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THE WORLD BANK
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The World Bank
1818 H Street NW
Washington DC 20433
Telephone: 202-473-1000
Internet: www.worldbank.org

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IVERMECTIN DISTRIBUTION

APOC



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Briefings, Public/Private Partnership Files - Ivermectin Distribution - African Programme for Onchocerciasis Control [African Programme for Onchocerciasis Control [APOC]]

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Ivermectin - Distrib.

Sept 10 return

Bob Pond, M.D.
1301 Willivee Dr.
Decatur, GA 30033
Tel: 404-982-0221
FAX: 404-296-9164

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Mr. Bruce Benton
Onchocerciasis Coordinator
The World Bank
1818 H. St., N.W.
Room J 9047
Washington, D.C. 20433

Dear Mr. Benton,

Enclosed are the documents I wrote for the Procedural Manual for Ivermectin Distribution:

1. A chapter entitled "Procedures for Ivermectin Distribution"
2. A chapter entitled "What Strategies Can be Used to Distribute Ivermectin?"
3. A chapter entitled "Record Keeping and Reporting"
4. A chapter entitled "Supervision"
5. A chapter entitled "Program Evaluation"
6. A chapter entitled "Assessing the Cost-Effectiveness of Ivermectin Distribution Programmes"
7. Sixteen sample record keeping forms to be included in the appendix of the manual

Brian Duke also asked me to review most of the other chapters of the manual. I enclose a copy of the FAX I sent him with my lengthier comments on these other chapters.

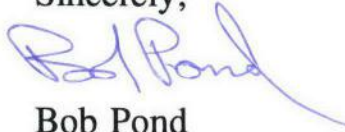
Between the writing and the editing I have worked a total of ten full days on the manual: eight days from July 13 to July 31 and two days from August 16 to 19. My work with CDC finished on July 2 so I was self-employed throughout the period that I have worked on the manual.

I also enclose copies of receipts for various communication expenses I incurred on behalf of the project. Together these amount to \$79.28.

I hope that the Bank is interested in supporting this work.

If you have any questions I am available at (404) 982-0221 until sometime on Wednesday, August 25.

Sincerely,



Bob Pond

Procedural Manual

PROCEDURES FOR IVERMECTIN DISTRIBUTION

Executive Summary

The following steps need to be carried out whenever ivermectin is distributed:

1. Exclusion of people who are ineligible

Aside from weighing and a quick visual check to see that the person is able to walk and not obviously sick, the screening of potential ivermectin recipients involves asking only 2 questions of women of childbearing age:

- a. Is it possible that you are pregnant?
- b. Have you delivered a baby within the last week?

People who are excluded from taking ivermectin based on the above criteria should be instructed when and where to go to get the drug at a later date.

2. Selection of dose

Currently, The Mectizan Expert Committee recommends that the dose of ivermectin should be based upon the person's weight.

3. Record keeping

The minimum information needed by managers and evaluators is a record of the number of people treated and the number of tablets dispensed in each community. It is usually not necessary to record the name and other information about each person treated

4. Dispensing Medication

Each person should swallow the tablet(s) in the presence of the drug dispenser. No one should be permitted to take the drug away without swallowing it.

5. Final instructions

A worker who is fluent in the vernacular should explain the following to each drug recipient:

- a. "You should take ivermectin again in one year. "
- b. "If you have any problems in the next few days, then you should contact a local health worker."

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PROCEDURES FOR IVERMECTIN DISTRIBUTION

What are the procedures involved in ivermectin distribution?

The following steps need to be carried out whenever ivermectin is distributed:

1. Exclusion of people who are ineligible
 - a. *Pregnant women should not be given ivermectin.*
Someone fluent in the local language needs to ask women of child-bearing age "Is it possible that you are pregnant?" Some effort should be made to allow women to answer this question confidentially. If possible, a woman should ask the question. It is not necessary to ask a woman about the timing of her last menstrual period.
 - b. *Mothers breast feeding babies who are less than one week old should not be given ivermectin.*
A small amount of the drug is excreted in breast milk. However, because of the "blood-brain barrier", the drug cannot reach the brain of a newborn infant. To be on the safe side, The Mectizan Expert Committee recommends that babies should be at least one week old before their breast feeding mothers take the drug.
 - c. *Small children should not be given ivermectin.*
Children weighing less than 15 kg should not take the drug. There is no evidence that the drug is harmful to small children. However, there is no convenient way to give a proper dose to small children since they would require less than one-half of a tablet. Parents are frequently mistaken about a child's age. If a parent says that a child is less than 5 years old but the child weighs more than 15 kg, the child should still be treated with ivermectin.
 - d. *People who are severely ill should not take ivermectin.*
"Severe illness" includes severe wasting of the body, high fever, possible meningitis, and conditions that make a person unable to walk. If someone is already quite ill a reaction to ivermectin could make them worse. If a person who is already sick becomes worse after taking ivermectin this could lead to rumors that the drug is unsafe.

It will be quite obvious if a person is severely ill. It is not necessary to perform even the simplest of physical exams before giving a person ivermectin. If the person can walk normally and does not appear ill, then they are fit enough to be given the drug.

In summary, aside from weighing and a quick visual check to see that the person is able to walk and not obviously sick, the screening of potential ivermectin recipients involves asking only 2 questions of women of childbearing age:

- a. Is it possible that you are pregnant?
- b. Have you delivered a baby within the last week?

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People who are excluded from taking ivermectin based on the above criteria should be instructed when and where to go to get the drug at a later date.

2. Selection of dose

Currently, The Mectizan Expert Committee recommends that the dose of ivermectin should be based upon the person's weight. It is not necessary to use expensive medical scales to weigh people. Simple (but sturdy) "bathroom" scales are adequate. These are portable enough to be carried on a motorcycle or from house-to-house if necessary.

3. Record keeping

The minimum information needed by managers and evaluators is a record of the number of people treated and the number of tablets dispensed in each community. It is usually not necessary to record the name and other information about each person treated unless program managers want to later perform spot checks to verify who was treated.

4. Dispensing Medication

Eligible persons receive from 1/2 to 2 tablets of ivermectin. Each person should swallow the tablet(s) in the presence of the drug dispenser. No one should be permitted to take the drug away without swallowing it.

5. Final instructions

A worker who is fluent in the vernacular should explain the following to each drug recipient:

- a. "You should take ivermectin again in one year."
- b. "If you have any problems in the next few days, then you should contact a local health worker."

A resident of the community is the ideal person to give this final message.

Maybe, it could be of interest to record the names of people who have not received the pill - ?

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WHAT STRATEGIES CAN BE USED TO DISTRIBUTE IVERMECTIN?

Executive Summary

Programs have developed a variety of strategies to distribute ivermectin. Most strategies are variations of one of three basic approaches:

1. Mobile team:

With the mobile-team strategy two or more health professionals travel from one community to another to distribute ivermectin. The strategy makes heavy use of vehicles or motorcycles and depends upon regular payment of field allowances. Mobile teams have been sustained only as a result of unprecedented lobbying and commitment of funds by national governments and major international donors.

2. Community-based distribution:

In community-based strategies the ivermectin is delivered by non-professionals who are trained to work unaccompanied. Community-based strategies can deliver ivermectin directly to the target households without requiring heavy use of vehicles. The community-based strategy achieves maximal coverage but the non-professionals must be motivated and they must be supervised.

3. Clinic-based:

Many health planners have assumed that clinic-based distribution of ivermectin will have little impact. For a variety of reasons, however, this strategy warrants closer examination.

The choice of strategy depends upon many factors such as the number of endemic communities to be reached, the number of clinics and professional health workers located near to the endemic communities, the availability (short-term and long-term) of transport and money to pay field allowances and the availability of community health workers in the endemic communities.

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WHAT STRATEGIES CAN BE USED TO DISTRIBUTE IVERMECTIN?

Programs have developed a variety of strategies to distribute ivermectin. Most strategies are variations of one of three basic approaches:

Mobile team

With the mobile-team strategy two or more health professionals travel from one community to another to distribute ivermectin. For at least a few hours each year the drug is thus made available at a central location in each endemic village. The strategy makes heavy use of vehicles or motorcycles and depends upon regular payment of field allowances. Mobile teams have been widely employed by Expanded Programs for Immunization (EPI) but have been sustained only as a result of unprecedented lobbying and commitment of funds by national governments and major international donors. Future operational trials may show that it is practical to "piggy back" the mass distribution of ivermectin and other drugs onto EPI mobile team campaigns. Meanwhile, EPI mobile teams reach only a small percentage of the communities with endemic onchocerciasis and the use of mobile teams to distribute ivermectin alone appears to be an expensive strategy that few programs will be able to sustain¹.

Community-based distribution

In community-based strategies the ivermectin is delivered by non-professionals. In each endemic community, non-professional community-based distributors (CBD's) are trained to work unaccompanied and register people, weigh them and treat them with ivermectin. CBD's can either distribute the drug from house-to-house or dispense it from a central location. Even though most CBD's have no prior experience as health workers it typically takes only three days to train them adequately. In one week one CBD can distribute the drug to up to 500 people. Typically the CBD keeps a record with the names and addresses of all the people he or she has treated. In this way program staff can visit the village and perform a spot check on a random sample of households to determine whether the CBD has made any mistakes in ivermectin administration or produced any fraudulent records.

Community-based strategies can deliver ivermectin directly to the target households without requiring heavy use of vehicles. Unlike mobile teams which can only stay in a village for a few

¹One exception appears to be the program operated by CBM in Sierra Leone. By making use of the staff and facilities at their eye hospital in Lunsar they have been able to operate a very cost-effective mobile team ivermectin distribution program.

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hours before returning to headquarters, CBD's live in the target village and are available to dispense the drug and manage any reactions 24 hours a day for several days in a row.

The community-based strategy achieves maximal coverage but at a cost. The CBD's must be motivated (e.g. paid an incentive) and they must be supervised by a health professional. Thus, a community-based strategy can only be sustained over many years if health administrators, donors and/or communities themselves will continue to commit funds and attention.

Clinic-based

The simplest way to distribute ivermectin or any other pharmaceutical is through existing clinics, health centers and hospitals. This is sometimes referred to as the "clinic-based" or "fixed-center" strategy². Each of the countries in which onchocerciasis is endemic have extensive networks of clinics operated by governments, churches or other non-profit organizations. There are several reasons, however, why many health planners have assumed that clinic-based distribution of ivermectin will have little impact. First, the majority of people blinded by onchocerciasis live in small, remote villages 10 km or more from a clinic. Transport in these rural areas is sporadic and relatively expensive. For these reasons, clinic attendance drops off rapidly as the distance from the patient's home to the clinic increases.

It is not just the traveling expense that discourages people from remote communities from seeking services at clinics. To make matters even more difficult, the hours of operation of rural clinics are sometimes unpredictable, and because of past experience with shortage of drugs and insensitivity of modern health professionals, much of the public may be reluctant to make use of clinic services. Due to such factors, many public clinics in developing countries are now under-utilized and nearly dormant.

A final reason that clinic-based services are sometimes de-emphasized is that foreign donors promoting public health interventions often prefer to develop "vertical" strategies that can function and succeed independently of the regular health service. For a foreign donor such vertical strategies are attractive because they permit centralized control and monitoring and by pass many of the administrative problems of the health

²Another term sometimes used for a clinic-based strategy is "passive" distribution. This term incorrectly implies that no outreach is involved. An effective clinic-based strategy depends upon active outreach efforts to inform people and to encourage them to seek treatment at the nearest clinic.

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service bureaucracy.

In spite of the bias against clinic-based delivery of services there are several reasons why this strategy warrants closer examination:

- a. It is the cheapest of strategies. This is because distribution itself (as opposed to the publicity required to motivate people to seek treatment) uses only existing personnel and requires no field work.
- b. Many clinics are located in market towns that are visited at least once a year by a high percentage of people living in surrounding communities. Although it may be impractical for remote communities to depend upon existing clinics for treatment of many other health problems it may still be feasible for people living far from a clinic to travel to that clinic once or twice a year at their convenience to collect a prophylactic drug.
- c. Experience with existing ivermectin distribution programs³ has suggested that there is great popular demand for ivermectin in endemic communities even when people must travel long distances and wait in line two or more hours to obtain the drug.
- d. New public health interventions should be integrated into and strengthen the existing health service rather than divert funds, personnel and administrative attention to single purpose programs.
- e. In many countries, ministries of health are now implementing "cost recovery" (i.e. patient fees) policies which enable clinics to recoup the cost of drugs and other supplies and provide incentives to clinic employees and their supervisors. Cost recovery policies, if properly implemented, should lead to greater availability of drugs, clinic staff who are more responsive to the wishes of their "customers" and thus greater demand for clinic services.

Thus, there are important reasons to invest in clinic-based delivery of health services. More research is needed to better understand the potential as well as the limitations of such a strategy.

We can see from the above discussion that planners have a variety of strategies to choose from when designing an ivermectin distribution program. The choice of strategy depends upon many factors such as the number of endemic communities to be reached, the number of clinics and professional health workers located near to the endemic communities, the availability (short-term and long-term) of transport and money to pay field allowances and the availability of community health workers in the endemic communities.

³Particularly, the experience with the I.E.F. sponsored program in the department of Dja and Lobo, southern Cameroon and the experience with Africare/I.E.F. program in Kwara State, Nigeria

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RECORD KEEPING AND REPORTING

Executive Summary

1. Good record keeping system is essential for planning, for supervision and for program evaluation.
2. If the record keeping burden is too great or the workers are not trained, supervised and encouraged properly the records they complete will be incomplete and inaccurate.
3. Record forms should be kept as brief and concise as possible. Information should not be collected unless it will be used. The forms must be clear, uncluttered and quick to use. If possible, it is best to use existing forms designed for other health programs to collect information for the ivermectin distribution program. This will save time and help promote *integration* of ivermectin distribution into the primary health care system.
4. Field staff must be carefully trained if they are to complete record forms accurately. Training must include field exercises during which staff practice completing the forms.
5. Field staff who should receive verbal or written reports which summarize the data they have collected.
6. A model set of records forms is included in the appendix.

