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THE CARTER CENTER'S ASSISTANCE TO RIVER BLINDNESS CONTROL PROGRAMS: ESTABLISHING TREATMENT OBJECTIVES AND GOALS FOR MONITORING IVERMECTIN DELIVERY SYSTEMS ON TWO CONTINENTS

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Abstract. Periodic mass treatment with ivermectin in endemic communities prevents eye and dermal disease due to onchocerciasis. As part of an international global partnership to control onchocerciasis, The Carter Center's Global 2000 River Blindness Program (GRBP) assists the ministries of health in ten countries to distribute ivermectin (Mectizan®, donated by Merck & Co.). The GRBP priorities are to maximize ivermectin treatment coverage and related health education and training efforts, and to monitor progress through regular reporting of ivermectin treatments measured against annual treatment objectives and ultimate treatment goals (e.g., full coverage, which is defined as reaching all persons residing in at risk villages who are eligible for treatment). Since the GRBP began in 1996, more than 21.2 million ivermectin treatment encounters have been reported by assisted programs. In 1999, more than 6.6 million eligible persons at risk for onchocerciasis received treatment, which represented 96% of the 1999 annual treatment objective of 6.9 million, and 78% of the ultimate treatment goal in assisted areas.

INTRODUCTION

Infection with the vector-borne parasite *Onchocerca volvulus* (human onchocerciasis) is characterized by skin and eye lesions.[1] The infection is transmitted in rural areas by *Simulium* species black flies that breed in rapidly flowing rivers and streams, and the high prevalence of infection in agrarian communities located near rivers has led to the common name for the disease, river blindness. The adult male and female parasites live between eight and 15 years,[2] and often are found encased in fibrous, subcutaneous nodules. The pre-larval forms (called *microfilariae*) released by the thousands from the female worms emerge from the nodules and swarm underneath the skin, often inflaming the dermis. Microfilariae may enter the eyes, causing visual damage and, in some, blindness. The World Health Organization (WHO) estimates that 123 million people are at risk of infection in an estimated 37 countries in Africa, Yemen, and the Americas; more than 99% of the population at risk resides in Africa. Globally, some 270,000 persons are estimated to be blind from onchocerciasis, with another 500,000 severely visually impaired.[3]

Ivermectin (Mectizan®; Merck & Co., Rahway, NJ) is a potent, oral, microfilaricidal drug with a markedly improved safety profile compared with that of diethylcarbamazine.[4] The drug is not lethal to the adult *O. volvulus* parasites, but when given as a single dose at least annually it keeps levels of microfilariae in the body low enough to prevent skin[5] and eye disease[6] from developing in those who are infected. In 1987, Merck & Co. announced that it would donate ivermectin indefinitely to clinic and community based treatment programs, with the goal of ultimately achieving global control of river blindness. Supplies of ivermectin tablets are obtained by submitting annual applications to the Mectizan® Donation Program. The donation has spawned a remarkable 'public/private' global initiative that involves many partners and has enabled more than 100 million ivermectin treatments.[7,8] A detailed presentation of the initiative is found in a 1998 supplemental issue to volume 92 of the *Annals of Tropical Medicine and Parasitology.*

Governments of onchocerciasis endemic countries, through their ministries of health, have the primary responsibility to provide sustained, repetitive treatment to populations at risk for onchocerciasis. The ministry of health ivermectin distribution programs are often assisted by non-governmental development organizations (NGDOs), international organizations (WHO, UNICEF, World Bank), and donors. An ivermectin distribution program must accomplish the following activities: 1) recruit and train personnel, 2) educate and mobilize leadership and the general population, 3) acquire, securely store, and account for ivermectin, 4) provide health education to the population being offered ivermectin, so that there is general understanding of the benefits (better vision, improved skin conditions, expulsion of intestinal parasites) and risks (adverse reactions) related to treatment, 5) distribute the drug with high coverage, 6) monitor for and treat adverse reactions, and 7) document program activities and report to local, national, and international health authorities. Timely reporting to the Mectizan Donation Program is required to ensure uninterrupted donations of ivermectin to the programs.

