THE LEOGANE, HAITI DEMONSTRATION PROJECT: DECREASED MICROFILaremIA AND PROGRAM COSTS AFTER THREE YEARS OF Mass Drug Administration

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Abstract. To support the global program to eliminate lymphatic filariasis (LF), well-monitored demonstration projects are important for defining the relationship between coverage and reductions in microfilariaemia. We are using mass treatment with diethylcarbamazine (DEC) and albendazole in an effort to eliminate LF from Leogane, Haiti. Wuchereria bancrofti microfilariaemia prevalence at baseline ranged from 0.8% to 15.9% in four sentinel sites. After three rounds of DEC-albendazole mass drug administration (MDA), both microfilariaemia prevalence and intensity decreased dramatically. Mild and moderate adverse reactions after treatment were common, especially after the first MDA, but decreased after subsequent MDAs. Drug coverage for the first year was estimated to be 72%, but concerns about adverse reactions appeared to decrease drug coverage in the second MDA. As a result of community education efforts that focused on providing a greater understanding of adverse reactions, coverage increased dramatically for the third round. Program coverage increased substantially; the costs per person treated for three rounds of MDA were $2.23, $1.96, and $1.30 per person, respectively. The Leogane experience highlights the importance of adapting community education and mobilization campaigns to achieve and maintain good coverage.

INTRODUCTION

Approximately 120 million persons are infected with the filarial worms Wuchereria bancrofti and Brugia malayi. Despite these overwhelming numbers, there is substantial optimism that lymphatic filariasis (LF) can be eliminated. First, there is historical evidence that transmission of LF can be interrupted directly as a result of public health interventions or indirectly through economic development. Second, new tools have been developed to facilitate mapping of at-risk areas and implementation of mass treatment. Annual treatment with diethylcarbamazine (DEC) and ivermectin in combination with albendazole leads to substantial reductions in the prevalence and intensity of filarial infection in both humans and vector mosquitoes. Lymphatic filariasis elimination programs based on community education and mobilization have been successful in controlling LF transmission in parts of Africa and Asia; however, the costs of drug distribution in Leogane and our analysis of the costs of the program.

MATERIALS AND METHODS

Study site. Leogane is located approximately 30 km west of Port au Prince, Haiti. The commune includes two distinct zones: a coastal plain and a mountainous area. Surveys of school children showed that W. bancrofti antigen prevalence was as high as 50% or more in communities located in the coastal plain; infection levels in the foothills and mountains were significantly lower. Because of the lack of census information, neither the population of the plains nor of the commune of Leogane was known with certainty when the project started; estimates ranged from 100,000 to 200,000. Programmatic efforts were concentrated in the plains because of the higher endemicity in this region.

Community education and social mobilization. Nearly one year was spent on the community mobilization process prior to the first annual mass drug administration (MDA). Health education messages that focused on transmission and prevention of filariasis were developed and tested. These messages were used as the basis for training a team of health educators and Hopital Ste. Croix community health workers. To disseminate the filariasis messages as broadly as possible, health educators conducted hundreds of community meetings in schools, churches, and at vaccine posts to explain the nature of the program. In the weeks leading up to the annual MDA, radio spots, posters, banners, and a sound truck were used to mobilize the public to participate in the MDA and to provide information on the dates of the MDA and location of the distribution posts. Health messages were modified annually, based on community feedback obtained through knowledge, attitudes, and perceptions (KAP) surveys, focus groups, and
informed discussions between project staff and community residents. For example, a television powered by a portable generator was used to show LF videos in evening community meetings after the MDA in the second year and flip charts were used to address specific community concerns as discussed in this report. Community leaders also supported the program by recording public service announcements for local radio stations.

**Sentinel sites.** To monitor programmatic progress, four plains communities were selected to serve as sentinel sites. These communities were selected to be representative of the at risk population in terms of the type of community (e.g., rural versus urban) and the filarial antigen level. Sentinel sites served as the focus of research activities in the context of the overall public health program. Research protocols were reviewed and approved by Centers for Disease Control and Prevention and University of Notre Dame Institutional Review Boards and the Ethics Committee of Hopital Ste. Croix.

**Filarial infection.** Microfilaraemia prevalence and intensity as well as antigen prevalence were monitored at baseline and at annual intervals. Blood collections were done between 7:00 PM and 9:00 PM. Thick films were prepared (20 μL), stained with Giemsa, and examined for microfilaria. Antigenemia was detected with the immunochromatographic card test (ICT). For surveys conducted in 2000 and 2001, this was done with cards produced by Amrad-ICT (Melbourne, Victoria, Australia); for the 2002 surveys, the cards were produced by Binax (Portland, ME).

