LF Surveillance Strategy

for Pacific Island Countries and Territories

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Process and Contributors

This document was prepared by Dr Clare Huppatz, a Short Term Consultant for the WHO, employed to draft the ongoing LF surveillance strategy for the PICTs. This document was presented at the PacCARE meeting held on 19th June, 2007, in Nadi, Fiji. Following discussion, it was decided that this strategy would be trialled in three countries, namely, Vanuatu, Tonga and Niue. This strategy was also presented to the LF Program Managers meeting on 20th June, 2007.

It is expected that this document will become a "working document" and continue to be changed and modified where appropriate, particularly as new information and research findings become available.

Prior to the preparation of this document, a review of all the Pacific Island LF elimination program data available to date (1999 - June 2007) took place. This review forms an appendix (Appendix 7) to this document.

During preparation of the draft surveillance strategy, extensive discussions were conducted with others in the field, many of whom are listed below as authors. Their valuable contributions and time spent reviewing preliminary drafts are gratefully acknowledged. Technical advice and document review was also received from Tom Burkot and Mark Bradley. A special thanks is extended to Ms Masayo Ozaki, who assisted with the preparation of several of the appendices and provision of information to assist with the data review.

Other grateful acknowledgements are extended to a team who met in CDC, Atlanta, to review an early draft of this surveillance strategy and assist with finding answers to several of the challenging questions that post MDA LF surveillance poses. This group comprised: Rafe Henderson, Michael Deming, Tom Burkot, Frank Richards, Steve Williams, Pat Lammie and Eric Ottesen. In addition, discussions regarding the issues of Post MDA LF surveillance took place with Els Mathieu, who willingly shared her experiences from the LF elimination program in Togo, Africa.

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LIST OF ACRONYMS

CTS – Child Transmission Survey
ICT – Immunochromatographic test
LF – Lymphatic Filariasis
MDA – Mass Drug Administration
MF - Microfilariae
PICTs – Pacific Island Countries and Territories
PacCARE – Program Coordinating and Review Group, Pacific Programme for the Elimination of Lymphatic Filariasis
WHO – World Health Organization

Goal

PRIMARY GOALS:

- To detect all remaining foci of transmission
- To detect any new foci of transmission
- To ensure that transmission has been interrupted

Overview

This surveillance strategy is designed to be in effect until all PICTs reach the target of "No ongoing transmission of LF". It is hoped that this can be achieved within five years of stopping Mass Drug Administration (MDA), i.e. by 2012 for the first PICTs and by 2017 for most of the other endemic PICTs. It is acknowledged that Papua New Guinea will require a modification of this strategy due to its larger population; this should be developed as PNG nears completion of MDA.

In 2004, the WHO Pacific Program to Eliminate LF defined interruption of transmission as <0.1% of 5-year-olds being ICT positive by D survey. Interruption of transmission is extremely important, as it shows that the MDAs have been successful. However, it is the ONGOING absence of transmission that is required to prove elimination.

The LF Surveillance Strategy provides a means of demonstrating that transmission has stopped permanently within a population. It requires countries to look for transmission of LF with more rigor than previously. This is necessary, as the disease has become less prevalent. In addition, this strategy provides a mechanism of *detecting* and *eliminating* small foci of infection within a country, with an intentionally intensive follow-up of positive cases.

The strategy uses a *Primary* surveillance strategy, called the ***Child Transmission Survey (CTS).*** This is a modification of the previous D Survey. The endpoint marker remains the same, that is, evidence of interruption of transmission has occurred once <0.1% of children are ICT positive. Built into this new strategy is a mechanism of detecting and eliminating the source of transmission within the community, termed "Close Contact Testing". In addition, the recommended surveillance algorithms require repeated confirmation that transmission has been interrupted, over several years, so that a country can be sure that transmission has stopped permanently. It is anticipated that all countries will participate in this *Primary* surveillance strategy.