The Carter Center's Global 2000 River Blindness Program (GRBP) is one partner in this remarkable effort. The GRBP assists ministries of health in 10 countries on two continents in delivering ivermectin. It was established in 1996 as the continuation of the Houston-based River Blindness Foundation, which itself was founded in 1990 by philanthropists John and Rebecca Moores. A special partner in about 80% of GRBP-assisted activities are the Lions Clubs and the Lions Clubs International Foundation. An important focus of the GRBP program is the emphasis on routine reporting and

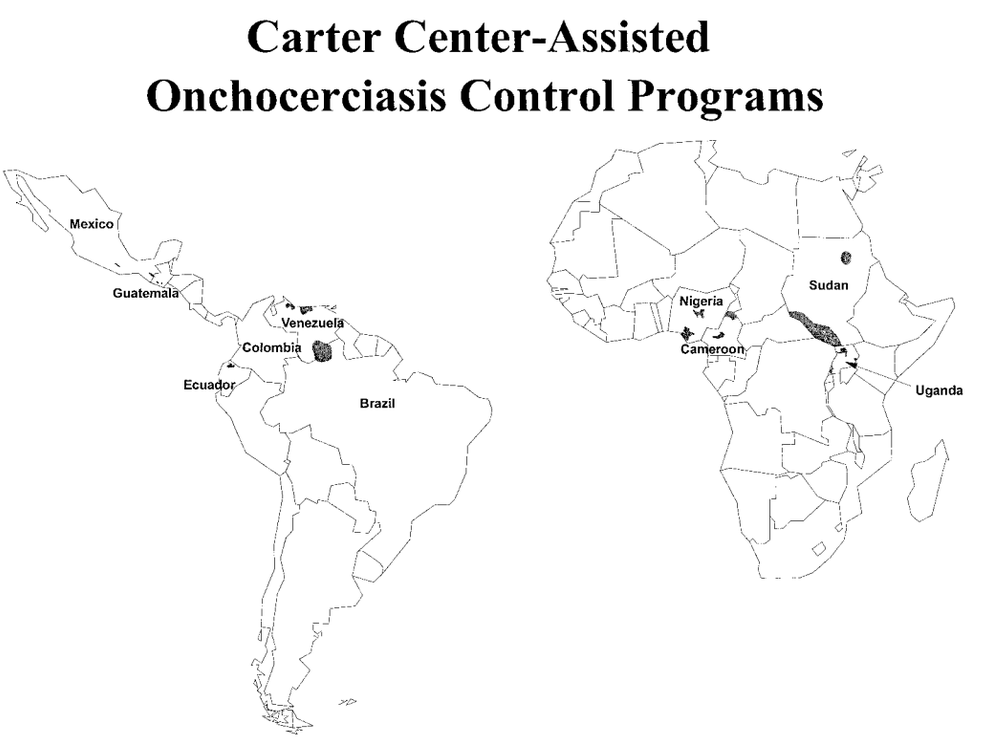

FIGURE 1. Areas in 10 countries assisted by the Global 2000 River Blindness Program of The Carter Center.

monitoring of treatments. This paper will present a compilation of the 1996−1999 treatment data reported by GRBP-assisted programs and discuss how treatment objectives and goals are established to assess how GRBP assisted areas are progressing toward reaching full treatment coverage.

METHODS

GRBP-assisted areas. During the period 1996−1999, the GRBP assisted ministries of health in ivermectin delivery activities in 10 countries in Africa and the Americas (Figure 1). The GRBP assisted in nine of 32 onchocerciasis endemic states in Nigeria (Abia, Anambra, Delta, Ebonyi, Edo, Enugu, Imo, Nasarawa, and Plateau States),[9,10] in 10 of the 18 endemic districts in Uganda (Adjumani, Apac, Gulu, Kabale, Kasese, Kisoro, Mbale, Moyo, Nebbi, and Rukungiri Districts),[11,12] and in two of 10 endemic provinces in Cameroon (North and West Provinces).[13] In Sudan, where the program must contend with a civil war that has waged for more than 15 years, the GRBP assisted the ministry of health (in Khartoum) to provide treatments in areas controlled by the Government of Sudan, as well as three NGDOs based in Nairobi (Aktion Afrika Hilfe, International Medical Corps, and World Vision International) to distribute ivermectin in parts of areas controlled by opposition forces in the south.[14−16] Through the Onchocerciasis Elimination Program for the Americas (OEPA), the GRBP assisted in all endemic areas of all six endemic countries in the Americas (Brazil, Colombia, Ecuador, Guatemala, Mexico, and Venezuela).[17]