**Mass drug administration.** Health clinics, churches, and private houses were used as distribution posts. Schools were added as distribution posts in 2001 and thereafter. Distribution posts were selected to cover the entire plains to provide convenient access for persons in all communities. Numbers of posts varied from 103 in 2000 to 71 in 2001 to 133 in 2002. Each post was staffed by community volunteers who received a small payment (350–500 Gourdes, approximately $10–15) for the work. These persons distributed the DEC and albendazole and provided the first care for treatment-related adverse reactions. Community health workers and program staff supervised the distribution posts. Diethylcarbamazine was distributed to all persons greater than two years of age, except pregnant women and those who were judged by drug distributors to be too ill to receive treatment. The dose of DEC was based on age for children less than 18 years old. We previously showed that age and height were strongly correlated with weight among children in the commune (Beach MJ and others, unpublished data). Adults received a standard DEC dose of 400 mg. All persons treated with albendazole received one 400-mg tablet (GlaxoSmithKline, Research Triangle Park, NC). At the request of the Ministry of Health, women of child-bearing age were not treated with albendazole in 2000 or 2001 because of concerns about albendazole treatment of women in early stages of pregnancy. These exclusion criteria were removed in 2002. The MDA in the mountains followed the drug distribution in the plains by approximately one month because of the limited supervisory staff.

**Adverse reaction surveillance.** For the initial round of MDA, a three-tiered referral system was developed for adverse reactions. Treatment of minor complaints (e.g., headache, low-grade fever) that developed after treatment was available at the distribution posts. Ten referral centers staffed by nurses were established to treat moderate adverse reactions, including scrotal pain, itching and other problems that interfered with daily activities. Persons with severe adverse reactions were referred to Hopital Ste. Croix for evaluation and hospitalization, if necessary. Surveillance for adverse reactions in the first year represented a substantial investment in project resources for the 2000 MDA, both to reassure health authorities in Haiti and to collect information. Less emphasis was placed on surveillance for adverse events in 2001 and 2002.

**Coverage surveys.** After the first round of drug distribution in 2000, three different techniques were used to assess coverage: two convenience methods and a more statistically rigorous method based on cluster sampling with probability proportional to size. As noted earlier in this report, the population of the plains of Leogane was not known with any certainty. The cluster survey was used to generate an estimate of the population size for the plains area. This number was used as the denominator for coverage estimates for 2001. A second cluster survey was performed after the third MDA in 2002. Coverage in sentinel sites was assessed annually by interviewing persons who participated in follow up sample collections. These took place approximately 8–10 months after MDA.

**Assessment of health education.** To assess the impact of the health education on the KAP of filariasis and the mass treatment program, KAP surveys were conducted after the first and third distribution, in parallel with the coverage surveys described earlier in this report. An analysis of the results of the first KAP survey has been reported elsewhere. In addition to the KAP surveys, focus groups were held after the second annual drug distribution to provide a deeper understanding of the reasons why some people refused treatment.

**Cost analyses.** Cost data were collected retrospectively because the program was already underway as the cost analysis began. Costs were estimated from expenditure records and interviews with administrators for each input that contributed to program operations in both the plain and the mountains. Primary outcome measures are the annual program costs (broken down by program activities), the cost per person treated and the cost per person at-risk.

There are five input categories that generate these costs: personnel, capital costs, equipment and facilities, supplies, and transportation. The costs of any inputs (such as personnel or transportation) that were used for multiple activities were distributed among the activities. Personnel, transportation, equipment, and facility costs were allocated based on the percentages of time they spent on a given activity. Other non-monetary data that are necessary for the cost calculations include the expected useful life and residual or scrap value of capital investments (e.g., vehicles), which are necessary to calculate their annuitized costs. Cost data were entered into Microsoft (Redmond, WA) Excel® worksheets for analyses. Costs for non-MDA activities (e.g., research projects) were excluded from the analysis.

