the 2001 and 2016 WHO onchocerciasis elimination guidelines (see Figure 3)^{13,15} and include:

- (1) Active transmission, when the black fly vectors are transmitting the *O. volvulus* infective (L3) stages.
- (2) Transmission suppression, marked by the point when infective larvae are no longer being transmitted to humans via black flies but the adult parasites still remaining in the human population could resume transmission in the absence of MDA.
- (3) Transmission interruption, when the parasite population is so low it is not expected to recover even in the absence of treatment and thus MDA can be halted.
- (4) Post-treatment surveillance (PTS) for 3–5 years. PTS includes health education to keep communities alert to the possibility of recurrence of the infection. At the end of PTS there is

an evaluation to determine if transmission remains interrupted after MDA has been stopped.

- (5) Assuming the PTS assessment is successful, declaration of elimination.¹⁶ A country can only apply for verification of onchocerciasis elimination when all of its endemic foci have completed their PTS phases.

A WHO-appointed IVT consisting of independent international experts confirms elimination of transmission during a country visit. The IVT, which works under the auspices of the WHO/PAHO, is of different composition for each evaluation to tailor key skills to each country's context. The team first studies the country dossier submitted by the MOH, often with support of a national onchocerciasis committee. Dossiers describe the entire history of the program since onchocerciasis work began in that country, including all treatments, coverages and results from all epidemiological, entomological and serological evaluations carried out by the national program. After this review, the IVT makes a country visit to meet with MOH authorities, program personnel and selected affected communities to verify that all activities described within the dossier were realized and that the epidemiological requirements stated within the guidelines have been met by the country program. The IVT delivers a report at a debriefing meeting with MOH authorities before departing the country and submits a complete report to the WHO/PAHO. The WHO/PAHO then decides if it will accept the recommendation. If it does, the Director General of the WHO writes a letter to the minister of health indicating formal verification of the elimination of onchocerciasis transmission.

Country details

Table 1 shows the current population and status of each of the 13 foci in the six countries as of the end of 2017.

Colombia

In 2013, Colombia was the first country in the world to be verified free of onchocerciasis transmission by the WHO under the

Table 1. Onchocerciasis in the Americas: population at risk, no longer at risk, under post-treatment surveillance (PTS), eligible for treatment and transmission status by focus in 2017

Country	Focus	Treatment approach	Rounds >85% through 2016	Number of communities	Population at risk	Population no longer at risk	Population eligible for treatment	Status of transmission
Colombia	Lopez de Micay	2x/year	20	1		1366		Eliminated in 2010
Ecuador	Esmeraldas	2x/year	25	119		25 863		Eliminated in 2012
Mexico	North Chiapas	2x/year	17	13		7125		Eliminated in 2010
	Oaxaca	2x/year	18	98		44 919		Eliminated in 2011
	South Chiapas	2x/year	25	396		83 218		Eliminated in 2014
		4x/year	35	163		34 607		
	Focus total			559		117 825		
Guatemala	Escuintla	2x/year	13	117		62 590		Eliminated in 2010
	Santa Rosa	2x/year	16	37		12 208		Eliminated in 2010
	Huehuetenango	2x/year	17	43		30 239		Eliminated in 2011
	Central	2x/year	22	321		126 430		Eliminated in 2014
Venezuela	Northcentral	2x/year	17	45		14 385		Eliminated in 2013
	Northeast	2x/year	20	330		73 212		Eliminated in 2017
		4x/year	9	135		22 355		
		Focus total		465		95 567		
	South	2x/year	16	66	4248		3744	Ongoing
		4x/year	9	236	10 838		9273	
	Focus total			302	15 086		13 017	
Brazil	Amazonas	2x/year	26	117	7209		5954	Ongoing
		4x/year	13	122	8266		6634	
		Focus total		239	15 475		12 588	
Regional total				2359	30 561	538 517	25 605	

2001 guidelines. Colombia's single focus was the community of Lopez de Micay, with a population of 1366. This focus received 23 rounds of treatment under a twice-per-year approach, 20 of which reached greater than 85% coverage.¹⁷

Ecuador

Ecuador had a population of 25 863 at risk in 119 communities in a single focus that comprised several river systems in Esmeraldas. Ecuador had the distinction of the highest baseline levels of mf in the skin of any of the 13 foci and one of the region's most efficient vectors for transmitting onchocerciasis, *Simulium exiguum*. The Esmeraldas focus received 36 treatment rounds under a twice-per-year approach prior to interrupting transmission in 2009; 25 of these treatment rounds reached greater than 85% coverage. It received WHO verification of onchocerciasis transmission elimination in 2014, the second country to do so.^{18,19} The elimination success in Ecuador was an indication that the twice-per-year OEPA ivermectin strategy would likely be successful against African onchocerciasis transmission systems driven by similarly efficient vectors.