In order to augment the Child Transmission Survey, a ***"Hot Spot" Survey,*** which looks more closely for transmission in areas of previously high prevalence is recommended, for countries that are able to identify such an area.

However in countries (or endemic regions or island groups within countries) where the population is less than 10,000 people, an alternative primary surveillance strategy can be used. In such countries, *mass screening* of at least 95% of the total population with active follow up and treatment of all positive cases until they turn negative can be considered and implemented. It is known as the ***Test and Treat (T&T)*** strategy.

In addition, a secondary surveillance strategy, called ***Border Detection,*** is proposed for consideration as a trial in some countries. It is recommended that some countries participate in Border Detection, which aims to detect potential sources of reintroduction of infection from outside the country.

Also contained within this document is a description of two *Control Measures* that can be used by countries to assist their progression towards elimination. These *Control Measures* are recommended to assist countries when they find that they have ongoing transmission of LF and are not meeting their target.

In addition, this document contains several appendices that offer further clarification for the main body of the document. The first of these (Appendix 1) is a *Rationale*, providing an explanation for many of the decisions that needed to be made to formulate the strategy. Appendices 2 and 3 contain flowcharts, maps and algorithms to further explain some of the main strategies within the text. Appendices 4, 5 and 6 contain additional protocols, guidelines and record keeping sheets required for implementing the CTS and Targeted MDA. Appendix 7 contains a sample of the standard Test & Treat Register form for the Pacific Program to Eliminate LF. Appendix 8 provides information on the drugs used (Albendazole and Diethylcarbamazine) and a Patient leaflet. The final appendix (Appendix 9) is an analysis of the available data from the Pacific elimination program between 1999 and June, 2007.

It is hoped that the next few years will bring new research findings that will provide recommendations that further refine this surveillance strategy so that the PICTs remain LF-free. It is anticipated that surveillance will need to continue in some form until elimination has been achieved throughout the world. Verification of elimination (leading to certification) will be performed by an outside team. Verification of elimination is beyond the scope of this document and does not form part of the LF Surveillance Strategy. It has been assumed during the preparation of this strategy that the process of verification will require countries to have more than a single survey demonstrating the interruption of transmission. Hence, it is hoped that participation in this LF Surveillance Strategy will help prepare each country for Verification.

SUMMARY OF SURVEILLANCE STRATEGIES and CONTROL MEASURES

Surveillance Strategies

1. **Primary Surveillance I – *Child Transmission Survey (CTS)* *or Test & Treat (T&T)***
   Detection of transmission in children followed by ACTION to *detect* and *eliminate* the source of infection within the community if present (CTS); or *detection* of all positives in a defined population with active follow up and *treatment of positive cases (T&T)*.

2. **Primary Surveillance II – "Hot Spot" Survey**
   Additional method to detect transmission in children in identified "Hot Spot" areas, followed by ACTION to *detect* and *eliminate* the source of infection

3. **Secondary Surveillance – *Border Detection***
   Detection and elimination of a source of infection at its point of introduction from outside the country

Control Measures

A. *Targeted Mass Drug Administration (Targeted MDA)*
Control measure using MDA within a target group that has a high prevalence of infection

B. *Vector Control (suitable countries only)*
Control measure using vector control to reduce transmission in areas where primary vector is *Anopheles sp.* or *Culex sp*.