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RECORD KEEPING AND REPORTING

Why is record keeping important?

Record keeping is tedious and time consuming. Workers sometimes resent the time they must spend filling out forms. If the record keeping burden is too great or the workers are not trained, supervised and encouraged properly they will do a poor job of keeping records. The result will be that the records will be incomplete, inaccurate and misleading. Why not dispense with record keeping altogether?

There are three major reasons why any public health program needs to keep good records. First, certain information (e.g. the inventory of drugs remaining or the time it takes to travel between certain villages) is needed for planning and resupply purposes. Second, certain records (e.g. a log for recording movements of a vehicle) are useful to supervise workers and their use of resources. Finally, certain statistics (e.g. the number of people treated with ivermectin each year) measure the important outputs of a program and are needed for external use. Thus, a good record keeping system is essential for **planning**, for **supervision** and for program **evaluation**.

One of the most important things to keep in mind when designing a record keeping system is to streamline the information which is gathered. The records should be kept as brief and concise as possible. Information should not be collected unless it will be used.

Those designing ivermectin distribution programs should also keep in mind that health workers may already be keeping records for other health programs. If possible, it is best to use these other record forms to collect information for the ivermectin distribution program. This will help promote *integration* of ivermectin distribution into the primary health care system and reduce the time required to train and supervise workers and to complete records.

It is important that the people who complete the records know how the information they collect will be used. Data should be transferred both UPWARD to project managers and DOWNWARD to field staff who should receive verbal or written reports which summarize the data they have collected. When the information's usefulness is demonstrated the people who complete reports will be more convinced of the importance of providing accurate data. Ideally, these same people should use the information themselves to monitor their performance and compare it with the performance of other workers.

Field staff must be carefully trained if they are to complete record forms accurately. Training must include field

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exercises during which staff practice completing the forms. During these exercises it may become apparent that staff have difficulty completing certain items. If this is the case the program planners should consider redesigning one or more forms. The record keeping system should be flexible enough to allow for improvements and modifications as the needs of the program and the users evolve.

A Model Set of Records for an Ivermectin Distribution Program

Included in the appendix is a set of forms that constitute a minimal record keeping system for reporting on field activities commonly conducted by ivermectin distribution programs:

- 1) Epidemiological Assessment-- Form 1
- 2) Health education-- Form 2
- 3) Ivermectin distribution
 - a) Clinic-based distribution-- Forms 3 and 4
 - b) Mobile professional distribution-- Forms 5 and 6
 - c) Community-based distribution-- Form 7
- 4) Treatment of side-effects of ivermectin
 - a) Treatment of mild side-effects by non-professionals-- Form 8
 - b) Treatment of mild side-effects by professionals-- Form 9
 - c) Treatment of serious side-effects by professionals-- Form 10
- 5) Supervision of the above activities
 - a) Supervision of health professionals-- Form 11
 - b) Supervision of CBD's-- Forms 12 and 13
 - c) Inventory of drugs and other consumables-- Form 14
 - d) Monthly Field Summary-- Form 15

These forms have purposefully been typeset with a standard typewriter font to demonstrate how they can be prepared with an ordinary typewriter and ruler.

Most programs will need only a subset of these forms (or forms collecting equivalent information). For example, programs which do not work with CBD's will not need to keep records equivalent to forms 7, 8, 12 or 13. In addition to the above forms, any worker driving a vehicle or motorcycle should complete a log (Form 16) and any worker disbursing money should keep accounts and fill out vouchers and receipts.

The physical design of record forms is important. They must be clear, uncluttered and quick to use. If a form is confusing or tedious to fill in staff may not be willing to complete it or they may provide inaccurate information. Non-literate CBD's may need forms with pictures and few words.

It may not be readily apparent why certain questions have

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been included on the forms. Everyone appreciates the need to keep count of the number of people receiving ivermectin (Forms 4 and 6). It is more difficult to understand the reasons for collecting the names of the people checked for nodules (Form 1) or receiving ivermectin (Forms 3, 5, 7) or the date and time of a health education session (Form 2). Such data appear to be extraneous when, in fact, they enable the supervisor to monitor the work performed and to confirm the accuracy of records by later spot checking in a small sample of communities. If managers do not intend to do such spot checking or if a program is so small that it is possible for managers to be present during each field activity then there is no point in recording such information.

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SUPERVISION

Executive Summary

1. Supervisors monitor and evaluate work, motivate workers, and provide training and supplies.
2. Supervision of community-based distributors is particularly important because of their limited training and because they usually work in isolation with little remuneration.
3. Supervisory checklists can be used to build a formal system of supervision into a program. Checklists provide standard measures for judging performance and they help make it clear to the workers what is expected of them.
4. Supervisors should not limit their supervision to items included on a form, however. Supervisors must address the particular needs of the workers. It is as important to recognize good work as it is to notice and correct an inadequate or flawed performance.
5. Direct supervision of most field work is not practical. Without an adequate record keeping system it is not possible for a supervisor who is away from the work site to verify and encourage superior productivity and to identify and correct substandard performance. The supervisor has the responsibility to review workers records, identify mistakes and, in some cases, verify the accuracy of the field records through spot checking.

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SUPERVISION

Supervision involves overseeing the work of others. Supervisors **monitor and evaluate** work, **motivate** workers, and provide **training and supplies**.

Supervision of community-based distributors is particularly important because of their limited training and experience and because they usually work in isolation with little contact with the rest of the program. Furthermore, remuneration for their work is often minimal or sporadic. Thus, it is especially important that supervisors take advantage of each encounter with CBD's to train them and motivate them.

It is important to build a formal system of supervision into a program. One way to do this is to use supervisory checklists. Form 12 in the appendix is an example of a checklist used for supervising a Community-Based Distributor. The instructions for the form say that "After a CBD has finished distributing ivermectin, the supervisor should visit the community one final time to do the following tasks:

1. Collect the weighing scale or tape measure.
2. Collect the remaining ivermectin ...
3. Collect the **Household Ivermectin Treatment Records**.
4. Use the **Ivermectin Distribution Tally Record** to add up the treatments recorded on the **Household Distribution Treatment Records...**
5. Collect the **Records of Reactions to Ivermectin**.
6. Interview the head of the community and ask these questions:
 - a) 'Is there anyone in the community who is not satisfied with the work done by the CBD?'
 - b) 'Are there some people in the community who did not receive the ivermectin?'
 - c) 'Are there some people in the community who had a bad reaction after taking the ivermectin?'
7. Pick at random five **Household Ivermectin Treatment Records**. Ask the CBD to help you find the house which corresponds to each of these five household records. Visit the five houses to interview the residents....Do you detect any major discrepancy between what is written on the household records and what the residents of the house tell you ?....Is there anyone who is not satisfied with the work done by the CBD?...Is there anyone here who will refuse to take the drug again?...In each house ask 'Which disease will this drug treat?'...In each house ask 'When should you take the drug again?'"

One advantage of using supervisory checklists is that they provide standard measures for judging performance and they help make it clear to the workers what is expected of them. Such checklists can be misused, however. If supervisors limit their monitoring to the items included on checklists they may fail to

address the particular needs of the workers.

There is also a risk that a supervisor who places great emphasis on a checklist will be viewed as a policeman. Ideally the supervisor should be a supportive problem solver rather than a critical disciplinarian. It is as important to recognize good work as it is to notice and correct an inadequate or flawed performance. When meeting with staff the supervisor should encourage open discussion. The workers will feel more comfortable sharing their problems and concerns if they are confident that they will not be punished for raising them.

Other record forms included in the appendix are completed not by the supervisor but rather by the worker who is being supervised. These forms monitor such things as distribution of ivermectin (Forms 3 to 7), treatment of side-effects of ivermectin (Forms 8 to 10), vehicle use (Form 16), inventory of supplies (Form 14) and health education activities (Form 2). Direct supervision of most field work is not practical. Without an adequate record keeping system it is difficult if not impossible for a supervisor who is not on site to verify and encourage superior productivity and to identify and correct substandard performance. The supervisor has the responsibility to review workers records, identify mistakes and, in some cases, verify the accuracy of the field records through spot checking. Form 11 in the appendix is an example of a checklist used to verify the accuracy of records completed by health professionals. It suggests that the supervisor visit a random sample of 5% to 10% of all communities where field work has been carried out. This includes communities where epidemiological assessment or health education activities were carried out as well as communities receiving ivermectin. While visiting, the supervisor can speak with the head of the community and other residents of the community to determine whether there are any complaints. The supervisor can bring along relevant records of field work performed in the community and ask questions to determine whether these records were completed accurately.

As noted in the section on record keeping, it is important that workers receive feedback on the forms they complete. It is best if these forms can be reviewed on-site at the time that they are collected so that workers are persuaded of the importance of record keeping, they are made aware of the results, problems are promptly identified, the worker can correct mistakes and the supervisor can request any necessary changes in record keeping procedures.

PROGRAM EVALUATION

Executive Summary

1. Sponsors need evaluations to make decisions about funding and about replicating programs. Program managers and staff need evaluations to collect information for planning, to monitor program activities and to learn how a program can be improved.
2. For evaluation to be most effective it should be conducted continuously and at many levels. This may include self-evaluation by field workers, day-to-day monitoring of field activities by managers, internal evaluation staff meetings and external evaluations assessing the program as a whole.
3. Most of the ivermectin distribution programs now operating use the coverage achieved with ivermectin distribution as an indirect indicator of their impact preventing blindness and other severe onchocercal morbidity. Coverage with ivermectin is an acceptable indicator of program impact if the statistics on ivermectin distribution are credible and if the program reports not only the total number of people treated but the number treated in hyperendemic communities, the number treated in mesoendemic communities and so forth. The impact from treating a person in a hypoendemic community is much less than the impact of treating a person living in a hyperendemic community.
4. Output indicators assess training, health education, epidemiological assessment, ivermectin distribution and management of reactions to the drug. It is important to assess not only the quantity but the quality of these program outputs.
5. Management indicators assess the quality of program planning, record keeping, supervision, monitoring and progress toward sustainability. Most of the lessons learned from an evaluation come from careful assessment of management indicators.
6. Table 1 outlines the most important indicators used to assess ivermectin distribution programs.

PROGRAM EVALUATION

What is evaluation?

Evaluation is a process that **measures progress** toward program objectives and **suggests improvements** needed to better meet those objectives. Sponsors and other outside agencies need evaluations to make decisions about funding and about replicating programs. Program managers and staff need evaluations to collect information for planning, to monitor program activities and to learn how a program can be improved.

When we talk about evaluation many people think of **external** evaluation. This type of evaluation, also called an "**effectiveness** evaluation"⁴, is typically requested by a program's sponsors at the middle or end of a funding cycle. External evaluations are designed and organized by external evaluators (i.e. outside consultants rather than regular staff of the program) in collaboration with the program's sponsors. Such evaluations usually aim to assess whether the program has produced certain outcomes. There are advantages to using an impartial and expert external evaluator. However, external evaluators sometimes fail to collaborate with and involve regular program staff in the design and conduct of the evaluation. External evaluators are sometimes perceived as playing a policing role.

Another type of evaluation is an **internal** evaluation (also called "**participatory** evaluation"⁵). An internal evaluation is typically requested by the creators and organizers of an on-going program and designed and organized in close collaboration with the regular staff of the program. Internal evaluations usually aim to determine how a program can be upgraded and refined. For these purposes, comparisons with other programs are not as useful as information about how well the program itself has been implemented and why the program has succeeded in some respects and fallen short of targets in other ways. This information is so useful to program managers that this type of evaluation is also sometimes called an "**improvement** evaluation"⁶.

For evaluation to be most effective it should be integrated into the structure of a program and conducted continuously and at

⁴from Arlene Fink and Jacqueline Kosekoff. An Evaluation Primer. 1978: Sage Publications, New York

⁵Marie-Therese Feuerstein. Partners in Evaluation: Evaluating Development and Community Programmes with Participants. Macmillan Publishers, London. 1986

⁶Fink A. and Kosekoff J. *Op cit*

many levels. This may include self-evaluation by field workers, day-to-day monitoring of field activities by managers, internal evaluation staff meetings after distribution is completed in each district, and external evaluations assessing the program as a whole.

Indicators for assessing ivermectin distribution programs

An indicator is a measure of progress toward an objective. For example, an ivermectin distribution program might have as an objective of its health education activities to increase knowledge of ivermectin in endemic communities. One indicator of this objective would be the percentage of adults who, when surveyed, could state one correct benefit of the drug.

Table 1 outlines the most important indicators used to assess ivermectin distribution programs. These indicators are divided into **measures of impact, measures of output and measures of management.**

1. Impact indicators

Impact indicators measure progress toward the ultimate objective(s) of the ivermectin distribution program. For most programs in Africa this ultimate objective is the prevention of blindness or other severe onchocercal morbidity. For some programs it may be possible after several years to document a decline in the prevalence of blindness in communities where 5% or more of the population have been blinded by onchocerciasis. This is because, on average, people blinded by onchocerciasis die sooner than those who are not blind. If ivermectin distribution prevents new cases of blindness in the community, the prevalence of will decline.

For most communities and most programs, however, it will probably take many years before a significant reduction in the prevalence of blindness can be documented. For most programs the impact will have to be measured indirectly by measuring the effectiveness of ivermectin in reducing microfilaria. For this purpose the Community Mean Microfilarial Load (CMFL) is the best indicator. This is an average⁷ for all the people in a community of the number of microfilaria per milligram of skin. It is important to realize that the prevalence of microfilaria in the skin is a much less sensitive indicator of the effect of ivermectin than the CMFL. This is because many people still have a small number of microfilaria in their skin after taking ivermectin. As long as the number of microfilaria in the body is

⁷The CMFL is actually a geometric average obtained through a $\log(x + 1)$ transformation.

kept low the person is protected from blindness yet the person may still be "positive" on skin snipping.