Mexico

Mexico had three onchocerciasis-endemic foci (South Chiapas, North Chiapas and Oaxaca) and overall the second largest population at risk in the Americas: 169 869 persons residing in 670

communities distributed within the states of Chiapas and Oaxaca. North Chiapas and Oaxaca received 26 and 28 rounds of treatment (17 and 18 reached greater than 85% coverage), respectively, utilizing a twice-per-year treatment strategy. The North Chiapas focus was the first to eliminate transmission in Mexico in 2010, followed by the Oaxaca focus in 2011.^{18,20} In the third and largest (559 communities) focus, South Chiapas, where the endemicity of the infection was highest, a four-times-per-year approach was implemented from 2003 to 2008 in 50 communities and from 2009 to 2011 in 163 communities; 36 four-times-per-year treatment rounds were distributed during that period, with 35 of them being greater than the 85% coverage goal. This was the first time this approach was used in the region and it helped South Chiapas achieve transmission elimination in 2014. The 396 communities that remained under the two-times-per-year approach received 34 treatment rounds from 1995 to 2011, of which 25 were greater than 85% coverage. The WHO verified Mexico as onchocerciasis transmission free in 2015.^{3,21}

Guatemala

Guatemala had the largest population at risk in the Americas (231 467 persons residing in 518 communities distributed in four different foci). Two Guatemalan foci (Santa Rosa and Escuintla) were the first to interrupt transmission in the Americas region (in 2006 and 2007).^{14,22} They were later followed by the Huehuetenango

Table 2. Yanomami Area: onchocerciasis treatment approach, population at risk, eligible population and communities

Focus	Treatment approach	Population at risk	Eligible population	Number of communities
South focus, Venezuela	2	4248	3744	66
	4	10 838	9273	236
	Focus total	15 086	13 017	302
Amazonas focus, Brazil	2	7209	5954	117
	4	8266	6634	122
	Focus total	15 475	12 588	239
Regional figures	2	11 457	9698	183
	4	19 104	15 907	358
	Regional total	30 561	25 605	541

focus (in 2008) and finally the Central focus (in 2011).^{23,24} The Guatemalan program eliminated onchocerciasis using the twice-per-year approach ranging from 18 to 28 rounds of treatment (13 to 22 reaching greater than 85% coverage) among the four foci. Guatemala received WHO verification of onchocerciasis transmission elimination in 2016 and was the first country to do so utilizing the revised WHO guidelines issued in 2016.¹

Venezuela

Venezuela has interrupted transmission of onchocerciasis in two of its three foci, where the combined at-risk population is 109 952. The Northcentral focus has successfully completed the 3 years of PTS required to declare elimination after 20 rounds of treatment (17 of which reached greater than 85% coverage) under the twice-per-year approach. In the Northeast focus the twice-per-year approach was altered in 2010 to four-times-per-year in 40 of the most endemic communities in an effort to hasten interruption of transmission. In 2011, another 95 communities were added to the quarterly treatment approach. Treatment was halted in 2013 after 24 (20 greater than 85% coverage) treatment rounds under the twice-per-year approach and 12 rounds under the four-times-per-year approach (9 rounds greater than 85% coverage). This focus successfully completed its PTS assessments in 2017 and transmission was declared eliminated.²⁵ The South focus of Venezuela had the highest baseline rate of mf in the skin registered in the Americas (72% in 1998). It is contiguous to Brazil's Amazonas focus and comprises the Yanomami Area.

Brazil

Brazil has only one focus (Amazonas), which, together with the South focus of Venezuela, comprises the Yanomami Area, which is discussed below. Amazonas had the second highest baseline rate of mf in the skin in the region (63% in 1995).

The Yanomami Area of Venezuela and Brazil

The Yanomami Area harbors the last active transmission of onchocerciasis in the Americas. The 30 561 persons at risk present

a special challenge in that they are a largely migratory population that moves freely across the border of the two countries. The Yanomami are not only difficult to reach, but can also be difficult to locate.

The latest PAHO resolution (CD55.R9 from 2016) pertaining to elimination of all regional NTDs calls for onchocerciasis elimination by 2022 in Brazil and Venezuela.¹¹ The majority of treatments in the Yanomami Area now fall under the four-times-per-year approach in order to aggressively pursue the 2022 target (see Table 2). Venezuela's South focus currently has 15 086 individuals at risk, distributed in 302 communities, with 236 of these (all hyper- and mesoendemic communities) targeted for receiving treatment four times per year. The remaining 66 communities are hypoendemic and under the twice-per-year treatment scheme. In Brazil's Amazonas focus, 15 475 persons are at risk in 239 communities, of which 100 are hyperendemic, 66 are mesoendemic and 73 are hypoendemic. While Brazil decided to treat quarterly in all of its endemic communities in the Amazonas focus in 2016, it was often unsuccessful in reaching the 85% coverage targets. Therefore Brazil is planning to revert back to twice-per-year treatments in 117 meso- and hypoendemic communities for 2017 in order to focus its limited resources for four-times-per-year treatments in the 122 communities that are meso- and hyperendemic. Many communities in both countries have successfully suppressed transmission due to sustained high coverage for numerous treatment rounds; there is indeed evidence that transmission has been suppressed in about 70% of the endemic communities in Venezuela.²⁶ Table 1 gives more detail on the rounds of treatment exceeding high coverage in this shared focus.