At risk villages (arv). Rapid assessment techniques were used to define villages in need of mass ivermectin treatment. The approach used in Africa varied from that used in the Americas. In Africa, a staged village sampling scheme (called Rapid Epidemiological Mapping of Onchocerciasis)[18] is recommended by WHO to identify 'zones' that capture most or all villages having onchocercal nodule rates $> 20\%$ for mass treatment. The strategy is based on studies that show most morbidity from onchocerciasis occurs in village populations having nodule rates $> 20\%$.[3] Survey villages were selected from areas that are environmentally likely to support intense *Simulium* breeding and therefore transmission of *O. volvulus.* In the second stage, the survey villages were visited and a convenience sample of 30−50 adults were examined (by palpation) for onchocercal nodules. The mean nodule prevalence for the villages, along with their latitude and longitude coordinates, were analyzed by a geographic information system that defined endemic zones surrounding villages having nodule rates $> 20\%$. Any village falling within the treatment zone was considered at risk and offered annual mass ivermectin treatment. In the Americas, where the goal is to eliminate both morbidity and transmission from *O. volvulus,* any village where onchocerciasis transmission occurs was considered at risk and offered mass ivermectin treatment. All villages in known or suspected endemic areas were assessed through evaluation of a sample of 50 long-term adult residents (who have both palpation examinations and superficial skin biopsies to identify *O. volvulus* microfilariae in skin).[3] Villages where one or more persons examined were positive were considered at risk, and recommended for mass ivermectin treatment.

Eligible populations. The eligible at risk population (earp) was defined as all persons living in at risk villages

who can receive ivermectin in accordance with the Mectizan® Donation Program guidelines. Persons who should *not* receive treatment (ineligibles) were young children (less than five years of age, body weight less than 15 kg, or height less than 90 cm), anyone in poor health, pregnant women, or women nursing newborn infants less than one week of age. Annual orders for ivermectin tablets were calculated based on known or estimated (calculated to be 85% of the total population) eligible population figures.

GRBP data reporting for 1996–1999. The GRBP/Carter Center program offices submitted monthly reports to Atlanta headquarters that included numbers of villages [TX(arv)] and persons treated [TX(earp)] during the previous month (or quarter for the Americas), and cumulative treatments for the year. The data that were reported originated from records prepared during mass treatment activities carried out by village distributors and national ministry of health personnel. The accuracy of these reports was routinely confirmed through random spot checks performed primarily by ministry of health personnel, supplemented by GRBP/OEPA staff site visits, and by Lions Clubs members in Cameroon (District 403B) and Nigeria (District 404). Summary reports of numbers of villages and persons treated were compiled at the district level and forwarded (whenever possible) through ministry of health reporting channels to the headquarters of the national onchocerciasis programs and the national Carter Center offices. In Sudan, reports of treatments by the government were compiled in Khartoum, while reports from opposition-held areas of south Sudan through a coordinating NGDO (HealthNet International) in Nairobi. In the Americas, treatment reports by the six national programs were compiled at OEPA headquarters in Guatemala City. The data from these reports were reviewed and supplemented with additional information at annual GRBP Program Reviews held each February at The Carter Center in Atlanta (a Proceedings for the latest Program Review is available from the corresponding author upon request).

Treatment indices. Cumulative numbers of at risk villages and eligible at risk persons treated were divided by annual (calendar year) treatment objectives (ATOs) to show percentages of objectives achieved. The ATO for at risk villages [ATO(arv)] was the number of at risk villages that a program projected it could reach during the year. The ATO for eligible at risk population [ATO(earp)] was the number of persons who could receive ivermectin known or thought to be living in those at risk villages. The ATO(earp) was expected to be the same figure used in the annual request for tablets submitted to the Mectizan® Donation Program. The ATO figures were scrutinized and revised annually (when it was time to prepare new tablet orders) against the latest mapping information and village census data during provincial level review exercises with district program managers. The accuracy of these data varied among programs. In Sudan, in particular (given war, famine, and population displacement), only a rough estimate of the ATO(earp) could be made, and the ATO for at risk villages has never been established.

Full geographic coverage, ultimate treatment goals, and full treatment coverage. Full geographic coverage was reached when the program was able to extend mass treatment services [TX(arv)] to all at risk villages in the assisted area. The ultimate treatment goal (UTG) was defined as the sum of the known or estimated eligible populations living in all at risk villages in the assisted-area. That is, the UTG was that number of persons to whom the program *ultimately* has to provide ivermectin treatment. Full treatment coverage occurred when a given program treated the UTG; in other words full coverage was defined when the reported values for TX(earp), ATO(earp), and UTG were equal. The GRBP program progress was judged by the ability to meet ATO objectives, and to increase those objectives over a reasonable time period to reach the ultimate treatment goal.