The annual cost of any given activity is the sum of each input’s cost (or use) for the year multiplied by its percent allocation to that activity for that year. Equipment/facility and transportation costs are comprised of operational costs and annuitized capital costs. A straight-line depreciation method was used to annuitize capital costs. Personnel and supply costs have only an operational cost component.
The calculation of annual cost per person treated consisted of dividing the total cost of the program by the number of persons given drugs in that year of distribution. Annual cost per person at risk is the total program cost divided by the number of individuals residing in the commune. The population of Leogane was assumed to be constant over the three-year period that data were analyzed.

Adjustments were made for inflation over the three rounds of the analysis. The base year of the dollar was set to 2002 and all costs previous to this date were inflated to 2002 dollars. Costs were collected in U.S. dollars and Haitian Gourdes. Final results are presented in 2002 US dollars. A Gourde-Dollar exchange rate was calculated for each round of the program. Rates were obtained from www.oanda.com and are the average of the daily rates between the first and last dates designated for that round.

Statistical analysis. Parasitologic data were entered into an EpiInfo version 6.0 (Centers for Disease Control and Prevention, Atlanta, GA) database. Changes in infection prevalence and intensity were analyzed by chi-square and Kruskal-Wallis tests, respectively.

RESULTS

Baseline infection level. At baseline, antigen prevalence in the four sentinel sites ranged from 10.2% to 50.1% and microfilaremia prevalence ranged from 0.8% to 16% (Table 1). The communities represent urban, rural, and mixed settings. The community that had the lowest level of *W. bancrofti* infection, Mapou, was located near the foothills. Previous studies have shown that antigen prevalence decreases with increasing altitude.\(^\text{11}\)

Mass drug administration. For the first MDA in October 2000, more than 70,000 persons were treated in the plains during four days of distribution (Figure 1). Based on coverage surveys, 72% of the plains population received treatment.\(^\text{13}\) In the first year of the program, we implemented a system of enhanced surveillance for adverse reactions. More than 16,000 people (23.1 per 100 persons treated) reported to a distribution post with complaints of adverse reactions, especially fever and headache (Figure 1). Most complaints were minor; however, more than 2,500 men reported scrotal pain.\(^\text{12}\)

The KAP surveys after the first MDA led us to anticipate better coverage in year 2; however, on the first day of the distribution, there was a substantial decrease in the number of persons treated relative to year 1 (5,900 persons versus 26,000 persons). In response to the lower numbers, the staff responded vigorously with visits to churches, schools, and radio stations during the remaining days of the drug distribution. As a result, the numbers treated increased daily; nonetheless, the number of persons treated and the overall coverage decreased in 2001 (Figure 1 and Table 2).

![Figure 1](image)

FIGURE 1. Changes in the number of persons treated and in those reporting adverse reactions. The number treated in each round of mass drug administration is shown in the bars. The percentage of persons reporting adverse reactions is plotted as a line. In response to the lower coverage in 2001, health communications strategies were modified to place greater emphasis on the relationship between adverse reactions and treatment. We also tried new methods to motivate the community, including showing videos about filariasis in the communities and broadcasting radio spots with statements from community leaders supporting the program. As a result of all these changes, the number of persons treated and the drug coverage increased significantly in 2002 (Figure 1 and Table 2). Reported adverse reactions decreased with each MDA, from 23.1 per 100 persons treated in the first year to 9.0 in 2002 (Figure 1).

Effect on infection prevalence and intensity. Microfilaremia prevalence decreased significantly in each of the sentinel sites following MDA except Mapou (Figure 2). By 2003, microfilaremia prevalence had decreased to less than 2% in all of the sentinel sites except the urban setting of Leogane town. Of those who were microfilaria positive, mean (and median) microfilaria density also decreased significantly (Table 3). Antigen prevalence decreased in 2003 to 8.6%, 20.1%, 15.4%, and 29.8% for Mapou, Masson/Mathieu, Barrier Jeudi, and Leogane, respectively; however, it was not possible to analyze trends in antigenemia because the transition from AMRAD to Binax ICT cards in 2002 was accompanied by an artifactual increase in antigen prevalence.

Cost analyses. A multiyear comparison shows that the overall costs of the Leogane MDA decreased from round 1 to round 2 and increased slightly again for round 3 (Figure 3). The decrease in cost was related to a decrease in MDA expenditures and a steep decrease in the costs of adverse event surveillance (Table 4). The decrease in MDA costs for rounds 2 and 3 was the result of lower personnel costs because of the reduction in the number of volunteers manning the posts after

![Table 2](image)

**Table 2**

Comparison of overall coverage in the plains of Leogane with that of the sentinel sites*.