Some programs also have as an objective to control the transmission of onchocerciasis. For this purpose, the best indicator is the incidence of new onchocercal infections in some group of people not receiving ivermectin. The best group to monitor for this purpose are the children who do not yet weigh enough to qualify for ivermectin.

There are several problems with measuring any of the impact indicators discussed above. First there is the problem of representativeness. A baseline measurement is needed with which to compare the result of any impact indicator. It would be too time consuming to collect such baseline data on every community receiving ivermectin. Thus, impact indicators can only be monitored on a limited number of sentinel communities. These sentinel communities, even if randomly selected originally, may receive preferential treatment by staff who are aware that the sentinel communities are being used to evaluate the program. Thus, the results from sentinel communities may not be representative of the results for other communities targeted by the program.

There are additional problems with any indicator that requires skin snipping. People are reluctant to be skin snipped and there is some risk, if the equipment is not sterilized properly, that skin snip instruments can transmit Hepatitis or HIV. These problems can be overcome by offering an incentive to people who consent to snipping, minimizing the frequency of snipping (e.g. once each three years), snipping different people each time (as is the case when snipping children weighing less than 15 kg) and carefully training and supervising the skin snip technicians to be courteous and to disinfect the instruments after each snip.

For the reasons discussed above, most of the ivermectin distribution programs now operating have not yet attempted to directly measure their impact. Instead most programs use the coverage achieved with ivermectin distribution as an indirect indicator of program impact. Strictly speaking, ivermectin distribution is an output rather than an impact of a program. But, this is an appropriate compromise if the statistics on ivermectin distribution are credible and if the data are broken down according to the baseline endemicity of the communities treated. In other words, programs should cite not only the number of people treated but the number treated in hyperendemic communities, the number treated in mesoendemic communities and so forth. A person living in a hypoendemic community is quite unlikely to go blind from onchocerciasis even if not treated. Thus, the impact from treating a person in a hypoendemic community is much less than the impact of treating a person

living in a hyperendemic community.

2. Output Indicators

Output indicators measure the important outputs of an ivermectin distribution program. These include training of staff, health education, epidemiological assessment, ivermectin distribution and management of reactions to the drug.

One type of indicator is the absolute number of staff/people/communities reached with these outputs. Coverage is another type of indicator. It is the percentage of the total population reached with these outputs. For example, if the program distributed ivermectin to 3000 people in a group of villages with a total population of 4000 then the coverage was 75%. As another example, if health education meetings were planned for 40 villages but took place in only 30 then the coverage was 30%.

In those cases where a geographic target was set, another type of indicator is the percentage of the target which was achieved. For example, if the program had as an objective to train CBD's for 100 communities and CBD's were actually trained for 125 communities then the program exceeded its target by 25%.

For evaluation of the second and subsequent rounds of distribution another type of indicator is the percentage change from the previous year. For example, if the coverage was 75% during the first round of distribution but only 60% during the second round, then coverage fell by 15% of the total population or 20% (15/75) of the previous year's coverage.

It is important to assess not only the quantity but the quality of program outputs. For example, the evaluation should consider not only the coverage achieved by health education efforts but the effectiveness of these efforts as measured through K.A.P. surveys and focus group investigations.

3. Management Indicators

Management indicators are used to assess the quality of program planning and administration. Most of the lessons learned from an evaluation come from careful assessment of management indicators. The indicators listed in Table 1 should be self-explanatory.

Table 1:
Indicators for Evaluating Ivermectin Distribution Programs

1. **Measures of Impact**
 - a. Prevention of blindness and other severe morbidity
 - Prevalence of blindness in sentinel communities
 - CMFL in sentinel communities
 - Coverage with ivermectin (data stratified by baseline endemicity of communities)
 - b. Control of transmission
 - Incidence in children weighing less than 15 kg in sentinel communities

2. **Measures of Output**
 - a. Training of health professionals and CBD's
 - i) Quantity⁸
 - trainers
 - staff trained
 - communities/clinics/districts with enough staff trained
 - ii) Quality
 - knowledge of staff as assessed through tests and records
 - b. Information/Education/Communication
 - i) Quantity
 - mass education meetings, posters, broadcasts, etc...
 - people/communities reached
 - ii) Quality
 - knowledge, attitudes and practice as assessed through surveys and focus-groups and other qualitative methods
 - Are there any rumors circulating about the advantages or disadvantages of ivermectin or of the program in general?
 - c. Epidemiological assessment
 - i) Quantity
 - communities assessed
 - ii) Quality
 - validation of results through spot checking
 - Is distribution being delayed because of the slow pace of epidemiological assessment?
 - If skin snipping is performed, do workers adequately disinfect the scleral punch with a flame or glutaraldehyde?

⁸see text for a discussion of various quantitative indicators.

Table 1: Indicators (cont'd)

- d. Ivermectin distribution
 - i) Quantity
 - persons/communities treated (see text for explanation)
 - ii) Quality
 - incorrect dosing
 - inappropriate treatment (pregnant, sick, < 5 Kg, etc...)
 - missing ivermectin
 - inaccurate, incomplete, messy or fraudulent record keeping as assessed through review of records and spot checking
- e. Management of serious reactions
 - incomplete investigation/incomplete reporting
 - inappropriate medical management

Table 1: Indicators (cont'd)

3. Measures of Management

- a. Planning and Decision Making
 - Are the goals of the program well defined?
 - Is there a detailed implementation plan for the current year including a budget and a timetable?
 - Are short-term plans prepared?
 - Have most activities been carried out according to plan and on schedule?
 - Do partner agencies (e.g. government, local NGO's) actively participate in planning and decision making?
 - Do junior staff contribute to planning and decision making?
- b. Record keeping, supervision and monitoring
 - Does management communicate well and have a supportive relationship with staff?
 - Have record forms been adequately designed?
 - Are record forms completed adequately?
 - Do field staff receive "feedback" reports on the records they submit?
 - Is distribution and consumption of supplies adequately monitored?
 - Is use of the vehicle and motorcycles adequately controlled and monitored?
 - Is there an accountant and are accounts kept properly?
 - Are thorough audits performed at least once a year?
 - Is there any evidence that field workers or office staff have embezzled funds or stolen supplies or equipment?
- c. Progress toward sustainability
 - i) Political will of host government
 - Political will as shown in policy statements and apparent commitment of high level officials
 - Official action assigning personnel, funds, vehicles to program
 - ii) Long-term planning
 - Is there a long-term plan for sustaining the financing and the management of the program?
 - iii) Progress toward financial sustainability
 - If program sponsors cannot continue their current level of commitment for at least another five years what percentage of running costs are now paid for by host governments or fees?
 - iv) Progress toward integration
 - To what extent has ivermectin distribution been integrated with other health service programs?
 - Does management communicate well and have a supportive relationship with staff?

ASSESSING THE COST-EFFECTIVENESS OF
IVERMECTIN DISTRIBUTION PROGRAMS

Executive Summary

1. Cost-effectiveness analysis will help in the planning and implementation of ivermectin distribution programs that are financially sustainable. Thus, cost-effectiveness analysis should routinely be included in program evaluations. Cost-effectiveness analysis inherently involves a comparison. The comparison is fair and enlightening only if the outputs of competing programs are comparable and the methods used to calculate costs are adequate and consistent.
2. Evaluators of IDP's should report more than just the number of people treated. Any cost-effectiveness analysis should specify the number of people treated from communities with prevalences in various ranges (greater than 60%, 40% to 59%, 20% to 39%, less than 20%).
3. Avoid comparing programs which serve widely different communities.
4. Analyses of start-up costs should be clearly distinguished from predictions of long-term running costs. Both types of analysis are important but they need to be distinguished from one another.
5. When attempting to predict long-term running costs analysts should not forget the additional and recurring cost of two key program components: First, cost analysts should include the salaries and benefits paid by the government or other local agency. The easiest way to estimate the additional cost of staffing is to assume that entirely new people must be hired to replace the government staff now working on the IDP. Second, cost analysts should include the sometimes hidden costs of long-term management of the program.

ASSESSING THE COST-EFFECTIVENESS OF IVERMECTIN DISTRIBUTION PROGRAMS

Donors, planners and managers must study the costs of a program to determine the amount of funding required to keep it running or to expand or replicate it. If cost data can be related to information on program impact such as the number of cases of blindness prevented then it is possible to assess program efficiency.

Properly conducted cost-effectiveness studies should permit planners to select between alternative distribution strategies: fixed-center versus mobile team versus community-based distributor. Cost-effectiveness analysis should also permit funders to assess the efficiency of different implementing agencies.

Cost-effectiveness analysis is not as simple to perform as it may appear, however. This is shown by the wide range of results obtained from recent cost analyses of ivermectin distribution programs (IDP's). These analyses have suggested that the cost per year per person treated with ivermectin may be as low as U.S.\$ 0.10 or as high as U.S.\$5.00. An overly simplistic or incomplete accounting of program costs and outputs is more likely to mislead than it is to enlighten.

This section will caution against some of the pitfalls of cost-effectiveness analysis as it applies to IDP's and it will suggest some measures to be taken to assure that cost-effectiveness analysis provides decision makers with reliable information.

A cost-effective program is one which delivers a given output at lower cost than alternative programs. Cost-effectiveness analysis inherently involves a comparison. The comparison is fair and enlightening only if the outputs of the competing programs are comparable and the methods used to calculate costs are adequate and consistent.

Problems with measuring program effectiveness

For most IDP's in Africa the ultimate objective is the prevention of blindness or other severe morbidity from onchocerciasis. However, very few programs have ever attempted to estimate their effectiveness at preventing blindness. Instead, the number of people treated with ivermectin is frequently cited as the best evidence of program effectiveness. This is unfortunate because **the total number of people treated with ivermectin is a poor indicator of the impact of an IDP.**

To begin with, in a village where the prevalence of onchocerciasis is less than 50%, many people who are treated by a community-wide distribution program are not even infected. Moreover, many of those who are infected are not at significant risk of visual impairment or other serious disability or deformity. Fortunately, in the majority of communities where onchocerciasis is endemic there is only a small risk of serious morbidity from the disease. Research conducted by the WHO-Onchocerciasis Control Program has shown that in the setting of the West African savanna, communities do not face a significant risk of onchocercal blindness unless at least 40% of the population are infected^{9,10}. A person living in a hypoendemic community is quite unlikely to go blind from onchocerciasis even if not treated. Thus, **the impact from treating a person in a hypoendemic community is much less than the impact of treating a person living in a hyperendemic community.**

Ideally, cost-effectiveness analyses would determine such parameters as the cost per case of blindness prevented or the cost per case of "hanging groin" prevented. Indeed it would be appropriate for the few programs which include an extensive research component to calculate such cost ratios. Unfortunately, the only indicator of disease severity which most programs can routinely collect is the prevalence of infection. Even the most modestly funded IDP should be able to provide statistics on the number of people treated from communities with prevalences in various ranges (e.g. $\geq 60\%$, 40% to 59%, 20% to 39%, less than 20%).

The prevalence of infection is far from an ideal indicator

⁹Remme J et al. Ocular onchocerciasis and intensity of infection in the community. Trop. Med. Parasit. 40(1989), 340-354. In many forested areas, in contrast to savannah areas, onchocerciasis is significantly less likely to cause blindness even in the most heavily infected communities. However, other severe morbidity such as lymphatic obstruction may occur in hyperendemic forest communities. There is no data to suggest that the risk of severe non-ocular morbidity is significant in communities or in individuals with low levels of infection.

¹⁰Communities where 55% or more of the population is infected account for 80% of the onchocercal blindness while communities where 40% or more of the population is infected account for more than 97% of the blindness caused by this disease. Remme J. Strategies for community based and hospital based distribution systems. Presented at the WHO Meeting on Strategies for Ivermectin Distribution Through Primary Health Care Systems. WHO, Geneva, 22-25 April 1991. PBL/FIL/IVER/91/WP.12

of disease severity, however. People who live in a tiny and remote village which is heavily infected are at greater risk of blindness than people living in a town with an equal prevalence of infection¹¹. Moreover, the costs per person treated are higher for the more remote communities. **A program operating in a sparsely populated area should probably not be compared to a program operating in a densely settled area.** For similar reasons a program operating in a forest area where onchocerciasis rarely blinds should not be compared to a program operating in a savanna area.

Problems with measuring program costs

If comparing IDP outputs is problematic, evaluating their costs is even more complex. There are a multitude of ways to calculate costs. Cost-effectiveness comparisons are misleading unless they are based upon explicit accounting rules that are applied consistently.

From the donor's perspective it is the **start-up costs** that matter most. Start-up costs can be defined as the expenditures prior to the time that financial and management responsibilities are fully handed over to the government or other local agency. With many IDP's the start-up phase is expected to last two to five years.

The money spent up-front goes to pay for local and international management and overhead, international conferences, evaluations, operations research, vehicles and other capital equipment as well as the running costs for the first few years. The money spent on each of these categories has played an essential role generating the momentum that now exists to make full and optimal use of ivermectin. Thus far IDP services have been extended to roughly 5 million recipients per year. By studying the total budgets of IDP's (including overhead) we can learn much about the real cost of launching programs and we can estimate how much it will cost to extend IDP services to an additional 5 million persons per year. Thus, it is important that we analyze start-up costs.

On the other hand, few of the donors or NGO's now supporting IDP's are prepared to sustain indefinitely their current levels of financing for these programs. The financial sustainment of IDP's will depend upon whether governments, other local agencies and the few long-term donors can afford the long-term **running costs**. The challenge with which we are faced is to estimate the

¹¹WHO Technical Report Series #752, p. 131.

long-term running costs based upon financial data from the start-up phase.