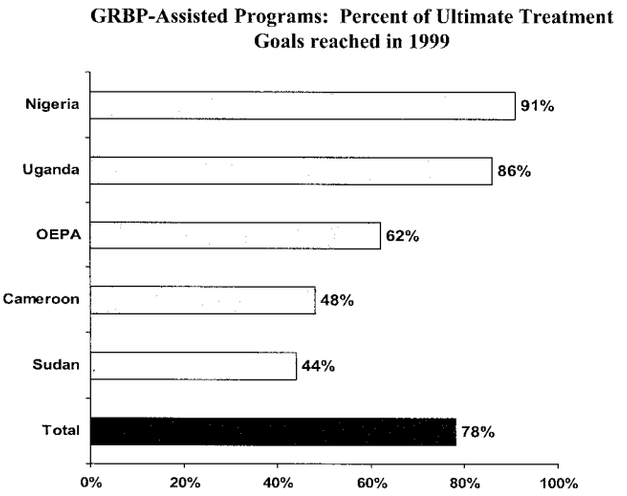

FIGURE 2. The Carter Center's Global 2000 River Blindness Program (GRBP) program progress is shown toward reaching the ultimate treatment goal of 8,554,746 persons (defined as the sum of the known or estimated eligible populations living in all at risk villages in the assisted area). Overall success in 1999 averaged 78%, led by the Nigerian (91%) and Ugandan (86%) programs.

RESULTS

Treatments over the period 1996–1999. Cumulative reports of 21.2 million ivermectin treatment ''encounters'' were received since GRBP began in 1996, which represent 93% achievement of 1996–1999 ATO(earp) objectives. The GRBP assisted areas reported an ultimate treatment goal of 8,554,746 persons, and therefore treatments in 1999 (6,631,242) reached 78% of the ultimate treatment goal (Figure 2). The Nigerian GRBP program's 1999 ATO(earp) was 90% of its UTG, and Uganda's 1999 ATO(earp) was approximately 86% of the UTG. The six American countries, reported as a combined figure (OEPA), reached 62% of the regional UTG. Both Cameroon and Sudan ATO(earp)s were at less than 50% of their UTGs. The objective set by GRBP-assisted programs for 2000 of 7,415,440 represented 87% of the GRBP UTG. The Nigeria, Uganda, and American regional programs all aimed for greater than 90% of their UTGs in 2000.

Figure 3 shows the distribution of GRBP-assisted treatments, by program and year, with the proportion the treatment objectives met, and a final bar for each group representing the ultimate treatment goals. The Nigerian GRBP program routinely reached more than 95% of its ATO(earp). Similarly, in Uganda, assisted treatments in 1998 and 1999