<table>
<thead>
<tr>
<th>Year</th>
<th>Leogane plains†</th>
<th>Sentinel sites‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>73</td>
<td>78.4</td>
</tr>
<tr>
<td>2001</td>
<td>52</td>
<td>87.8</td>
</tr>
<tr>
<td>2002</td>
<td>78</td>
<td>92.9</td>
</tr>
</tbody>
</table>

* Microfilaria and antigen prevalence differed significantly by sentinel site (\(P < 0.001\) for both sets of comparisons).
† As assessed by cluster surveys.
‡ As determined by interview of persons providing blood specimens during follow-up surveys.
round 1 and a reduction in supply expenditures. For example, whereas $22,295 was spent on distribution supplies for round 1, an average of only $9,435 was spent in the next two rounds (a reduction of 58%). The cost for treatment of adverse reactions also decreased markedly after the first round of the MDA. These costs initially consumed 24% of total program costs but decreased to only 4% and 7% in the following rounds. Social mobilization costs increased steadily from 10% to 28% of total costs.

Table 5 shows the cost per person treated. Cost per person treated decreased substantially each round. Round 3 was the most cost-efficient round of the Leogane MDA with cost per person treated decreasing to $1.30.

**DISCUSSION**

Lymphatic filariasis elimination programs hold the promise of reducing the burden of filarial infection and disease while providing important public health benefits through reduction in intestinal helminth infections. After only three rounds of DEC-albendazole treatment, Leogane has experienced dramatic reductions in both filarial and geohelminth infections while achieving concurrent gains in program cost and efficiency; thus, broad public health benefits are being realized through implementation of the program. Based on our experience, we suggest that social mobilization plays an important role, both in developing a distribution post-based MDA program and in addressing community concerns that result in lower coverage.

A key programmatic indicator for public health programs is coverage. Coverage decreased from 72% in the first MDA to only 52% in the second MDA (Table 2). Although the reasons for this decrease are undoubtedly complex, it appeared from focus groups that fear of adverse reactions was a component of the community’s aversion to treatment in the second year. Since the coverage needed to eliminate transmission is thought to be much higher than 50% of the total population, this decrease represented a real threat to the program. The program increased the investment in social mobilization to address these issues (Table 4). Enhanced social mobilization can overcome problems with decreased coverage if the root causes of the problem are adequately addressed through messages tailored to the community. Health educators working with the program used feedback from KAP surveys and focus groups to develop flip charts and other materials that dealt specifically with issues related to adverse reactions and the relationship between the adverse reactions and the therapeutic action of the drugs. The increased coverage that resulted in the third MDA suggests that these efforts were effective and serves as a reminder of the critical importance of adapting health communications messages to the needs of the program. The KAP surveys have emphasized that participation in MDA is associated with knowledge of LF, unfortunately, social mobilization activities are typically the first to be cut in the face of budgetary shortfalls.

Coverage surveys provide essential information for monitoring program implementation and for validating coverage estimates derived from distribution posts. It is important to assess coverage patterns as well as raw numbers. Coverage surveys conducted after the third MDA were designed to assess the degree to which noncompliance was systematic. A significant proportion of the adult population (approximately 18%) reported that they had not taken the drugs in any round of the MDA (Mathieu E and others, unpublished data). In settings where initial microfilaremia prevalence is high (e.g., > 10%), it is clear that significant levels of systematic noncompliance represent a threat to the target of elimination. Preliminary assessments of serologic responses after the first MDA showed that antifilarial antibody responses were influenced by proximity to untreated infected persons. Thus, noncompliant persons are likely to represent a reservoir of infection that can lead to focal transmission. Defining the conditions under which microfoci can persist is an important objective for future research. Similarly, understanding more about noncompliance and about how to motivate noncompliant persons to participate in MDA is an urgent research issue.

We observed substantial reductions in microfilaria prevalence after three cycles of mass treatment with DEC and albendazole (Figure 2). The site where microfilaria prevalence remained the highest was the urban setting. Although we assumed that lower coverage was the explanation for the difference between the urban (Leogane town) and more rural setting (e.g., Masson/Mathieu), coverage surveys indicate that coverage was comparable in these settings (Mathieu E and others, unpublished data). It is possible that population migration into Leogane town, from communities where no MDA is conducted, contributed to the maintenance of higher infection levels. Higher mosquito densities in the urban setting may provide an alternative explanation.