General Principles

- The goals of this surveillance strategy are in keeping with those of the Global Programme for Elimination of Lymphatic Filariasis.
- Children will be used to detect areas where there may be residual pockets or 'foci' of transmission still occurring within a country. This *primary* surveillance strategy is called the **Child Transmission Survey (CTS)**.
- Children ≤8 years old are likely to provide the best indicator of new transmission, as these children were born after the MDAs commenced. However, as it is not feasible for countries to test ALL children ≤8 years old, the Child Transmission Survey (CTS) proposes various sampling methods. In the first, School Year 1 children have been chosen, because they are relatively easy to access through the school system. For countries in which school attendance is low (<80%), it is recommended that surveillance is done through villages/communities, as well as schools. In this method, one age group is targeted (5 year olds).
- Country LF Managers will need to choose between the two survey methods (Primary School vs. Community) prior to the implementation of the survey in their country.
- While the proposed CTS strategy identifies School Year 1 (or 5 year old) children as the suitable 'marker' of transmission, ongoing research is being done to compare the results of testing children of different age groups. As such, when the research findings are known, the age group recommended for the CTS may change to reflect these research findings.
- It is necessary to test **ALL** School Year 1 (or 5 year old) children, as LF is now becoming increasingly rare within the PICTs community and it is important that no infections are missed. By testing a group such as School Year 1 children or 5 year olds, the intention is that the method will include samples from all villages/communities, to address the heterogeneity demonstrated by LF. In addition, this surveillance strategy uses repeated surveys which will increase the likelihood that all villages are adequately sampled over time.
- Papua New Guinea will require a modification of this surveillance strategy that uses a different sampling method (and a smaller sample size), given their larger population.
- A School Year 1 (or 5 year old) child that is ICT positive is a "marker" that there is a source of infection within their community. The important next step is to find and treat that source of infection within the community. "Close Contact Testing" has been devised to ensure elimination of the source of infection is achieved.
- "Close Contact Testing" aims to find the source of infection within the child's community. It is recommended that all *household contacts* of the child and all *near neighbours* are tested.
- *Near neighbours* to the index case (the child found to be ICT positive) that need to be tested can be found by one of two methods described within this strategy. The first of these methods requires the measurement of 200m around the household of the index case and the second requires counting 24 houses around the index case. It is hoped that these two methods will be trialled and compared by mapping studies in the next year to verify each method. For now, the decision about which method to use will need to be made by each Country LF Manager, prior to implementation

within each country. One method only should be used within each country for Close Contact Testing. This decision should be based on which method will be more *feasible* for field workers to perform.

- If anyone (child or adult) is found to be ICT positive, they need to be treated until their ICT becomes negative. The ICT should be done yearly and the person treated every time the ICT is still found to be positive. This may take several years.

- Where feasible, it is recommended that ICT testing of children >8 years and adults be supplemented with MF slide testing. This testing should be repeated on any MF positive person one month after their first treatment, then yearly, to ensure microfilariae have been and remain suppressed. MF testing should continue until the ICT test becomes negative.

- Treatment of someone who is ICT positive should be with Albendazole and DEC. It is recommended that as a minimum, a single dose regime, given yearly, is used and treatment **must be observed**. Treatment can stop once the ICT is negative. It may be necessary to treat an ICT positive person for a few years (sometimes 5 years) using these drugs. Following consultation with a country Medical Officer, a more intensive regime could be considered for people found to be MF positive by slide (eg Stat dose of DEC and Albendazole, followed by 12 days of DEC).

- In countries with ≤10,000 people then the **Test and Treat (T&T)** strategy is recommended as an alternative to the CTS. This also applies to endemic regions or islands within countries.

- The T&T strategy should aim to test 100% of the population using ICT, with a minimum acceptable level of 95% of the population.

- Following mass screening and treatment of at least 95% of the total population, all positives are then followed up and treated every 3 months for 12 months, with a regime of 400mg Albendazole and 6mg/kg DEC.

- After 12 months of treatment, each positive case should again be tested with ICT. The process of quarterly treatment and yearly testing should continue until the antigenemia positive case becomes antigenemia negative.

- The **"Hot Spot" Survey**, calls for countries to identify at least 2 known "hot spots" (areas of previously high prevalence) and survey all children 4-8 years old (inclusive) in these areas. This will be done in conjunction with the Child Transmission Survey with the intention of augmenting it.