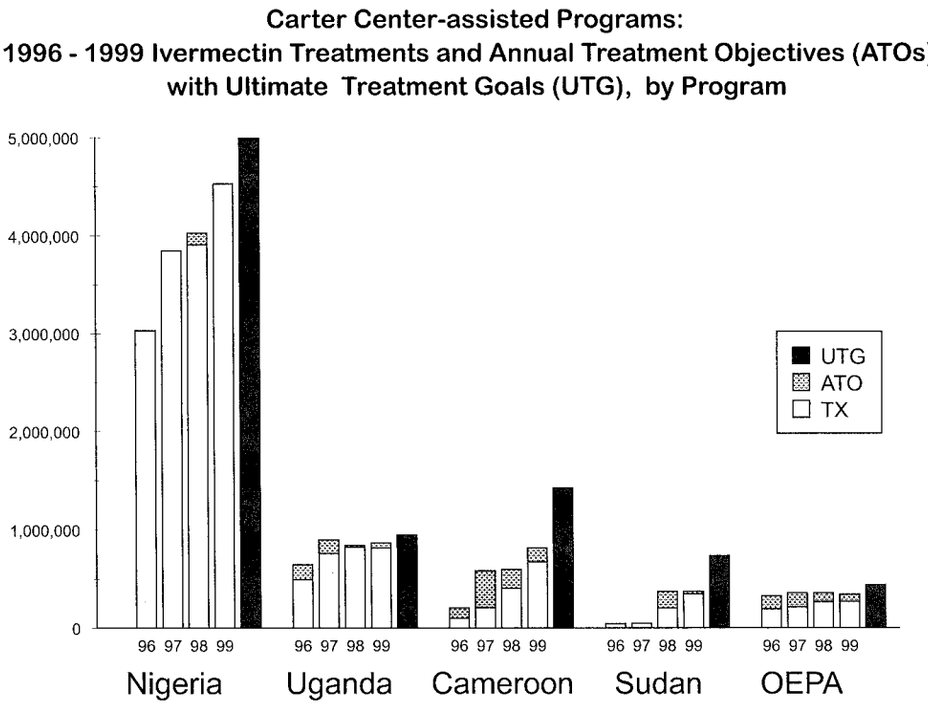

FIGURE 3. Distribution of Global 2000 River Blindness Program-assisted treatments of the eligible at risk population (TX), by program and year. Also shown (**stacked bars**) is the proportion the TX represents of the annual treatment objective (ATO) for that year, and a final bar for each group represents the ultimate treatment goals (UTG).

reached more than 90% of its ATO(earp)s. In contrast, the data shows that in Cameroon only between 60% and 80% of the treatment objectives were met as overly ambitious ATO(earp)s were set to quickly expand to full geographic coverage. In Sudan, there has been a remarkable increase in GRBP-assisted treatments during the time period, with a 343% increase between 1997 and 1998, and a 69% increase between 1998 and 1999, despite the difficult conditions. The Sudan effort reached 94% of its 1999 ATO(earp) (the first year such an objective was established). In the Americas, treatments in 1998 and 1999 appeared to have reached a plateau at about 270,000 over the period as Ecuador, Mexico, and Colombia reached their UTGs. The Guatemalan and Brazilian programs' poorer performances prevented OEPA from reaching its regional ATO(earp). The gap between the 1999 American regional ATO(earp) of 345,512 and the regional UTG (442,114) is almost entirely due to Venezuela, where the national program just completed its villages risk assessment surveys in 1999, and plans to establish mass treatment program in all at risk villages identified by the end of 2001.

The 1999 treatment year. Table 1 shows monthly treatment figures reported by GRBP-assisted programs in 1999, with the six American countries reported as a combined figure (OEPA). Mass treatment activities were provided to 6,631,242 persons in the 10 assisted countries, and in at least 13,375 at-risk villages in nine countries (Sudan village figures were not reported). The treatment of eligible persons represented 96% of the 1999 ATO, and an 18% increase in GRBP treatments assisted in 1998 (5,626,767). As in other years, most (69%) GRBP-assisted treatments in 1999 were provided in Nigeria, where GRBP helped provide ivermectin to 4,532,677 persons in 7,924 at risk villages. In Sudan, there were 326,779 GRBP-assisted treatments (87% of the ATO(earp)), with 261,094 provided in partnership with the Government of Sudan, and 65,685 through the collaborating NGDOs operating in the rebel-held south. In the Americas, 273,875 treatments were provided, 79% of the 1999 ATO(earp). Ninety percent of ivermectin treatments in the Americas took place in three countries: Mexico, Guatemala, and Ecuador.

DISCUSSION

The international initiative against river blindness is based on a public/private partnership that involves at risk populations, ministries of health, industry, international organizations, NGDOs, research organizations, academia, and donors.[17,19,20] Fundamentally, however, the credit for the 21.2 million ivermectin treatment encounters reported here belongs to district level health care workers and community residents. It should also be stressed that the treatments achieved resulted from both the delivery of tablets and the health education and training needed to empower those with onchocerciasis to be full partners in the program and to sustain the drug delivery process.[19] Many other international and local NGDOs in addition to The Carter Center are involved in the river blindness initiative, which points to the important role NGDOs can and should play as partners in international health initiatives.[9,11,21]

There are two key elements of the full coverage equation used by our program. The first is complete geographic cov-

TABLE 1

Onchocerciasis: 1999 ivermectin treatment figures for The Carter Center's Global 2000 River Blindness (GRBP)-assisted areas in Nigeria, Cameroon, Uganda, and collaborative programs in Latin America and Sudan