Consider the hypothetical example of a non-governmental organization (NGO) with headquarters in the United States and an office in an African capital. With funds from a donor the NGO collaborates with agencies of the African government to start an IDP. Clearly, the running costs include expenditures on all field incentives, gasoline, vehicle maintenance, field office rental and utilities, photocopying/printing and drugs for side effects. Any estimate should also include the salaries and benefits paid to field staff employed by the IDP. Expenditures on short-lived equipment, including vehicles and motorcycles, should also be included in the calculations of the long-term running costs of the program¹².

Some IDP cost analyses¹³ have stopped here with their accounting. One category omitted from the above listed items are the salaries and benefits paid by agencies of the African government. The rationale for omitting these items is that they appear to be fixed costs (similar to the costs of using vacant buildings) which the government would have to pay for even if the program had not been launched. The fact that some government employees are available to work on the IDP suggests to the NGO and the donors that they must have previously been under-utilized. Under these circumstances neither the donor nor the government appear to have any increased costs as a result of the

¹²The simplest way to account for short-lived capital expenditures is to amortize the purchase price (including transport, taxes, duties) over the life span of the item. For vehicles and motorcycles operating on rural roads in most parts of Africa or Latin America it might be reasonable and convenient to assume that the life span is 1,000 days of use. As a conservative estimate it may also be reasonable and convenient to assume that during this 1,000 days maintenance and repairs will cost 50% of the purchase price. Thus, for each day of use, excluding fuel, a motorcycle with a purchase price of US\$ 2,000 would cost US\$ 2 to amortize and US\$ 1 for maintenance and repairs.

¹³One example is the analysis done by the author of the present article which is cited in the WHO Report of the Meeting on Strategies for Ivermectin Distribution through Primary Health Care Systems. Geneva, 22-25 April, 1991. WHO/PBL/91.24. Pages 11 and 62

work which government staff perform for the IDP¹⁴.

The problem with such an analysis is that it assumes that government employees are, like vacant buildings, waiting to be put to work. It should not surprise us when a government, anxious to please a foreign donor, is willing to press some of its employees into service for an IDP. When this happens, however, we should not assume that the government was not previously benefiting from other work performed by those employees.

Even if the IDP uses government employees who were previously under-utilized it is not appropriate to assume that the program can long continue getting something for nothing. The low productivity of public sector employees is often a direct result of inadequate wages. Many governments have learned that under-motivated workers are only willing to increase their productivity for brief periods such as mass immunization campaigns. The experience of the Expanded Program for Immunization over the last ten years has been that such campaigns have considerable opportunity costs.

Thus, it is best to assume that:

- a) the government staff was fully utilized before the IDP began, and
- b) the IDP will continue to benefit from the work performed by government staff only if the government increases its salaries and or hires new staff at the current wages¹⁵.

Another set of costs has yet to be accounted for-- the costs associated with *managing* the IDP. In the hypothetical example, during the start-up phase, much of the management might be provided by or paid for by the NGO. The NGO's budget for the program might include items such as salary for an expatriate adviser; part of the overhead of various offices; program evaluations; operations research;.... These expenses typically consume the majority of the money provided by the donor and yet many cost analyses predicting the long term running costs will

¹⁴Technically, financial sustainment of an IDP depends upon the ability to pay for the increase in cost, also known as the *marginal cost* due to the program.

¹⁵Some government staff might work only part-time on the IDP. The challenge is then to determine the fraction of their total time which such a worker dedicates to the program. The cost analyst can then calculate the fraction of the person's salary and benefits which should be included in the IDP cost estimates.

omit all of these items.

The reason that these expenditures on NGO administration are frequently omitted from estimates of running costs is that they are viewed as purely start-up costs. Good management yields benefits that last for many years: training, long-term plans and research findings. Thus, the NGO's expenditures on management are similar to capital costs such as those for construction of a building.

What this perspective overlooks, however, is that the management capacity provided by an NGO also meets some of the immediate and recurring needs of the program for refresher training, supervision, accounting, evaluation and short-term planning. The management paid for by an NGO is a substitute for the management which must ultimately and recurrently be paid for by whatever agency sustains the program in the long-run. **Cost analysis should not ignore the running cost of good administration.** This seems obvious. Yet many cost analyses have omitted the government-paid salaries/benefits and office overhead expenses of the local officials who ultimately are expected to run the program.

Cost analysts should estimate the cost of replacing the start-up management with local management capacity. One way to do this is to identify within the existing bureaucracy managers with sufficient ability, motivation, and office support then determine the full cost of assigning those managers and their office support to the IDP. In the public sector, however, much of the cost of good management may be hidden. In many government bureaucracies salaries and direct benefits are only part of what motivates the most productive administrators.

There is an alternative and perhaps more reliable way to estimate the cost of good management. We can ask the private sector, for example a local bank, how much they would pay for salary and support for a management position with similar responsibilities.

Table 2 lists the expenditures which should be accounted for when attempting to predict the long-term running costs of an ivermectin distribution program.

**Table 2: Estimating the Long-Term Running Costs
of an Ivermectin Distribution Program**

A. Some costs paid for by the donor during the start-up phase

Recurrent field costs¹⁶

- Field/training allowances
- Salaries/benefits of field workers employed by program
- Fuel for vehicles and motorcycles
- Rental of vehicles and motorcycles
- Field office rental and utilities
- Printing/photocopying or record forms, training materials
- Drugs for treatment of side effects

Costs of short-lived capital items

- Vehicles and motorcycles
- Office equipment (photocopier, FAX, computer, printer)

B. Some costs paid for by government or other local agency during the start-up phase

- Staff salaries and benefits¹⁷
- Field allowances
- Donations of short-lived equipment
(e.g. part-time use of vehicles)

C. Some costs which may be hidden during the start-up phase

- Long-term management

¹⁶When estimating running costs it is appropriate to exclude field expenditures for survey work (skin snipping or rapid epidemiological assessment). Money spent on survey work should either be treated as a non-recurrent start-up cost or as an expense which recurs only once in five to ten years.

¹⁷For government staff who work only part-time on the program it will be necessary to determine what fraction of their salary and benefits to charge to the IDP.

Form 4: Ivermectin Distribution Tally Record

Place of distribution _____

This record includes distribution from _____ to _____
(date) (date)

How many tablets did you have at the beginning of this period? _____

Mark in the appropriate space for each person given ivermectin
1/2 tab:

Sub-Total _____ x 0.5 = _____

1 tab:

Sub-Total _____ x 1 = _____

1 1/2 tabs:

Sub-Total _____ x 1.5 = _____

2 tabs:

Sub-Total _____ x 2 = _____

Total people treated _____

Total tablets distributed _____

How many tablets do you have at the end of this period? _____

How many tablets are missing?

(tabs at beginning) minus (tabs at end) minus (tabs distributed)
= _____

**On the back of this paper please comment if any tablets are missing
or if any problems occurred during drug distribution**

Form 6: Ivermectin Distribution Tally Record

Place of distribution _____

This record includes distribution from _____ to _____
(date) (date)

How many tablets did you have at the beginning of this period? _____

Mark in the appropriate space for each person given ivermectin

1/2 tab:

Sub-Total _____ x 0.5 = _____

1 tab:

Sub-Total _____ x 1 = _____

1 1/2 tabs:

Sub-Total _____ x 1.5 = _____

2 tabs:

Sub-Total _____ x 2 = _____

Total people treated _____

Total tablets distributed _____

How many tablets do you have at the end of this period? _____

How many tablets are missing?

(tabs at beginning) minus (tabs at end) minus (tabs distributed)
= _____

On the back of this paper please comment if any tablets are missing or if any problems occurred during drug distribution

Form 8: Record of Reactions to Ivermectin

Health worker _____ Date _____
 Name of patient _____ Age of patient _____
 Community of patient _____ District _____

1. Ask "Is it **difficult to breathe**?" YES NO
 If "YES", go get a nurse immediately
2. Ask "Are you **lightheaded** when you stand up?" YES NO
 If "YES", tell the person to **lie down and drink water**.
3. Ask "Is it **difficult to walk**?" YES NO
 If "YES", go get a nurse immediately
4. Ask "Do you have **itching or rash or swelling**?" YES NO
 If "YES", give **phenergan**
5. Ask "Do you have **pain**?" YES NO
 If "YES", give **paracetamol**
6. Ask "Do you have **fever**?" YES NO
 If "YES", give **chloroquine and paracetamol**

Phenergan dose depends upon age

<u>Age</u>	<u>Dose</u>	<u>Total tabs</u>	<u>Tabs given</u>
5 to 15 years	1/2 tab, 3 times a day	3 tabs	_____
older than 15	1 tab, 3 times a day	6 tabs	_____

Paracetamol dose depends upon age

<u>Age</u>	<u>Dose</u>	<u>Total tabs</u>	<u>Tabs given</u>
5 to 15 years	1 tab, 3 times a day	3 tabs	_____
older than 15	2 tabs, 3 times a day	8 tabs	_____

Chloroquine dose depends upon age

<u>Age</u>	<u>First Dose</u>	<u>After 6 hours</u>	<u>After 1 day</u>	<u>After 2 days</u>	<u>Total tabs</u>	<u>Total given</u>
5 to 12 years	2	1	1	1	5	_____
13 years or older	4	2	2	2	10	_____

Form 10: Record of Serious Reaction to Ivermectin

Complete this record at the same time that you treat the patient

Remember to also complete an "Adverse Experience Report Form" and send it to Merck/France

Health worker _____ Date _____

Name of patient _____ Age of patient ____

Community of patient _____ District _____

1. Ask "Is it **difficult to breathe**?" YES NO
2. Ask "Are you **lightheaded** when you stand up?" YES NO
If "YES", tell the person to **lie down and drink water.**
3. Ask "Is it **difficult to walk**?" YES NO
4. Respiratory rate (RR) _____
5. Pulse rate _____
6. Wheezing heard with a stethoscope? YES NO

If you hear wheezing with a stethoscope and the person has difficulty breathing then give the person a subcutaneous injection of adrenalin (follow the directions "How to Treat Asthma with Adrenalin")

Check the time, RR, pulse and wheezing each time that you give adrenalin and use the following chart to keep a record:

<u>Time</u>	<u>RR</u>	<u>Pulse</u>	<u>Wheezing</u> <u>(Yes or No)</u>	<u>Dose of</u> <u>adrenalin</u>
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc

What is the total amount of adrenalin given? _____ cc

Please turn over and complete the opposite side of this form.

Form 10: Serious Reactions (continued)

7. Blood pressure (BP) lying down ____/____
8. Blood pressure (BP) standing ____/____

Note: if the person is too lightheaded to stand, then measure the BP when the person is sitting up. After you have measured the BP, ask the person to lie down again.

9. Does the systolic BP fall more than 15 when the person sits up or stands? YES NO
10. Is the systolic BP less than 75 when lying down? YES NO

If the patient has difficulty walking and you answered "YES" to question 9 or question 10, then begin to give an intravenous infusion.

(follow the directions "How to Give an Intravenous Infusion")

Repeat the measurements of pulse and BP (lying down) every 30 minutes until the patient can walk without being lightheaded.

Use the following chart to record the Time, Pulse, BP, whether the patient is still lightheaded when walking and the amount of infusion which the patient has received before this time.

<u>Time</u>	<u>Pulse</u>	<u>BP</u>	<u>lightheaded (YES or NO)</u>	<u>Volume of infusion</u>
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc
_____	_____	_____	_____	_____ cc

What is the total volume of infusion given? _____ cc

If you answered "NO" to question 9 and question 10 do not give any infusion. Ask the patient to rest and drink water. Stay with the patient until he or she can walk without feeling lightheaded. Measure the pulse and BP every 30 minutes and record them on the chart above.

If the patient begins to feel worse, then measure the BP standing (or sitting) and answer questions 9 and 10 again. Follow the instructions above to decide whether an infusion is necessary.

Form 11: Supervisory Checklist
(for evaluation of work done by health professionals)

Name of supervisor: _____

Name of area: _____

Name of community: _____ Date: _____

Instructions: The supervisor should visit a random sample of 5% to 10% of all communities benefiting from the ivermectin distribution program. This includes communities where epidemiological assessment or health education activities were carried out as well as communities receiving ivermectin. While visiting, the supervisor should speak with the head of the community and other residents of the community to determine whether there are any complaints. The supervisor should bring along relevant records of all field work (Epidemiological Assessment Records, Health Education Records, Community Ivermectin Treatment Records, Clinic Ivermectin Treatment Records, Log for Vehicle or Motorcycle) and **ask the following questions** to determine whether these records were completed accurately. **Skip any section that is not relevant**

1) Supervision of epidemiological assessment

- a. Did someone come to this village to examine men for nodules or to take a sample of skin (demonstrate) Yes/No
- b. When was that (e.g. "2 weeks ago", or "3 days ago")
- c. What was his name? _____
- d. How long did the person stay in the community? _____ minutes
- e. How many people did he examine? (5? 10? 30?) _____
- f. Does anyone have any complaints about the work that this person did? Yes/No (If "Yes", record the complaint below)

2) Supervision of health education

- a. Did someone come to this village to teach people about _____ (use vernacular term for onchocerciasis) and a new drug that can treat this disease? Yes/No
- b. When was that? (e.g. "2 weeks ago", or "3 days ago")
- c. What was his name? _____
- d. How long did the person stay in the community? _____ minutes
- e. How many people did he speak to? (5? 20? 100?) _____
- f. Did you hear him when he talked about the new drug? Y/N
- g. Who should take this new drug? _____
- h. Who should not take this new drug? _____
- i. How often should a person take this new drug? _____
- j. Does anyone have any complaints about the work that this person did? Yes/No (If "Yes", record the complaint below)

Form 11: Supervision of Health Professionals (continued)

3) Supervision of community distribution

(for evaluation of distribution by mobile professionals)

- a. Did a health worker come to this community to distribute a new drug for treating _____ (use vernacular term for onchocerciasis) ? Yes/No
- b. When was that? (e.g. "2 weeks ago", or "3 days ago")
- c. How many workers came to distribute this new drug? _____
- d. How long did they stay in the community? _____ minutes
- e. How many people did they treat? (20? 100?) _____
- f. When should people in this community take this new drug again?
- g. Does anyone have any complaints about this drug or the way that it was distributed? Yes/No
(If "Yes", record the complaints below)
- h. Please help me to find these five people
Select five names at random from the list of people treated. To help people identify the person read the names that precede and follow the selected name. Visit the house of each person. Ask someone to tell you the age of the person. Ask whether the person received ivermectin. Ask when they received ivermectin. Ask how many tablets they received. Are there any major discrepancies between what is written on the Community Ivermectin Treatment Record and what people tell you?
i. Yes/No ii. Y/N iii. Y/N iv. Y/N v. Y/N

4) Supervision of clinic-based distribution

- a. In the last year did many people from this community go to a clinic to get a drug for treatment of _____ (use vernacular term for onchocerciasis) ? Yes/No
- b. What is the name of the clinic they went to? _____
- c. When should people in this community take this new drug again?
- d. Does anyone have any complaints about this drug or the way that it was distributed? Yes/No
(If "Yes", record the complaints below)
- e. Please help me to find these five people
Select five names at random from the list of people treated. To help people identify the person read the names that precede and follow the selected name. Visit the house of each person. Ask someone to tell you the age of the person. Ask whether the person received ivermectin. Ask when and where they received ivermectin. Ask how many tablets they received. Are there any major discrepancies between what is written on the Community Ivermectin Treatment Record and what people tell you?
i. Yes/No ii. Y/N iii. Y/N iv. Y/N v. Y/N

Form 12: Supervisory Checklist
(for final evaluation of the Community-Based Distributor)

After a CBW has finished distributing ivermectin, the supervisor should visit the community one final time to do the following tasks. Place a check mark next to each task after completing it.