- If a "target group" with a high prevalence is identifiable, the recommended *Control Measure* is to give that group a **Targeted MDA** or implement **T&T** if the population is ≤ 10,000 people. If implementing targeted MDA, as a minimum, the MDA would need to be given yearly for 5 years, however, more frequent dosing schedules could be considered. Treatment must be **observed** in the target population and **>80% coverage** needs to be achieved. During this time, the CTS surveillance strategy *should* continue at the planned intervals.

- Vector control is a Control Measure that is recommended for some countries, particularly in areas where the mosquito vectors bite between dusk and dawn (i.e. *Anopheles sp* or *Culex sp* vectors). Implementation of this strategy should only follow consultation with WHO/SP office and/or vector control experts.

- It is highly recommended that if a country does not meet their CTS or T&T targets, the reasons for this are discussed with the WHO/SP office and assistance is provided. Prior to the implementation of further rounds of MDA or Targeted MDA, it is recommended that **social science research** be undertaken to determine any barriers to the continued use of MDA.

- To prevent reintroduction from outside the country, a *Secondary* surveillance strategy has been proposed, called **Border Detection**. This is to identify anyone entering the country that will stay for > 6 months that may be a source of LF infection. Such a person may be a migrant from an endemic country, or a returning national who missed some or all of the MDAs. As the value of such surveillance is unknown, it is recommended that some countries commence Border Detection surveillance to trial its effectiveness.

Recommended LF Surveillance and Control Measures

	Primary Surveillance IA "CTS"	**Primary Surveillance IB "T&T"**	**Primary Surveillance II "Hot Spot" Survey**	**Secondary Surveillance "Border Detection"**	**Control Measure "Targeted MDA"**	**Control Measure "Vector Control"**
Endemic and post-endemic countries	Recommended to do 3 times over 10 years	Recommended if total population or an endemic region or island is ≤10,000 people.	Recommended to do at the same time as the first CTS	Recommended to trial in some countries	Recommended if C survey ≥ 1% or CTS ≥ 0.1% and population ≥10,000 people.	Recommended if *Anopheles sp* or *Culex sp* is Primary Vector
Non Endemic Countries	Recommended to do at least once			Suggest to trial in some countries		

1. PRIMARY SURVEILLANCE 1A: CHILD TRANSMISSION SURVEY (CTS)

Aim: Detection of transmission in children with ACTION leading to *detection* and *elimination* of the source of infection from the community

Target: Country CTS target is **<0.1%** ICT positive[1]

Options (choose most appropriate method for each country):

1.1 Primary School Method:

If countrywide school attendance is ≥80%, it is recommended that **ALL** Primary School Year 1 children are sampled. This may include children of ages 4-7 years, which is acceptable, as all children ≤8 years old can be markers of new transmission.

1.2 Community Method:

If country wide school attendance is <80%, it is recommended that **ALL** 5 year old children are sampled, through village or community visits, which will involve recruiting children in the community. Such a method should utilise existing groups within the community, such as primary schools, churches, mother's groups, day-care, and primary health care centres (medical clinics). This may involve two survey teams visiting each area at the same time. One team could access the Year 1 children in the Primary School and the second team could seek out any 5 year old children within the community who are not attending school.

NOTE: Papua New Guinea will require a customised CTS surveillance plan with sampling of 5 year olds or School Year 1 children, given their large population size.

Case Definition:

"LF Case": Any Child ≤ 8 years old who is ICT positive on repeat testing (same day)

OR

Any community member who is subsequently found to be ICT positive (repeat ICT testing is not required, as they have an epidemiological link to the Index child)

"LF Source": Any person who is MF positive by MF slide testing

[1] For number of children that a country would expect to find positive if target of <0.1% is achieved, refer to Appendix 1, Table 2.

1.1 Child Transmission Survey (CTS): Primary School Method

1. Testing is to be done in **ALL** primary schools within a country – may need to obtain consent from Education Dept/Ministry, school, community and parent/carer, as appropriate within the specific PICT.