Country/Tx Category	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	% ATO	% All GRBP TX
Nigeria	ATO(earp) = 4,475,000		ATO(arv) = 7,859												
TX(earp)	694	58,917	725,212	286,772	435,729	1,046,684	376,844	522,614	445,982	138,233	366,456	128,540	4,532,677	101%	69%
TX(arv)	2	164	1,385	498	845	1,664	704	828	806	115	800	113	7,924	101%	59%
Uganda	ATO(earp) = 868,466		ATO(arv) = 1,730												
TX(earp)		13,966	173	16,230	145,995	135,944	68,869	34,477	99,827	164,298	139,440	248	819,467	94%	12%
TX(arv)			31	166	166	255	344	50	171	299	248		1,730	100%	13%
Cameroon	ATO(earp) = 817,134		ATO(arv) = 2,476												
TX(earp)	72,902	28,849	20,325	20,015	56,551	32,367	65,069	85,704	104,671	116,336	38,729	36,926	678,444	83%	10%
TX(arv)	210	155	85	109	134	77	150	501	298	134	49	265	2,167	88%	16%
OEPA	ATO(earp) = 345,512		ATO(arv) = 1,798												
TX(earp)			126,987			1,479				139,727		5,682	273,875	79%	4%
TX(arv)			986							499		69	1,554	86%	12%
Sudan	ATO(earp) = 376,310		ATO(arv) = Unknown												
TX(earp)	6,689	8,556	23,045	32,108	44,261	28,017		1,072	7,379			175,652	326,779	87%	5%
TX (arv)															
Total	ATO(earp) = 6,882,422		ATO(arv) = 13,863												
TX(earp)	80,285	110,288	895,742	355,125	682,536	1,382,739	510,782	643,867	657,859	558,594	544,625	347,048	6,631,242	96%	100%
TX(arv)	212	319	2,487	773	1,145	1,996	1,198	1,379	1,275	1,047	1,097	447	13,375	96%	100%

ATO = annual treatment objectives; earp = eligible at-risk population; arv = at-risk villages; TX = mass treatment; OEPA = Onchocerciasis Elimination Program for the Americas.

erage, which occurs when the treatment services have expanded to all at risk villages defined through rapid assessment exercises. The second element is full population coverage, which occurs when ivermectin tablets reach all eligible persons known or estimated to live in those at risk villages. Combined, these two elements define a numerical end point value (the UTG) to be reached by the program. In contrast to the ATO(earp), which is established with careful consideration of program maturity and 'on the ground' capacity, the ultimate treatment goal is based on the actual and total need for ivermectin delivery services in the areas being served. The full coverage approach employed here may be useful to other mass treatment programs for lymphatic filariasis, schistosomiasis, intestinal helminthiasis, and trachoma.

Coverage percentages provided in this report may not be comparable to those communicated by other ivermectin treatment programs. The denominator we used (persons eligible for ivermectin treatment in at risk villages [ATO(earp)]), results in higher coverage rates than treatment coverage rates calculated based on total population residing in at risk villages. There are several reasons we elected to use eligible population as denominator in our coverage calculations. First, the estimate of eligible persons in at risk villages must be determined to make the annual request for ivermectin tablets, and that treatment projection is an accountable figure to the Mectizan® Donation Program for subsequent resupply. Second, we have found that fixing the ATO(earp) denominator at state, district, and village level each year helps to establish a basis for monitoring at all program levels. In our hands, use of total population as the denominator caused confusion in the reporting chain since village census figures were continuously being updated, and, as a result, district denominators were rarely consistent with those held at higher levels in the reporting system. Lastly, use of the eligible population as denominator allows for a maximum coverage of 100%. Poor coverage (defined as $<$ 80%) could indicate poor program function, drug shortages, or lack of community acceptance. Similarly, coverages $>$100% could indicate poor planning, the need to revise census figures, or treatment of nonresidents (immigrants, visitors) in at risk villages. Coverage figures using total population denominators cannot by definition reach 100% due to the ineligible component. The composition of the ineligible component may vary with changes in the population pyramid that occur in areas with civil unrest and population migration (such as in Sudan).

We believe that this report demonstrates the usefulness of routine ivermectin treatment surveillance, and the need to monitor program progress towards clearly defined annual treatment objectives and ultimate treatment goals. In some countries and programs, there remains a lack of emphasis on surveillance of ivermectin treatments. Although the onchocerciasis initiative has been celebrated for extending the peripheral primary health care system to previously underserved areas,[22] more focus could be placed on the process of projecting and reporting treatments. This might strengthen the national surveillance infrastructure, enhance the routine discourse between village workers and peripheral preventive/public health personnel, and prepare the way for other programs based on similar mass treatment strategies.

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