- ___ 1. Collect the weighing scale or tape measure.
- ___ 2. Collect the remaining ivermectin. Count the number of tablets of ivermectin remaining. Record this on the **Ivermectin Distribution Tally Record**. Also write on the tally record the name of the community, the name of the CBD, the dates of distribution and the total number of tablets of ivermectin originally supplied to the CBD.
- ___ 3. Collect the **Household Ivermectin Treatment Records**. How many of these records are there? ___
- ___ 4. Use the **Ivermectin Distribution Tally Record** to add up the treatments recorded on the **Household Distribution Treatment Records**: for each person who was treated place a mark on the tally record to indicate the number of tablets given to that person. Add up the the treatments and determine how many tablets are missing. If more than 10 tablets of ivermectin are missing question the CBD carefully to learn why and record the reason on the back of the tally record. Use a stapler, pin or paper clip to attach the completed tally record to this Supervisory Checklist.
- ___ 5. Collect the **Records of Reactions to Ivermectin**. How many of these records are there? ___
Ask "How many serious reactions occurred in this community?" ___

For each serious reaction, ask the CBD to show you the specific record of the reaction. Discuss each serious reaction with the CBD to make sure that it was managed appropriately. If the reaction was mismanaged, comment in detail on the back of the record of the reaction. Use a stapler, pin or paper clip to attach the records of all serious reactions to this Supervisory Checklist.

- ___ 6. Interview the head of the community.
 - a) Is there anyone in the community who is not satisfied with the work done by the CBD? (Yes or No)
 - b) Are there some people in the community who did not receive the ivermectin? (Yes or No)
 - c) Are there some people in the community who had a bad reaction after taking the ivermectin? (Yes or No) ___

If the head of the community answers "Yes" to any of these three questions find out why and report.

Form 12: Supervision of CBDs

7. Pick at random five **Household Ivermectin Treatment Records**. Ask the CBD to help you find the house which corresponds to each of these five household records. Visit the five houses to interview the residents:

a) Read the names listed on the household treatment record. Ask whether each of these people actually lives there and whether they received ivermectin. Ask someone to tell you the age of each person listed. Check that the age roughly agrees with what is written on the household form. Do you detect any major discrepancy between what is written on the household records and what the residents of the house tell you ?

i. Yes/No ii. Yes/No iii. Yes/No iv. Yes/No v. Yes/No

b) In each house ask "Is there anyone who is not satisfied with the work done by the CBD?"

i. Yes/No ii. Yes/No iii. Yes/No iv. Yes/No v. Yes/No

c) In each house ask "Is there anyone here who will refuse to take the drug again?"

i. Yes/No ii. Yes/No iii. Yes/No iv. Yes/No v. Yes/No

If the answer is "Yes" for any house explain on the back of the tally record.

d) In each house ask "Which disease will this drug treat?" For each house indicate whether their answer is right or wrong.

i. Right/Wrong ii. R/W iii. R/W iv. R/W v. R/W

e) In each house ask "When should you take the drug again?" The correct answer is "one year from now". For each house indicate whether their answer is right or wrong.

i. Right/Wrong ii. R/W iii. R/W iv. R/W v. R/W

8. How much allowance should the CBD be paid? _____

Form 13: Ivermectin Distribution Tally Record

Place of distribution _____

This record includes distribution from _____ to _____
(date) (date)

How many tablets did you have at the beginning of this period? _____

Mark in the appropriate space for each person given ivermectin

1/2 tab:

Sub-Total _____ x 0.5 = _____

1 tab:

Sub-Total _____ x 1 = _____

1 1/2 tabs:

Sub-Total _____ x 1.5 = _____

2 tabs:

Sub-Total _____ x 2 = _____

Total people treated _____

Total tablets distributed _____

How many tablets do you have at the end of this period? _____

How many tablets are missing?

(tabs at beginning) minus (tabs at end) minus (tabs distributed)
= _____

On the back of this paper please comment if any tablets are missing or if any problems occurred during drug distribution

Form 15: Monthly Field Summary

Administrator _____

Area for which you are responsible _____

For the time period beginning _____ (date) and ending _____ (date)

1. Epidemiological assessment

List the communities in which epidemiological assessment was completed during this period.

2. Health education

List the communities in which health education meetings (10 or more people) were held during this period. Give the number of meetings if more than one meeting was held in a community.

3. Training of community workers

List the communities for which community workers have been trained during this period. Give the number of workers if more than one worker was trained in a community.

4. Training of health professionals

List the sites where training courses were held for health professionals during this period. Give the number of health professionals trained at each site.

Monthly Field Summary

5. Ivermectin distribution

List the communities from which people were treated and the number of people treated from each of these communities.

6. Ivermectin inventory

During this period how many tablets did you ...

...have at the beginning of the period? _____
...receive from the central store? + _____
...return to the central store? - _____
...issue to the field? - _____
...collect from the field? + _____
...have at the end of the period? - _____
...not account for = _____

Comment in a separate report about tabs not accounted for.

7. Vehicle/motorcycle movement

License plate number _____
Odometer at beginning _____
Odometer at end _____

Comment on a separate piece of paper about repairs costing more than U.S. \$20.

8. Serious reactions

During this period how many people had serious medical problems (wheezing, fainting, other) within 4 days after taking ivermectin? _____

For each serious reaction include along with this summary copies of the "Record of Serious Reaction to Ivermectin" and the "Adverse Experience Report Form"

Facsimile

Date: August 19, 1993
To: Brian Duke
FAX: 44-524-388-942
From: Bob Pond
Tel: (404) 982-0221

Brian,

I've received the copies of the chapters that you mailed. For most chapters I have only a few spelling and grammatical changes to suggest. I am mailing you my edited copies although you have probably already corrected many of the mistakes I found.

In this FAX I would like to suggest a few things that might be added to chapters 12, 15 and 19.

1. In Chapter 12, the following sentence might be added to the first paragraph under "Problems and methods of cost recovery":

IDP's introducing fees should *document* how the resulting fees are spent.

The following sentence might be added to the second paragraph in the same section:

IDP's introducing fees should *monitor* the impact of cost recovery on demand for ivermectin by women, children and economically disadvantaged social groups.

2. In the outline of "Costs to be met" in Chapter 15:

- item a-i might read "Wages, per diem and transport costs of distributors *and their supervisors*"

- section (a) might also include item (v): "*salary, benefits, transport and office overhead for planners, administrators and evaluators*"
- item b-i might read "Additional training of pre-existing health centre personnel, and their periodic refresher training *and supervision*."

3. I appreciate your frankness when you note in chapter 19 that "Against this background of uncertainty, it may be difficult to persuade potential donors to contribute the very considerable funds necessary to extend ivermectin coverage" What effect will this paragraph itself have on donors?

4. I would like to suggest that chapter 19 include the following as a separate item:

Impact of integrating ivermectin distribution with the existing PHC system

Many communities with endemic onchocerciasis are currently covered by expanded immunization programs, clinic-based services or community-based health worker programs. In addition to identifying and determining the number and percentage of villages with serious onchocerciasis which are reached by existing PHC services, researchers should examine how the additional responsibilities involved in ivermectin delivery affect the workload, output (e.g. vaccination coverage), morale, availability of transport and financial support of primary health workers and the managers and agencies that must supervise and support them in the long-term.

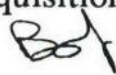
5. The following item might also be added to chapter 19:

Impact of user fees on the effectiveness, efficiency and sustainability of IDPs

Operational research is needed to determine how fees affect demand for ivermectin; whether coverage of certain socio-economic groups, large families, women or children will suffer as a result of such fees; whether the revenues generated by fees are indeed used to defray the expense of ivermectin distribution; and whether health workers' motivation and courtesy improve when they are paid a portion of such fees.

6. The final section of chapter 19 ("Other topics") might include
Cost-effectiveness of alternative ivermectin distribution strategies
7. It would be appropriate to change the expression "KAP studies" to "KAP and focus group studies" in order to emphasize the usefulness of qualitative research methods to studying human behavior. KAP surveys with their pre-coded answers yield data about the prevalence of certain well defined and already well described perceptions and practices. With qualitative research methods, on the other hand, we are much more likely to uncover new findings and learn *why* people hold certain beliefs or behave in certain ways. In many circumstances, the important questions can be answered with a focus group making an expensive and time-consuming KAP survey unnecessary.

Finally, "off the record", I would like to make a few remarks about the general concepts of regional planning and national planning (chapters 2 and 4). Clearly, the NGO's are venturing into uncharted territory when they hypothesize about these topics. The success of the OCP has depended upon such centralized planning and administration. Ivermectin, however, cannot be distributed by helicopters and fixed-wing aircraft. Ivermectin delivery depends upon the efforts of thousands of foot soldiers and the lieutenants who supervise them. Much of the considerable progress achieved to date in delivering ivermectin has been possible only because the OCP and NGOs have by-passed the centralized Ministry of Health hierarchies and bureaucracies to directly train and manage local health workers. What will happen when ivermectin distribution is the responsibility of a national Co-ordinating Board which formulates policy guidelines, draws up a nationwide plan of operations and time-tables, selects personnel, organizes training sessions, provides equipment, supplies and logistical support and administers the entire national IDP? Is there a Ministry of Health anywhere in Africa which is up to performing these tasks? I suspect not. We should be careful lest we get what we ask for. Do we really want the Nigerian NOCP to serve all these functions? I think not. In Africa, national and regional planning usually work only on paper. In practice, it is most often best to decentralize authority. End of speech.