2. Test **ALL** children in Year 1 at primary schools (need to test as near to 100% of enrolled children as possible). If possible, do this in conjunction with another primary school health program. May require the same school or area to be revisited several times.

3. Test children by ICT AND read strictly at 10 minutes (refer Appendix 4.1).

4. If a Year 1 child is ICT positive – retest (same day) by ICT with strict attention to testing protocol (Appendix 4.1).

5. If a Year 1 child is positive on repeat testing by ICT – follow protocol for "LF case" below.

Protocol for "LF Case" found by Primary School Method:

(i) Every child ≤ 8 years old who is ICT positive, should be treated with Albendazole and DEC and **Close Contact Testing** should be performed (see method outlined below and Appendix 2 "maps").

(ii) **Close Contact Testing**:
For every child ≤ 8 years old test ALL people living within the child's home (as source may be within their home).

For every child ≤ 8 years old test ALL people living within 200m of that child's home OR in the closest 24 surrounding houses to the child's home (as the "source" may be from nearby their home). Refer to the description and maps in Appendix 2.

NOTE: The decision on which approach to use (200m or 24 houses) must be made by Country LF Manager prior to survey and only one method should be used consistently within a country.

Additionally, for every child ≤ 8 years old who is found to be ICT positive, their parent/carer should be asked if that child visits another home/household daily. If they visit another house daily, that is >200m from their own home, then the other house could be where (or near) the source of infection. This second house should also be treated as the "child's home" and **Close Contact Testing** for this home should be completed by the same method as for the Child's home.

Testing of children >8 years and adults should be with ICT AND MF slide. If a country is unable to process MF slides, these can be sent by arrangement to another country for testing (discuss with WHO/SP office).

(iii) Everyone who is found to be ICT positive must be treated with Albendazole and DEC and their name recorded for follow-up (refer Appendix 5).

(iv) Follow-up 12 months later in a child ≤ 8 years old that was positive, is by ICT alone. If negative, no further follow-up is needed. If positive, the child must be treated and followed up 12 months later. Each child who is found to be ICT positive again, will need to be treated and tested yearly until their ICT is negative.

(v) Follow-up in adults and children >8 years that was positive, should be by ICT and MF slide (if possible). Testing and treatment must continue 6 monthly until ICT is negative. If an individual is found to be MF positive, they are considered an "MF source" and a repeat MF slide should be taken 1 month after treatment to ensure that the MF are suppressed by the treatment (more intensive therapy, such as 12 day DEC treatment could be considered for people found to be MF positive). Future testing for MF positive individuals should include an MF slide, however, the decision to stop treatment and testing should be made only once the ICT is negative.

Special notes:

- If **any school** is found to have **>5 ICT positive children from different villages**, who are ≤8 years old, the WHO/SP office should be notified immediately for assistance. It may not be feasible for the testing team to perform Close Contact Testing for >5 children during the visit and Targeted MDA could be considered.
- If **a village or small community** is found to have **>2 ICT positive children** who are ≤8 years old, the WHO/SP office should be notified immediately for assistance. Once again, the village may be considered for Targeted MDA instead of Close Contact Testing (unless the ICT positive children are from the same household).
- If **>2 people** in one community are found to be **MF slide positive** amongst the "Close Contacts", then the WHO/SP office should be notified immediately for assistance and targeted MDA may be considered.

Record Keeping:

1. Record the names and ages of all Year 1 children enrolled in the primary school and their record of testing by ICT, including the unique identifier that allows the school and child to be identified if the test is positive. If a Year 1 child was not tested, record the reason for not testing (refer Appendix 6.1).

2. For each "LF case" that is ≤ 8 years old: make a separate record of Close Contact Testing performed (see Appendix 6.3). This will need to include the names of everyone living in the positive child's home and the names of everyone in the houses within 200m from their home or in the 24 houses closest to their home, as well as the record of testing +/- treatment.

3. Record the names and addresses of all ICT positive people and a record of the treatment given and arrange for 12 monthly follow-up.