The reduction in microfilaria level that we observed, though encouraging, must be interpreted with some caution. Because some persons in sentinel sites refused to be re-tested after baseline data collection in 2000, bias was introduced into the follow up sampling. In general, persons who agreed to be
re-checked were also more likely to participate in the MDA. Coverage among persons sampled in the sentinel sites was consistently higher than that of the general population (Table 2). These differences suggest that spot checks, as called for in the Program Manager’s Guidelines, may be a useful tool for verifying programmatic progress.18

Decreases in adverse reactions were noted in the second and third years of the program, consistent with the decrease in microfilaria prevalence. We did not make any systematic attempt to establish a link between filarial infection and adverse events; thus, it is likely that a substantial number of visits to the health posts reflect health needs of the population that are unrelated to MDA. The rapid decrease in adverse reactions (Figure 1) suggests that enhanced surveillance for adverse reactions is not needed beyond the first year if coverage is adequate, even in settings such as Leogane where initial infection prevalence is high. Decreasing the surveillance for adverse events led to substantial cost savings in 2001 and 2002 (Table 4).

The cost analysis provides essential insight for existing and planned national LF programs in other countries. In Haiti, where little infrastructure exists, start-up costs are higher than in other settings where support from the national government or other existing health programs helps divert much of the cost burden away from the program. Program efficiency increased over time as the program management gained practical experience with the program. Decreasing costs (Table 4) and increased coverage led to lower costs per person treated in 2002 (Table 5).

A comparison of the costs in Haiti to the few cost studies done on MDA programs in India and Tanzania showed that the Leogane program costs started out higher but are approaching values that are comparable to those in the other countries. Krishnamoorthy and others in their cost effectiveness analysis of an MDA program in southern India obtained an annual cost per person treated of $1.21 and $1.18 for two rounds of distribution, respectively, and $0.65 and $0.69 per person at-risk.19 Similarly, Michael and others conducted a study in Tanzania that showed a cost per person at-risk of $0.70 over the course of three years.20 A systematic study of

### Table 4
Program input costs by activities and round of mass drug administration (MDA) (US$)

<table>
<thead>
<tr>
<th>Activities</th>
<th>Round 1, 2000</th>
<th>Round 2, 2001</th>
<th>Round 3, 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Personnel</td>
<td>Transportation</td>
<td>Equipment/Facilities</td>
</tr>
<tr>
<td>Mapping</td>
<td>8,979</td>
<td>4,755</td>
<td>935</td>
</tr>
<tr>
<td>Social Mobilization</td>
<td>11,540</td>
<td>4,755</td>
<td>4,479</td>
</tr>
<tr>
<td>MDA</td>
<td>63,461</td>
<td>7,263</td>
<td>7,143</td>
</tr>
<tr>
<td>Adverse event treatment</td>
<td>32,371</td>
<td>0</td>
<td>3,527</td>
</tr>
<tr>
<td>Monitoring</td>
<td>11,540</td>
<td>7,266</td>
<td>3,416</td>
</tr>
<tr>
<td>General administration</td>
<td>11,540</td>
<td>4,755</td>
<td>1,199</td>
</tr>
<tr>
<td>Total</td>
<td>139,432</td>
<td>28,793</td>
<td>20,699</td>
</tr>
</tbody>
</table>

Figure 3. Program costs by year of distribution. The costs of the indicated program activities are plotted by year. MDA = mass drug administration.
costs, using standardized data collection methods, is needed to understand variations in costs across programs.

Intensively monitored demonstration projects provide ideal opportunities to learn how to build and monitor LF elimination programs. Many lessons have been learned from the experience in Leogane (Table 6). For example, initial concerns about treating pregnant women with albendazole led to the decision to exclude all women of child-bearing age from albendazole treatment, which prevented women from receiving the benefits of this drug.\textsuperscript{15} After two years of MDA, this decision was reversed when it was noted that other Ministry of Health programs were using questionnaires to ascertain pregnancy status. This simplified treatment decisions at the post level and reduced confusion about women taking part in the MDA that led to women being inappropriately excluded from MDA.

Clearly, there is much we still need to learn. We do not yet know how many years of MDA will be required to eliminate transmission. As noted earlier in this report, the effect of systematic noncompliance also must be carefully evaluated. Nonetheless, even at this stage of the program, MDA has delivered significant public health gains to the population of Leogane. We should not allow concerns about current financial challenges facing the LF elimination program to diminish the intensity of our efforts to achieve this goal.

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