I hope things are going well integrating the efforts of a Belgian, a Brit, several Yanks of different persuasions, a Frenchman and a Ghanaian. Nicholas, our son, is indeed a great acquisition. I have to stop here as he seems to need some attention. Regards, 

```

*****
*                                                                 P.01 *
*                                                                 *
*              TRANSACTION REPORT                                *
*              ----- JUL-30-93 FRI 18:29                    *
* DATE   START   RECEIVER   TX TIME   PAGES   NOTE *
*-----*-----*-----*-----*-----*-----*
* JUL-30 18:18 0524 388942   10'27"   20     OK *
*
*****

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\$ 0.98 for 1st min
\$ 0.60/min thereafter

0.98
6.00

\$ 6.98

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*****
*                                                                 P.01 *
*                                                                 *
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\$ 0.98 for first minute
+ \$ 0.60/min thereafter

0.98
6.00

\$ 6.98

TRANSACTION REPORT

JUL-30-93 FRI 17:49

DATE	START	RECEIVER	TX TIME	PAGES	NOTE
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~~\$ 0.98 for 1st minute~~
~~\$ 0.50/min thereafter~~
 \$ 1.15 for 1st minute
 \$ 0.71/min thereafter

~~0.98~~
~~0.60~~
~~1.58~~
 1.15
 7.71
~~8.89~~ 1.15
 0.71
 \$1.86

TRANSACTION REPORT

JUL-30-93 FRI 18:03

DATE	START	RECEIVER	TX TIME	PAGES	NOTE
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~~\$ 0.60/min thereafter~~
 \$ 1.15 for 1st min
 \$ 0.71/min thereafter

~~0.98~~
~~0.60~~
~~7.56~~
 1.15
 7.81
 \$8.96

< TRANSACTION REPORT >

08-19-1993(THU) 20:37

[TRANSMIT]

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14387	8-19	20:35	0524 388942	3	0° 02' 07"	NORM.E	OK
				3	0° 02' 07"		

Kinko's - the copy center (404) 270-1544
480-A Briarcliff Rd.
Atlanta, GA 30345

QUANTITY	UNIT PRICE	DISC.	AMOUNT
1	7.00	0.00	7.00
FAX INTERNATIONAL REGULAR SEND 1ST PART			
2	2.00	0.00	4.00
FAX INTERNATIONAL REGULAR SEND ADDITION			
SUB-TOTAL			11.00
TAX			0.00
TOTAL			11.00
CHECK SALE			11.00
CHANGE			0.00

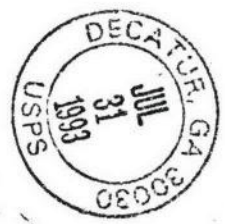
Receipt Number : 325 Register 2
Date : 08/19/93
Time : 8:53 PM
Co-Worker : 6
Kinko's Thanks You For Your Patronase

899 POSTAGE 6.78

TOTAL: \$ 8.78
189 PVI 16.86

899 POSTAGE .29

TOTAL: \$ 16.29
CHECK TENDERED \$ 16.80



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IB547868882 US

ORIGIN	Date M D Y In: 7/31/93	Postage \$ 16.00
Post Office ZIP Code 31030	Time In: A.M. P.M. 12:54	Return Receipt \$
Initials of Receiving Clerk [Signature]	Weight lbs. 1.9 oz.	C.O.D. \$
ACCEPTANCE	<input type="checkbox"/> International Country Code GB	
<input type="checkbox"/> Next Day Delivery OR <input type="checkbox"/> Second Day Delivery		Total Postage & Fees \$ 16.00
<input type="checkbox"/> By 12 Noon OR <input type="checkbox"/> By 3:00 PM.		
<input type="checkbox"/> Military 2nd Day OR <input type="checkbox"/> Military 3rd Day		

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 SIGNED: _____

CUSTOMER RECEIPT

FROM:
 Dr Bob Pond
 1301 Willyree Dr
 Decatur, GA 30033
 USA
 404 952-0221

TO: Telephone Number: 44-524-61187
 Dr B.O.L. Duke
 2 Hillside
 Lancaster, LA1 1YH
 United Kingdom

Label 11-B (April 1990)

Thank You For Using Express Mail Service

*** U.S. POSTAL SERVICE ***
MAIN POST OFFICE 223
DECATUR, GA, 30030

CLERK #13

DATE: 08/20/93 01:25:05 PM

109 PVI

2.90

TOTAL: \$ 2.90

*** THANK YOU ***

*Package to
Brian Duke*

CHECK TENDERED \$ 16.00

*** U.S. POSTAL SERVICE ***
MAIN POST OFFICE 223
DECATUR, GA, 30030

CLERK #13

DATE: 08/20/93 01:26:25 PM

090 POSTAGE

16.00

TOTAL: \$ 16.00

CHECK TENDERED \$ 16.00

*** THANK YOU ***

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Aug 20
Date Mailed: *1600*

Initials:

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(See section 295 of the Domestic Mail Manual for exclusions of coverage, such as negotiable items and consequential loss.)

- (1) **Merchandise Insurance.** Merchandise is insured against loss, damage or rifling up to a maximum of \$500. Indemnity will not be paid for spoilage of perishable items.
- (2) **Document Reconstruction Insurance.** Non-negotiable documents are insured against loss, damage or rifling up to \$50,000 per piece subject to a limit of \$500,000 per occurrence.
- (3) The maximum indemnity payable for negotiable items, cash, currency, or bullion is \$15.

Claims:

- Claims for delay, loss, damage or rifling must be made within 90 days. Claim forms may be obtained and filed at any post office.
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IB491840954 US

ORIGIN	Date In: <u>8/18/93</u>	Postage <u>\$11.50</u>
Post Office ZIP Code <u>30033</u>	Time In: <u>12:31</u> <u>PM</u>	Return Receipt \$
Initials of Receiving Clerk <u>JWZ</u>	Weight <u>3</u> lbs. <u>3</u> oz.	C.O.D. \$
ACCEPTANCE <input checked="" type="checkbox"/> International Country Code <u>EB</u>		
<input type="checkbox"/> Next Day Delivery OR <input type="checkbox"/> Second Day Delivery		Total Postage & Fees <u>\$11.50</u>
<input type="checkbox"/> By 12 Noon OR <input type="checkbox"/> By 3:00 P.M.		
<input type="checkbox"/> Military 2nd Day OR <input type="checkbox"/> Military 3rd Day		
Express Mail Corporate Account No.:	Federal Agency Account No.:	
FROM: <u>Bob Pond</u> <u>1301 Williams Dr</u> <u>Doraville GA 30033</u> <u>USA</u>		

Service Guarantee: If this shipment is mailed at designated USPS Express Mail service facilities on or before the specified deposit time for overnight delivery to the addressee, it will be delivered to the addressee or agent before noon or 3:00 p.m. the next day. Upon application by the mailer, USPS will refund the postage for this shipment if it is not delivered before noon or 3:00 p.m. of the next day unless delivery was attempted, but could not be made, or because this shipment was delayed by strike or work stoppage. Consult your local Express Mail directory for morning and afternoon delivery areas. See The Domestic Mail Manual, Chapter 2, for details. Signature of the addressee, addressee's agent, or delivery employee is required upon delivery. Express Mail International Service mailings are not covered by this service guarantee. See the International Mail Manual for details.

Insurance Coverage: (See section 295 of the Domestic Mail Manual for exclusions of coverage such as negotiable items and consequential loss.) (1) *Merchandise Insurance.* Merchandise is insured against loss, damage or rifling up to a maximum of \$500. Indemnity will not be paid for spoilage of perishable items. (2) *Document Reconstruction Insurance.* Non-negotiable documents are insured against loss, damage or rifling up to \$50,000 per piece subject to a limit of \$500,000 per occurrence. (3) The maximum indemnity payable for negotiable items, cash, currency or bullion is \$15.

Claims:

- Claims for delay, loss, damage or rifling must be made within 90 days.
- Claim forms may be obtained and filed at any post office.
- The Customer Receipt must be presented when a claim is filed.

Waiver of Signature and Indemnity (Domestic Only)

I wish delivery to be made without obtaining the signature of the addressee or the addressee's agent (if in the judgement of the delivery employee, the article can be left in a secure location) and I authorize the delivery employee to sign that the shipment was delivered and understand that the signature of the delivery employee will constitute valid proof of delivery.

SIGNED: _____

CUSTOMER RECEIPT

TO: Telephone Number: 404 529 69187

Brown Duke
River Birchwood Park
2 Hillside
Doraville GA 30033
USA

Label 11-B (April 1990)

Thank You For Using Express Mail Service

Fold and Detach Stub Here

IB491840954 US

Customer:

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PRIVACY ACT: Your name and address may be used by the Postal Service to send you updated information about Express Mail service. You may request removal of your name and address from our mailing list by writing Assistant Postmaster General, Marketing Department, USPS, Washington, DC 20260-6300. Authority: 39 U.S.C. 401, 403, 404.

Additional information on Express Mail Service can be obtained at any post office or by writing USPS Headquarters, Washington, DC 20260-6334.

Date Mailed: _____ Initials: _____

Service Guarantee:

If this shipment is mailed at designated USPS Express Mail service facilities on or before the specified deposit time for overnight delivery to the addressee, it will be delivered to the addressee or agent before noon or 3:00 p.m. the next day. Upon application by the mailer, USPS will refund the postage for this shipment if it is not delivered before noon or 3:00 p.m. of the next day, unless delivery was attempted, but could not be made, or because this shipment was delayed by strike or work stoppage. Consult your local Express Mail directory for morning and afternoon delivery areas. See The Domestic Mail Manual, Chapter 2, for details. Signature of the addressee, addressee's agent, or delivery employee is required upon delivery. Express Mail International Service mailings are not covered by this service guarantee. See the International Mail Manual for details.

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Claims:

- Claims for delay, loss, damage or rifling must be made within 90 days. Claim forms may be obtained and filed at any post office.
- The Customer Receipt must be presented when a claim is filed.

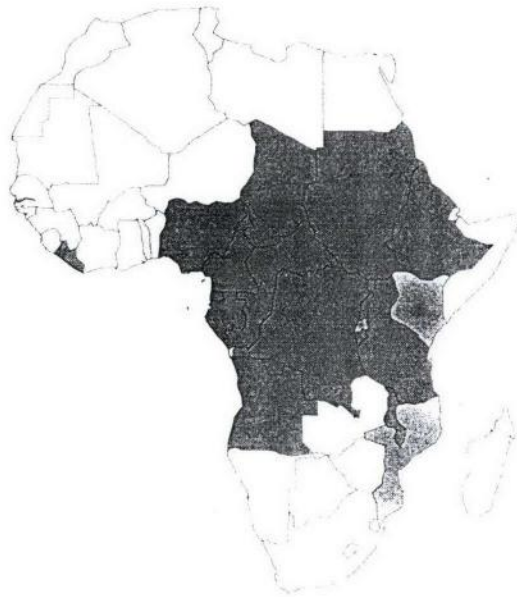
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Ivermectin
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AFRICAN PROGRAMME
FOR
ONCHOCERCIASIS CONTROL
(APOC)



GUIDELINES FOR DEVELOPMENT OF NATIONAL
PLAN AND PROJECT PROPOSAL FOR SUSTAINABLE
COMMUNITY-BASED IVERMECTIN TREATMENT

May, 1996

IMPORTANT INFORMATION

In order to apply for funding to the African Programme for Onchocerciasis Control (APOC) you are required to:

1. Submit a national plan for onchocerciasis control from the national onchocerciasis task force. Information on this procedure is found on page 9.
2. Submit a proposal for funding for community-based ivermectin treatment (CBIT). This should be submitted jointly by the Ministry of Health (MOH) of the country concerned and their partner (NGDOs) through the National Onchocerciasis Task Force (NOTF) to cover the whole or part of the National Plan.

Proposal forms to be directly filled in: pages 11 to 36

If necessary and upon request, WHO/APOC may provide consultant advice to the National Onchocerciasis Task Force (NOTF) to assist in the preparation of their proposals.

It must be noted that a proposal to APOC for financial support of a CBIT does not eliminate the requirement to apply for ivermectin to the Mectizan® Expert Committee.

Please note that request for ivermectin and report of its subsequent use must be made directly and separately to the Mectizan® Expert Committee, using the forms provided by the Mectizan® Donation Program and a copy sent to APOC.

3. Submit a signed request to APOC from the National Onchocerciasis Task Force (i.e. Ministry of Health and partner NGDOs) (page 6)
4. Submit a signed letter of endorsement from the Ministry of Health (page 7)

The national plan, the completed proposal form for funding, signed request from NOTF and letter of endorsement from Ministry of Health should be sent to:

**African Programme for Onchocerciasis Control
B.P. 549
Ouagadougou
Burkina Faso**

The forms should be received by:

August 31, 1996 for review in October, 1996 or February 28, 1997 for review in April, 1997.

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PART I

***BACKGROUND INFORMATION ON THE AFRICAN
PROGRAMME FOR ONCHOCERCIASIS CONTROL
(APOC)***

1. APOC: AN OVERVIEW

1.1 Objective

The objective of the Programme (APOC) is to establish, within a period of 12 years (1996-2007), effective and self-sustainable community-based ivermectin treatment throughout the endemic areas in the geographic scope of the Programme (i.e. those endemic countries of Africa outside OCP) and, if possible, to eliminate the vector and hence the disease, by using environmentally safe methods in selected foci.

The attainment of this objective will ultimately realize the goal of elimination of onchocerciasis as a disease of public health and socio-economic importance throughout Africa and so contribute to improving the welfare of its people.

1.2 Strategy

1.2.1 Principal strategy

The main control measure used by APOC will be mass treatment with the microfilaricidal drug Mectizan® (of which the active ingredient is ivermectin MSD), provided free of charge for as long as needed to as many people as necessary by the manufacturers, Merck and Co., Inc., under the terms of the Mectizan® Donation Program. Treatment will be through community-based distribution, in all areas of the programme where onchocerciasis is a disease of public health and socioeconomic importance.

The APOC will be a 12 year programme during which self-sustainable Community-Based Ivermectin Treatment (CBIT) will be established in all participating African countries. The CBITs must be designed to become self-sustaining, without APOC or other external support, within 5 years from their inception.

1.2.2 Local vector elimination

Where appropriate CBITs may be supplemented by local elimination of the blackflies (*Simulium*). Local vector elimination operations will be funded entirely by APOC except for any in-kind contribution from the Ministry of Health (MOH). APOC, through WHO, may provide external consultants to assist in the planning, training and execution of the vector elimination projects.

1.3. Definitions

1.3.1 Community-based Treatment

In community based ivermectin treatment, the execution of delivery is undertaken by members of the endemic communities themselves. Treatment may be provided by trained personnel, known as Community-Based Distributors (CBD's), selected from the various existing organizational structures at the community level, e.g. women cooperatives. Whatever the treatment approach used, it should be fully supported by the community itself and the community should be responsible for its execution under minimum but effective medical supervision, once it has received the necessary information and training.

1.3.2 Sustainability

The concept of sustainability in this development process refers to the ability of communities following initial external investment to maintain the viability and continuity of the ivermectin treatment process without external support.

1.4 **Partners**

The CBITs with financial and technical support from APOC and through the National Onchocerciasis Task Force (NOTF) shall be joint, co-operative undertakings of the Ministries of Health (MOH) of the participating countries, working in partnership with Non-Governmental Development Organizations (NGDOs) and other participating partners which have experience in running CBITs and which are prepared to continue to assist in implementing such projects and in achieving their full sustainability as stated above.

1.5 **Funding**

Funding for CBITs will be on the basis of up to 75% contribution from APOC, and a minimum of 25% budget contribution from the NGDOs and the host governments (working together as the NOTF), in cash or in kind (e.g. provision of personnel, office space, etc.). Contributions from the NGDOs shall not include overhead costs of these organizations outside the country whose CBIT they are assisting. Funds from the World Bank APOC Trust Fund will be channelled through WHO and APOC to the designated project bank account.

Disbursement of funds will require 2 signatures from members of the NOTF, one representing the MOH and one representing the NGDO partners.

Proposals for CBITs will be reviewed by a Technical Consultative Committee (TCC) of APOC, which meets twice a year, in April and September, and which will make recommendations for funding to the Committee of Sponsoring Agencies (CSA) of APOC.

1.6 **Organization**

The governing board of APOC is the Joint Action Forum (JAF), which is made up of representatives of:

- a) contributing parties
- b) participating countries
- c) four sponsoring agencies
- d) eleven representatives of NGDOs

The Committee of Sponsoring Agencies (CSA), consisting of representatives of the FAO, UNDP, WHO and the World Bank, acts as an executive secretariat.

APOC's funds are raised and held in trust by the World Bank. The Executing Agency for APOC is the WHO. The present Headquarters of APOC are located in Ouagadougou, Burkina Faso, and the interim Director of the Programme is also the Director of the OCP. The NGDO Coordination office for ivermectin distribution, a part of APOC's management, is based in the Prevention of Blindness and Deafness Division of WHO in Geneva, and acts as a liaison office.