Registry:

Results should be sent to country LF Manager AND to WHO/SP office. The target of ICT positive children should be **<0.1%**, using all data from the country-wide CTS.

1.2 Child Transmission Survey (CTS): Community Method

1. Testing is to be done on **ALL** 5 year old children within a country – obtain consent from parents prior to testing, as appropriate for the specific country.

2. Plan to visit EVERY VILLAGE or inhabited area within a country. Within each community, plan to visit all the existing groups that may include 5 year old children, such as: primary schools, churches, mother's groups, day-care, and primary health care centres (medical clinics).

3. Test all 5 year old children. This may require the same area to be revisited several times.

4. Test children by ICT AND read strictly at 10 minutes (refer Appendix 4.1).

5. If a 5 year old child is ICT positive – retest immediately by ICT with strict attention to testing protocol (Appendix 4.1).

6. If a 5 year old child is positive on repeat testing by ICT – follow protocol for "LF case" below.

Protocol for "LF Case" found by Community Method:

(i) Every child ≤ 8 years old who is ICT positive, should be treated with Albendazole and DEC and **Close Contact Testing** should be performed (see method outlined below and Appendix 2 "maps").

(ii) **Close Contact Testing**:
For every child ≤ 8 years old test ALL people living within the child's home (as source may be within their home).

For every child ≤ 8 years old test ALL people living within 200m of that child's home OR in the closest 24 surrounding houses to the child's home (as the "source" may be from nearby their home). Refer to the description and maps in Appendix 2.

NOTE: The decision on which approach to use (200m or 24 houses) must be made by Country LF Manager prior to survey and only one method should be used consistently within a country.

Additionally, for every child ≤ 8 years old who is found to be ICT positive, their parent/carer should be asked if that child visits another home/household daily or a childcare facility. If they visit another house or facility daily, that is >200m from their own home, then the other house or facility could be where (or near) the source of infection. This second house or facility should also be treated as the "child's home" and **Close Contact Testing** for this home should be completed by the same method as for the Child's home.

Testing of children >8 years and adults should be with ICT AND MF slide. If a country is unable to process MF slides, these can be sent by arrangement to another country for testing (discuss with WHO/SP office).

(iii) Everyone who is found to be ICT positive must be treated with Albendazole and DEC and their name recorded for follow-up (refer Appendix 5).

(iv) Follow-up 12 months later in a child ≤ 8 years old that was positive, is by ICT alone. If negative, no further follow-up is needed. If positive, the child must be treated and followed up 12 months later. Each child who is found to be ICT positive again, will need to be treated and tested yearly until their ICT is negative.

(v) Follow-up in adults and children >8 years that was positive, should be by ICT and MF slide (if possible). Testing and treatment must continue 6 monthly until ICT is negative. If an individual is found to be MF positive, they are considered an "MF source" and a repeat MF slide should be taken 1 month after treatment to ensure that the MF are suppressed by the treatment (more intensive therapy, such as 12 day DEC treatment could be considered for people found to be MF positive). Future testing for MF positive individuals should include an MF slide, however, the decision to stop treatment and testing should be made only once the ICT is negative.

Special notes:

- If **a village or small community** is found to have **>2 ICT positive children** who are ≤8 years old, the WHO/SP office should be notified immediately for assistance. Once again, the village may be considered for Targeted MDA instead of Close Contact Testing (unless >2 ICT positive children are from the same household).

- If **>2 people** in one community are found to be **MF slide positive** amongst the "Close Contacts", then the WHO/SP office should be notified immediately for assistance and targeted MDA may be considered.

Record Keeping:

1. Record the names and ages of all 5 year old children tested and their record of testing by ICT, including the unique identifier that allows the community and child to be identified if the test is positive. If a 5 year old child was not tested, record the reason for not testing (refer Appendix 6.2).