Challenges abound for the Yanomami Area. It is difficult to traverse the rugged and riverine terrain, with non-existent roads, potentially dangerous situations with illegal miners and conflict between Yanomami communities. Finding dedicated staff to work in the remote jungle for months at a time is no small feat. There is inadequate air transport (particularly helicopters on the Venezuelan side) to allow program personnel to reach the most remote areas, which more often require four-times-per-year treatment. The total number of communities in the Venezuelan Yanomami Area remains uncertain; each year since 2008, new communities have been identified in the South focus that were either unknown to the health system altogether or had been

untraceable in recent years. The identification of all such endemic communities represents one of the major challenges to the program. Upon evaluation, a significant proportion of new (or reintegrated) communities were found to be hyperendemic for onchocerciasis. Given their geographic and epidemiological overlap, the Amazonas and South foci will have to continue to give treatments (ideally under a coordinated binational approach) until transmission is interrupted on both sides of the Brazil–Venezuela border.

Solutions to these challenges also abound. There is a core group of dedicated ministry personnel on both sides of the border who are determined to reach the goal of onchocerciasis elimination and who are always developing new strategies to tackle the disease. The Yanomami people have begun to participate in the program ('Indigenous Health Agents') and they are expected to play a crucial role in obtaining and sustaining at least 85% treatment coverage in all targeted communities. Military and private aircraft assist in getting sustained treatment to the remote communities, and there is a project to recover abandoned airstrips, which reduces the need for more expensive helicopter transport. The quest to identify all untreated communities in the region has included remote sensing (satellite imagery) work with several organizations (National Aeronautics and Space Administration, University of South Florida, University of Georgia and others). In 2014, recognizing the need for implementation of binational treatment activities, the governments of Brazil and Venezuela signed a memorandum of understanding that they would work in a coordinated fashion to eliminate onchocerciasis as soon as possible in the border area. More needs to be done to implement this agreement, however.

Costs

The 25-year OEPA initiative has cost more than \$165 million. Approximately 40% of program costs have been supported by the country governments, 34% by MSD ivermectin donation and 26% by financial support from numerous partners donating to the OEPA through the Carter Center. The fact that the six endemic countries have provided the greatest percentage of support to

the effort is notable; they recognize the need to invest in freeing their people from onchocerciasis forever.

It is also important to note that for several years after major programmatic efforts related to treatment activities have been suspended, considerable costs associated with the program remain. PTS activities include maintenance of a health system that is ready to immediately re-establish treatment activities if the need arises. Health education is needed to explain to community members why their treatment was suspended after many years and to keep them alert and prepared for any evidence of transmission resurgence (such as the reappearance of nodules). In some cases, communities are disappointed to lose the several ancillary benefits associated with ivermectin, especially against intestinal parasites and ectoparasites, and this must be addressed by the program.²⁷ The last step in PTS is the cost associated with a final PCR-based entomological evaluation. Having successfully completed this evaluation, ministries of health must be prepared to make expenditures to compile a detailed dossier to submit to the WHO for verification of elimination and then to host the international verification team.

Discussion

The OEPA initiative has contributed in a very substantial way to the global agenda for onchocerciasis elimination. It was first to articulate a policy of twice-per-year ivermectin to break the transmission cycle, first to draft criteria for WHO consideration for certification of transmission elimination, first to operationally use laboratory-based OV16 antibody tests in children (instead of skin snips) as an elimination criterion and first to have countries verified as free of onchocerciasis transmission by the WHO. It is also the first regional initiative to help multiple national programs achieve the steps in the WHO onchocerciasis elimination pathway: reaching scale, maintaining treatment coverage, interrupting transmission, stopping MDA and ultimately demonstrating transmission elimination in the PTS period (Figure 4). The OEPA established a laboratory support system to perform ELISA-based