2. DEVELOPING COMMUNITY-BASED IVERMECTIN TREATMENT (CBIT)

The development of CBIT should pay appropriate attention to relevant socio-cultural factors at the community level and to the lessons learned from previous experiences. Continued development and improvement of CBIT will be important as was highlighted during a consultative meeting on APOC which concluded that *"CBIT should form the main basis for the control strategy of the new programme. However, because of the diversity of endemic communities, the need for local solutions, the particular needs associated with gender differences, and the need to learn from experience, it will be necessary to continue the development and improvement of community-based approaches during the new programme."*

The further development of CBIT will involve the reorientation of non-sustainable approaches to mass ivermectin treatment, the incorporation of operational research findings, careful evaluation of the implementation of new approaches, and adjustment of CBIT's when required. It will be a learning process in which the regional structure of APOC is used to ensure that lessons learned are available to all participating countries.

The development and implementation of CBIT will be undertaken by Ministries of Health and their partner NGDO's through projects supported by APOC. It is anticipated that the development, implementation and fine-tuning of a CBIT project will take up to five years. The main criterion for supporting projects will be their proposal for progression towards development and implementation of sustainable CBITs. It must be reiterated that the concept of sustainability shall be the underlying philosophy of the programme.

3. CRITERIA FOR PARTICIPATION IN APOC

Criteria for participation in APOC relate to the disease, APOC's principal strategy and partners' commitment.

3.1. The Disease

Onchocerciasis must be recognized at the national level as a public health problem warranting control.

The epidemiology of onchocerciasis must be documented in terms of geographical distribution, population at risk, prevalence and severity of the disease.

3.2. APOC Strategy

All involved partners (Ministry of Health, NGDOs other participating agencies and communities at risk) agree to the strategy of developing effective self-sustainable community-based ivermectin treatment which will continue beyond the duration of APOC in order to eliminate onchocerciasis in all areas where it is a disease of public health and socio-economic importance.

3.3. Partner Commitment

The Ministry of Health and NGDO partners agree to establish a National Onchocerciasis Task Force which will formulate and implement a National Plan for onchocerciasis control. The partners agree to meet at least 25% of the costs of CBITs, and to provide annual operational and financial reports to APOC. The partners agree to internal and external evaluations, including audits, and to facilitate visits and activities of APOC staff members, or their representatives.

PART II
FUNDING REQUEST AND ENDORSEMENT FORMS

National Onchocerciasis Task Force (NOTF) of
Application for support to
the African Programme for Onchocerciasis Control (APOC)

In accordance with the memorandum of agreement for the African Programme for Onchocerciasis Control:

1. The NOTF on behalf of the Government of (.....), (a partnership of government, the NGOs and other partners) hereby expresses its wish to enter into collaboration with the APOC and the MEC with a view to conducting an onchocerciasis control project in (.....).
2. Onchocerciasis in (.....) is considered by the health authorities as a problem of sufficient importance to warrant the implementation of a control project in the endemic areas with the aim of eliminating the disease as a public health and socioeconomic problem throughout the country.
3. It is estimated that out of a total population of000 in (.....), there are (number of infected people) people infected with the parasite, *Onchocerca volvulus*, causing blindness, serious visual impairment and debilitating skin disease.
4. The Proposed control project will rely on community-based ivermectin treatment as its main intervention tool.
5. The NOTF has scrutinized the criteria and conditions for application to the APOC and is satisfied that the proposed project(s) meets all the criteria and fulfills the conditions established by the APOC.
6. Details of the project proposal for control of onchocerciasis in (.....) including the support requested from APOC to successfully implement the project are provided in the enclosed proposal.
7. The NOTF of (.....) pledges its full collaboration with APOC in the expectation of acceptance of the present proposal.

 Signature, place and date
 NOTF Rep. of Gov.

 Signature, place and date
 NOTF Rep. of NGOs

 Name and title of signatory

 Name and title of signatory

**Letter of endorsement from the Government of.....
To the African Programme for Onchocerciasis Control (APOC) for
support of the proposed onchocerciasis control project**

In accordance with the memorandum of agreement for the African Programme for Onchocerciasis Control:

1. The Ministry of Health on behalf of the Government of (.....) hereby endorses the attached project proposal to be submitted to APOC for financial support.
2. This proposal reflects the collaboration between the members of the National Onchocerciasis Task Force and APOC with a view to conducting an onchocerciasis control project in (.....).
3. The National Onchocerciasis Task Force is a partnership of the Government, Non-Governmental Development Organisations and other participating parties which will be responsible for the implementation of this project.
4. The Government shall assure free entry of ivermectin into the country for delivery to the applicant without imposing duty, tax, or other costs.
5. The Government of (...) pledges its full collaboration with the APOC in the expectation of acceptance of the present proposal.

Signature, place and date

Name and title of signatory

PART III

**GUIDELINES FOR FORMULATING A NATIONAL
PLAN FOR ONCHOCERCIASIS CONTROL
THROUGH COMMUNITY-BASED IVERMECTIN TREATMENT**

GUIDELINES FOR FORMULATING A NATIONAL PLAN FOR ONCHOCERCIASIS CONTROL

The following questions should be considered in finalising a national plan

1. BACKGROUND INFORMATION

What is the administrative and health structure?
 What is the primary health care system?
 What is the knowledge of the distribution and endemicity of onchocerciasis in the country?
 How far has Rapid Epidemiological Mapping of Onchocerciasis (REMO) been carried out in the country?
 How far has Rapid Epidemiological Assessment (REA) been carried out in the country?
 What is the estimated population at risk?
 How many rural communities constitute the population at risk?
 What are the common clinical manifestations of the disease in affected communities?
 Is there a cross-border focus of onchocerciasis, if so which countries are involved?

2. OBJECTIVES

What are the national programme objectives?

3. STRATEGY

What is the overall strategy for the control of onchocerciasis?
 How are priority areas for onchocerciasis control identified?
 What are the criteria for including populations for CBIT (See paragraph 1.3 of the proposal form)?
 How will CBIT be developed, and how will communities be involved in this process?
 What are the plans for monitoring CBIT?
 How will ivermectin be procured?
 What mechanisms will be used to ensure delivery of ivermectin to CBITs?
 Is there a national policy for cost recovery and how will this affect CBITs?
 How are CBITs to be made sustainable without external support at the cessation of APOC support?
 If there are cross-border foci of disease what particular action is being taken to deal with these areas?

4. ADMINISTRATION/MANAGEMENT

Is there a National Onchocerciasis Task Force (NOTF)? If not what action is being taken to establish this body?
 Who are the members (organisations and positions) of the NOTF?
 Is there a National Co-ordinator? If not what action is being taken to establish this position?
 What is the formal link between the NOTF and Ministry of Health?
 How does the NOTF facilitate development and interact with CBITs?

5. TIME - PLAN

What are the major control activities to be undertaken year by year for the programme to achieve its objectives?

6. BUDGET

What is the estimated budget year by year for the programme to achieve its objectives?

PART IV

**PROPOSAL FORM FOR
COMMUNITY-BASED IVERMECTIN TREATMENT**

SECTION 1: COUNTRY PROFILE

1. INFORMATION ON THE PROJECT AREA FOR C.B.I.T.*

1.1 Geographical and administrative area(s)

Please describe the area(s) of the country in which the proposed CBIT will be carried out. (List the administrative units or parts thereof e.g., Local Government Areas, Districts, Arrondissements, Health areas etc. that will be covered and provide a map showing their layout)

1.2 Topography, climate, access

1.2.1 Please describe the type of country or bio-climatic zones that will be covered by the CBIT (e.g., rain-forest, forest-savanna mosaic, Guinea savanna, Sudan savanna, mountainous or flat), providing maps, if appropriate.

1.2.2 Give the approximate times of the rainy and dry seasons and the months covered by the farming season.

1.2.3 Provide information on the state of the roads and the effect of this on the movements of CBIT personnel in the area at different times of the year. (A map may be useful)

* Additional sheets may be used to provide information in this form where necessary

1.3 Onchocerciasis endemicity levels

The levels of onchocerciasis endemicity in communities in the CBIT area must be assessed by simple methods before treatment starts.

For the purposes of this proposal, the level of endemicity in a community or a group of similar communities is defined on the basis of the prevalence of nodule carriers. (See table 1)

TABLE 1. Classification criteria for endemicity levels in rural communities

ENDEMICITY LEVEL and recommended type of treatment	Percent of nodule carriers in REA sample (minimum sample 50 adult men)	Estimated prevalence of <i>O. volvulus</i> in the Whole community
HYPER-ENDEMIC Community Treatment (URGENT)	greater than 39%	greater than 59%
MESO-ENDEMIC Community Treatment (DESIRABLE)	20 - 39%	40 - 59%
HYPO-ENDEMIC (NON-URGENT)	less than 20%	less than 40%

- 1.3.1 Based on the system in Table 1 and using the format in Appendix 1, please indicate the estimated numbers of communities at each endemic level and the numbers of persons in them.
- 1.3.2 Complete Appendix 1 for each area covering the next 5 years of the project.
- 1.3.3 If methods of assessing endemicity thresholds other than nodule prevalence were used when your endemicity data were collected, please indicate the method used.
- 1.3.4 For areas still to be covered, where endemicity levels are not yet known, please describe the method you will use to collect the necessary endemicity data.

1.4 Community Structure

Provide background information on the social organizations of communities in the C.B.I.T. areas. This may include information on:

- Settlement pattern of the community (e.g. hamlets, seasonal farmsteads, dispersed populations, etc.)
- The ethnic group(s) in the community
- Please provide information about the area covered by CBIT indicating whether they are migrants, nomads, refugees or internally displaced populations.
- Community leadership structure
- Main occupation of community and periods of major communal activities
- Preferred channels of communication in the community
- Existing active community associations/groups in the area (e.g. social, religious, etc.)
- Established distribution systems in the community
- Social communal activities and months during which the activities take place
- Any previous experience of the community with development/health projects
- Description of other anthropological characteristics of the communities.

2. PAST AND CURRENT STATUS OF CBIT IN PROJECT AREA

- 2.1 Please indicate if the CBIT is an expansion of an existing CBIT.
- 2.2 State the number of years the programme has been operating, and if possible enclose previous statistical, financial and annual reports.
- 2.3 State the number of persons treated each year for the last 5 years
- 2.4 List the organization(s) involved in the programme, the sources and amount of funds used each year for the last 5 years.

SECTION 2: PROJECT EXECUTION OUTLINE

3. DESCRIPTION OF PROPOSED COMMUNITY-BASED IVERMECTIN TREATMENT (CBIT)

The main strategy of the project will be to develop and establish community-based ivermectin treatment systems which can be sustained by the endemic communities themselves without external support after the 5-year project period. This section should describe how the NOTF plans to develop and implement CBIT in all high-risk communities in the project area. The plan should take into account the need to develop approaches to CBIT which are appropriate for the different local situations, and the need to carefully evaluate the implementation of the selected approaches and adjust them when required.

3.1 Outline Plan and Timing

3.2 Health Education and Community Interaction and Participation

3.2.1 How will you approach and interact with the community

3.2.2 Health education

Health education and community mobilization will be an integral part of all approaches to CBIT. Health education activities should ensure a two way feedback with regards to knowledge, awareness, perception and observable attitudinal changes about onchocerciasis and its treatment. Appropriate health education messages in the form of posters, pamphlets and verbal presentations will need to be developed and tested. Health education should address the following issues (Table 2):

Table 2: Critical issues in the development of Health Education for CBIT

ISSUES	Health Education Messages
Knowledge of the disease	<ul style="list-style-type: none"> • Local name of the disease • Symptoms • Causation/transmission (simple)
Knowledge of treatment	<ul style="list-style-type: none"> • Previous experiences with Di-Ethyl Carbamazine (DEC) • Introduce Mectizan® (Ivermectin) • Dosage • Exclusions • Reactions • Beneficial side effects
Attitude to treatment	<ul style="list-style-type: none"> • Advantages of treatment Free Yearly treatment Possibility of self treatment at community level. Importance of maximal coverage
Attitude to disease	<ul style="list-style-type: none"> • The disease can be controlled • Onchocerciasis blindness and skin changes can be prevented
Attitude to good record keeping	<ul style="list-style-type: none"> • Minimum requirements for record keeping • Records are confidential and strictly of health issues • Records required are for subsequent drug supply

a) Have any KAP surveys been done in the project area and if so, what were the results?

b) What methods will be used to develop health education material for the communities and for the agents who will be responsible for ivermectin treatment?

c) What methods will be used to provide health education to the endemic communities and to the agents responsible for treatment?

3.2.3 Community Participation

It must be reminded that in community-based ivermectin delivery systems, the execution of ivermectin treatment is done by members of the endemic communities themselves. Treatment may be provided by trained personnel, known as Community-Based Distributors (CBD's), selected from various organizational structures at the community level ranging from women cooperatives to traditional organizational structures. Whatever the treatment approach used, it should be fully supported by the community itself and the community should be responsible for its organization and execution with minimum but effective medical supervision once it has received the necessary information and training.

a) Explain the organization of the intended community-based ivermectin treatment in the project.

b) How will ivermectin distributors be selected?

c) How will non-eligibles be identified and defaulters be followed-up?

3.3 Local Operational Research

Are there any plans to conduct local operational research? Yes No

If yes please give details

3.4 Training

Training and re-training of community-based distributors to operate the CBIT is a vital first step in organizing the programme and remains a continuing commitment thereafter.

a) What training will be provided to ensure the development and sustainment of the CBIT?

b) Indicate criteria for selecting trainees (supervisors and community-based distributors)

c) Indicate number, type and duration of training courses intended

4. SUPPLY, IMPORTATION, STORAGE, INVENTORY AND DELIVERY OF MECTIZAN TABLETS

This section is only a reminder and concerns the supply, importation, storage, inventory and delivery of ivermectin tablets, donated by Merck & Co, who will also pay handling charges for ivermectin to their accredited agents.

PLEASE NOTE THAT REQUEST FOR IVERMECTIN AS WELL AS REPORTING OF ITS SUBSEQUENT USE MUST BE MADE DIRECTLY AND SEPARATELY TO THE MECTIZAN EXPERT COMMITTEE, USING THE FORMS PROVIDED BY THE MECTIZAN DONATION PROGRAM AND A COPY SENT TO APOC

5. SUPERVISION/MONITORING AND EVALUATION

5.1 Supervision during CBIT

Projects require to be supervised and monitored. However, APOC funded projects will need to be designed to function with effective but minimum supervision compatible with its objectives.

a) Please describe the supervisory arrangements you consider will be required for the CBIT you propose. How will this continue at the cessation of APOC support?

b) Describe how you would ensure that supervision will:

- fall within the requirement accounting for ivermectin use
- be sustained when the programme ends in 5 years
- ensure maximum involvement of the communities in the process

5.2 Monitoring of CBIT

It is important to collect information to monitor the progress of the CBIT. What indicators will be used to monitor:

- ivermectin distribution?
- health education and community participation?
- management systems?

The following items may be considered

Ivermectin Distribution

- *numbers of communities and persons treated with ivermectin*
- *treatment coverage*
- *regularity of treatment exercise*
- *compliance*
- *reporting adverse reactions*

Health Education and Community Mobilization

- *numbers of communities being mobilized by the project*
- *evidence of impact of health education*

Management

- *are activities being carried out according to plan and on schedule?*
- *inventory control,*
- *are record forms accurate and completed on time?*
- *numbers of persons trained*
- *balance of genders in staff of the programme*

5.3 Evaluation of CBIT

Annual external review incorporating field visits will be undertaken to ensure that projects are meeting target indications outlined in this proposal. Such reviews will provide TCC with the assurance that each project is moving towards its long term stated goal and if appropriate make recommendations about any deficiencies or modifications to this project. Such reviews will draw on the indicators developed by TCC as a guide (see Appendix 3) for such evaluation.

6. SUSTAINMENT OF THE CBIT AFTER THE WITHDRAWAL OF EXTERNAL FUNDING

The concept of sustainability refers to the ability of countries and affected communities following initial external investment to maintain the viability and continuity of the ivermectin treatment process without external support. For APOC funded projects, such support will normally last 5 years, as the APOC donors demand that there shall be a visible and achievable end point for the external donation aspect of the programme, and that the community based distribution systems established shall thereafter be sustainable by the governments of the endemic countries concerned.

Progress and plans towards sustainment, including the phasing out of external and NGDO's support, must be reported annually and satisfactory progress in this direction will be a condition for each succeeding year's funding instalment. Please address the following areas that relate to sustainability: "integration into primary health care", "cost-recovery", and "other sustainment issues".

6.1 Integration of the CBIT into other Community-based or Primary Health Care (PHC) Systems

The principal goal of the APOC is to establish cost-effective ivermectin-based control for onchocerciasis which can be sustained by the endemic communities and countries. One way to ensure sustainment is to integrate the CBIT into the PHC system of the country, which means more than just using the system for ivermectin distribution.

6.1.1 Is there an official PHC policy and structure in the country? Yes No

If yes, please give a brief outline of what it is.

a) How functional is the primary health care system?

- Fully functional
- Partly functional (Please specify)
- Non Functional (Please specify)

b) Does it cover the whole country? Yes No

If no, in what part(s) of the country is there a fully functional PHC structure?

c) What percentage of communities where onchocerciasis is endemic, and which are eligible for community-based treatment, have an existing and functional PHC structure?

d) What organizations are supporting the development of PHC in your country?

e) Is there any past experience in the country of a programme integrating with the PHC? If so, what programme was it and how successful was the integration?

f) Are there any plans to integrate other rural health programmes, such as the Expanded Programme of Immunization, Maternal and Child Health Programmes or programmes for the control of other parasitic diseases, with the PHC system?

g) Describe how the CBIT will be integrated into the PHC system¹; the way the PHC system will be used to achieve integration and the key persons in the PHC system who will be needed to achieve the integration

h) Indicate how early in the CBIT the process of integration will be introduced; how it will continue thereafter, and after how many years within the externally-supported lifetime of the CBIT it will be completed.

6.1.2 If there is at present no PHC system in operation, or in those areas where these structures are non-functional, describe how the CBIT may be used to initiate and expand into such a system, giving a time-frame for intended progress.

6.1.3 In which way(s) can community-based ivermectin treatment initiate or strengthen PHC?

1. Simply stating that the project will be integrated into PHC is not enough.

6.2 Cost-recovery Systems during Community-based Ivermectin Treatment

Cost recovery for Primary Health Care is mandatory in some countries and it may be one means of sustaining an CBIT after APOC funding ceases. However, please note well that since ivermectin is donated free, there can be no cost recovery in respect of the value of the drug itself; cost recovery can only relate to the costs of distribution.

6.2.1 Please state whether there will be any system of cost recovery (such as is recommended in the Bamako Initiative) to help cover outlays on the distribution of ivermectin in the present CBIT.

6.2.2 State exactly how any such system will be organized, including answers to the questions listed below.

- What charge will be made per person or per family?
- Which groups of persons will be exempted from payment?
- Will payments be in cash or in kind? If in kind how will this ensure sustainability?
- What provision will be made to ensure that all those eligible to take ivermectin, but who are unable to pay, will also receive treatment? How will it be determined who is unable to pay?
- Who will collect the payments? How will this person safely transport funds to a place of safe keeping?
- Where and by whom will any funds collected be safely kept?
- What systems will be put in place to ensure the proper use and management of collected funds?
- For what purpose(s), including defrayment of distribution costs, will the funds collected be used?
- What role will Village Health Committees play in the management and allocation of the funds raised?

6.3 Other issues

Please provide information on other issues and constraints relating to sustainability of CBIT you anticipate and identify how they will be overcome. For example:

- the mobilization of endemic communities
- the maintenance of adequate supervision and monitoring
- inadequate human resources
- logistics and communications
- social/cultural factors
- declining community compliance

6.4 How do you intend to monitor and measure the progress towards sustainability (See Appendix 3 for a list of possible indicators of sustainability)?

7. CROSS-BORDER CONSIDERATIONS

Where an endemic area extends across the borders of two or more adjacent states, special problems of cooperation between the respective country CBIT may arise.

In the event that there are areas to be covered by your proposed CBIT where the endemic zone extends across the frontier into one or more neighbouring countries, and where there are likely to be transitory or even large-scale migrations of Onchocerca-infected persons either way across the border.

- 7.1 Please describe the particular situation as it is likely to affect ivermectin treatment , and the methods you will use to deal with it.

- 7.2 Include pertinent observations on current political and health relations with the neighbouring state(s).

8. SPECIAL RISK ISSUES

In some areas of some countries there may be special risks which could hinder the smooth running of an CBIT.

- 8.1 Please describe the situation in any areas covered by your proposed CBIT where this factor may interfere with the programme, and assess future prospects.

SECTION 3: ADMINISTRATION/FINANCIAL

9. ADMINISTRATION

9.1 Organogram of the CBIT Project

- 9.1.1 Please provide an organogram for the CBIT showing the organizational structure responsible for implementing this proposal.

9.2 Financial Administration

Mechanisms of disbursements and transfer of funds from the World Bank to countries

Funds from the World Bank APOC Trust Fund will be channelled through WHO and APOC to the Project bank account. Disbursements of funds will require 2 signatures from members of the NOTF, one representing the Ministry of Health (Government) and one representing the NDGO partners.

APOC will issue cheques (advances) in accordance with WHO rules and the previously agreed project documents and/or plans of operations. When the total payment in cash required for the project exceeds \$ 100,000, the payment must be made in installments. The first installment/advance could cover 3 months or 6 months of activity depending on the duration and magnitude of the project.

Management of funds by projects and WHO/APOC mechanism for monitoring

The size of the project will determine which of WHO's contractual systems is used, e.g. Technical Service Agreement, Letter of Agreement, Contractual Service Agreement or Agreement for the Performance of work.

A document on Administrative and Financial Procedure will be made available to projects being funded by APOC. Built into this document is an imprest mechanism, whereby the project will report its expenditure on a quarterly basis and receive further advances on that basis.

Each project funded by APOC will require a periodic external audit at project expense.

Each project must have one senior staff member who is accountable for the management and control of project funds. Standard internal financial checks and balances must be incorporated into each project's financial management plan.

9.2.1 Input from the Ministry of Health

a) Indicate resources that will be provided by the Ministry of health and other government agencies.

b) Please provide a list of personnel assigned by the MOH to this project, including their name and proposed time (state percentage of time allocated to the project) for the project and where appropriate, their experience in onchocerciasis control through ivermectin treatment.

9.2.2 Input from the Partner NGDO(s)

- a) Please provide a letter from the Executive Director or the Director of Onchocerciasis Programmes of each participating NGDO stating their intentions to participate in and support the National Onchocerciasis Control Programme.
- b) Give information of the input from each NGDO participating in this project.
- c) Please provide also a nominal list, grading and post description for the personnel to be provided by partner NGDO(s). Indicate clearly what will be their functions in the programme and their experience in onchocerciasis control through ivermectin distribution.

9.2.3 Input from other Agencies.

Please list any other agencies or parties that will be involved in the running or financing of the CBIT, and indicate clearly their roles, functions and contributions.

9.3 Timed plan of action

Provide a time chart(s) showing how the various activities of the CBIT will proceed over the course of the proposed programme. Numerical annual targets for all planned activities should be provided for each time point.

The time charts should also indicate how external support will be phased out over the 5 year period.

10 BUDGET

10.1 Budget estimate

Budgets must indicate total funds to undertake the project. The amount of funding requested from APOC, and the amount provided by the MOH, NGDO(s), and other partners. All estimates must be made in US dollars.

Each budget must include at least the following major categories (see Appendix 2) indicating the contribution of the partners to reflect sustainability of CBIT:

- personnel (services)
- capital equipment
- supplies
- training
- travel
- communications
- consultants
- operating expenses
- external audit

10.2 Budget Justification

Please provide a narrative description of the reasons for each proposed line items of the budget.

10.3 Current resources available in CBITs

Existing CBITs (for continuation or expansion) will have resources already available.

Please provide a detailed list of all existing personnel, equipment and supplies (including vehicles, etc.) belonging to the programme, indicating their ownership (MOH, NGDO, other Agency, etc.) and their level of functionality.

PART V: APPENDICES

APPENDIX 1: ESTIMATED NUMBERS OF COMMUNITIES AND PERSONS TO BE TREATED EACH YEAR, BY ENDEMICITY LEVEL

AREA COVERED:			
COMMUNITY ENDEMIC LEVEL	HYPER-ENDEMIC	MESO-ENDEMIC	HYPO-ENDEMIC
TYPE OF TREATMENT	Community-based	Community-based	Community-based
YEAR 1			
No. of communities to be treated			
Total population in above communities			
YEAR 2**			
No. of communities to be treated			
Total population in above communities			
YEAR 3**			
No. of communities to be treated			
Total population in above communities			
YEAR 4**			
No. of communities to be treated			
Total population in above communities			
YEAR 5**			
No. of communities to be treated			
Total population in above communities			

Onchocerciasis is not considered an important Public Health problem in hypo-endemic communities and APOC will not normally fund community-based treatment in such communities. The inclusion of such communities in the proposal will require a special justification for consideration by the TCC.

** It is understood that the figures for years 2-5 are likely to be estimates which may change as the project progresses.

APPENDIX 2: SAMPLE COPY OF BUDGET (1997 - 2001)

	1997				1998				1999				2000				2001			
	APOC	MOH	NGDO	TOTAL	APOC	MOH	NGDO	TOTAL	APOC	MOH	NGDO	TOTAL	APOC	MOH	NGDO	TOTAL	APOC	MOH	NGDO	TOTAL
Personnel																				
Capital Equipment																				
Supplies																				
Training																				
Travel																				
Communication																				
Consultants																				
Operating expenses																				
External audit																				
Other Expenses (specify)																				
Recapitulation for each year																				
Total																				

APPENDIX 3: INDICATORS FOR EVALUATION, SUSTAINABILITY/INTEGRATION OF CBIT

Project Evaluation

Management

- Financial management
- Effectiveness of communications
- Training and capacity building
- Institutional commitment
- Fulfilment of other relevant sectors
- Problem solving capacity
- Integration of operational research

Project effectiveness

- Result of KAP studies
- Treatment coverage
- Follow-up of non-eligible and absentees
- Management of adverse reactions
- Reliability of reporting

Sustainability/Integration

Political will of host government

- political will as shown in policy statements and apparent commitment of high-level officials
- official action assigning personnel, funds, vehicles to programme

Long-term planning

- is there a long-term plan for sustaining the financing and the management of the programme?

Progress toward financial sustainability

- if programme sponsors cannot continue their current level of commitment for at least another five year, what percentage of running costs is now paid for host governments or fees?

Progress toward integration

- to what extent has ivermectin distribution been integrated with other health service programmes?
- evidence of community empowerment and ownership
- change in KAP over time
- extent of involvement of both genders and non-literates
- extent of involvement of local community-based organizations