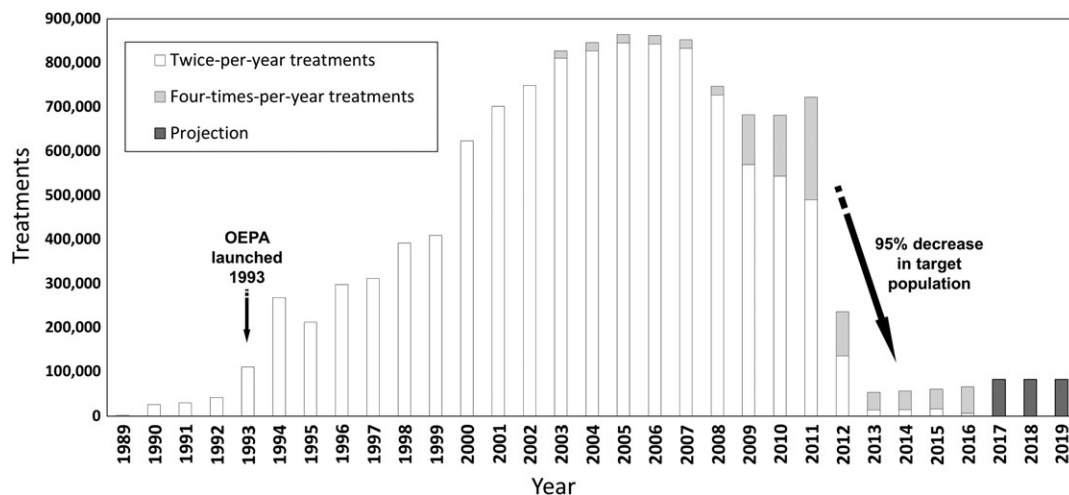


Figure 4. Mectizan treatment in the Americas 1989–2016 and projection for 2017–2019 showing twice- and four-times-per-year treatment approaches.

OV16 testing of dried blood spots and PCR-based pool screening of vectors to detect *O. volvulus* DNA. Beginning in 1996 the OEPA has documented its progress annually in the *Weekly Epidemiological Record*, and countries publish their progress in peer-reviewed publications. Some of these were cited as key information for revision of the WHO guidelines in 2016,¹⁵ guidelines that were used immediately after their publication for the verification of elimination of onchocerciasis transmission in Guatemala. The achievements in the Americas helped inspire several African programs to move from a control to an elimination strategy, especially Sudan in 2006 and Uganda in 2007.

The PCC of the OEPA has played a key role as the steering committee of the OEPA program. But another key PCC goal is to foster country ownership, decision making, investment and political will to succeed. The PCC provides independent programmatic recommendations to national programs, being ever careful to recognize that it is the governments and ministries of health of the countries that have the responsibility of making all decisions pertaining to their programs. The country decides when key milestones in the elimination pathway have been met, such as when to stop MDA or when to request WHO verification. Furthermore, it is the WHO, and not the PCC, that is involved directly with each country in the process of verification. The PCC terms of reference, defining its role as an independent advisory committee to each Ministry of Health, have served as a model and inspiration for national onchocerciasis elimination committees in Ethiopia, Nigeria and Uganda (more details on elimination committees in Africa are given in the section of this supplement entitled 'The role of national elimination committees in eliminating onchocerciasis').

The 'final inch'

As demonstrated by the Guinea Worm Eradication Program in Africa,²⁸ ultimately the most challenging piece of the elimination puzzle in the Americas will be the 'final inch,' the Yanomami Area. While representing just 5% of the population in the Americas initially at risk for onchocerciasis, the costs required for personnel, supplies, security needs, flight hours and time required to reach these extensive remote areas are staggering. The continued partnership and endurance of numerous donors, coupled with the dedication of the technical teams in the countries, are critical to the success of this endeavor.

However, it is the current lack of political will to accomplish this task in Brazil and Venezuela that is the greatest barrier to success. While the Yanomami people can move freely across the border between Brazil and Venezuela, program officials are not allowed to cross the border to treat them. While the closest landing strips to some high-endemicity Venezuelan communities are in Brazil, they cannot be used as staging points for air support. Despite the 2014 binational agreement pledging annual meetings to approach onchocerciasis elimination in a joint fashion, high-level government officials have only met once (in Caracas in February 2015). Since then, the two countries have had increasingly tense relations that are unlikely to improve in the near future. We commend the Ministry of Health technical staff of both countries for their courage, their excellent working relationships and their tireless work in the Yanomami Area despite a lack of attention to the program from their political leaders.

Conclusion

From its beginning, the well-documented OEPA initiative has served as an excellent example of 'walking the onchocerciasis elimination walk.' Colombia, Ecuador, Mexico and Guatemala are the first countries in the world to receive WHO verification of onchocerciasis transmission elimination. Active transmission of onchocerciasis in the region of the Americas is now limited to the Brazil and Venezuela cross-border Amazon rainforest Yanomami Area. As in all elimination efforts, finishing the last 5% (the final inch) will be an enormous challenge, and garnering the political will to complete the task surpasses even the daunting logistical and financial challenges of reaching the Yanomami. Costs will remain high, and investment is required for several years after a program ceases treatment, during PTS, during preparation of the elimination dossier and in hosting the international verification team.

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