2. For each "LF case" that is ≤8 years old: make a separate record of the Close Contact Testing performed. This will need to include the names of everyone living in the LF case's home and the names of everyone in the houses within 200m of their home or in the 24 houses closest to their home, as well as the record of testing +/- treatment (refer Appendix 6.3).

3. Record the names and addresses of all ICT positive people and a record of the treatment given and arrange for 12 monthly follow-up.

Registry:

Results should be sent to country LF Manager AND to WHO/SP office. The target of ICT positive children should be <0.1%, using all data from the country-wide CTS.

2. Primary Surveillance 1B: Test & Treat (T&T)

Aim: Detection of all ICT positive cases in population's ≤10,000 people with ACTIVE FOLLOW UP and treatment of all positive cases until they turn ICT negative.

Use: Countries with a population ≤10,000 people; OR endemic regions or islands within a country that have a population ≤10,000 people.

Targets: Countries should aim to test 100% of the population, with 95% being the minimum acceptable level.

Quarterly treatment (ie, every 3 months) and yearly testing of all positive cases.

Case Definition:

"LF Case": A person of any age who is Ag positive as measured by a single ICT test.

Method:

1. Plan to visit every village or town within a country or endemic area, and every household within each village or town. Testing and treating a minimum of 95% of the total population is required.

2. Testing and treatment is to be done on **ALL** household members – obtain consent from parents prior to testing and treating children, as appropriate for the specific country.

3. Test each individual with a single ICT test and read strictly at 10 minutes (refer Appendix 4.1).

4. After testing, give 6mg/kg DEC and 400mg Albendazole to ALL household members.

5. If a person is positive, record the name and details in a Test & Treat Register (refer Appendix 7).

6. Follow up and treat LF cases each quarter (i.e. every 3 months) with 6mg/kg DEC and 400mg Albendazole. This can be done effectively by working with local (i.e. provisional or village level) health staff to integrate quarterly treatment of LF cases into the local health services.

7. At the end of 12 months of quarterly treatment, re-test each LF case with a single ICT test and read strictly at 10 minutes. All people testing positive should be recorded in a new page in the Test & Treat Register.

8. Repeat steps 6 and 7 until all LF cases test negative.

9. Once all LF cases have tested negative, perform **another mass screening or CTS???? X years later.**

2. Primary Surveillance 2: "Hot Spot" Survey

Aim: To augment the Child Transmission Survey by an expanded sampling of children in known "Hot Spots". This will be followed by ACTION leading to *detection* and *elimination* of the source infection from the community

Definition of "Hot Spots":

Each country is asked to identify at least TWO "Hot Spots", or areas known to have a population with a high LF prevalence in previous surveys. More than two "Hot Spots" can be identified if this is appropriate and if funding is available to do testing. "Hot Spots" should be villages (or suburbs)[2] for which the prevalence was the highest when all surveys performed since 1999 are compared (recommended total population for a single "Hot Spot" no more than 1,000 people, this will lead to testing of approx 125 children aged 4-8 years).

Testing:

Within each "Hot Spot" ALL children between 4 and 8 years of age (inclusive) should be tested. The method of finding and testing children should be the same as that described for the Child Transmission Survey 1.2: "Community Method", however, instead of testing only 5 year old children, ALL children aged 4-8 are tested. Such a method should utilise existing groups within the community, such as primary schools, churches, mother's groups, day-care, and primary health care centres (medical clinics). This testing should be done at the SAME TIME as the CTS.

Case Definition:

"LF Case": Any Child ≤ 8 years old who is ICT positive on repeat testing (same day)

Method:

1. Testing is to be done on **ALL** 4-8 year old children (inclusive), within a "Hot Spot" – obtain consent from parents prior to testing.

2. Plan to visit the village or area identified as a "Hot Spot" at the same time as the CTS is being conducted. Within the community, plan to visit all the existing groups that may include 4-8 year old children, such as: primary schools, churches, mother's groups, day-care, and primary health care centres (medical clinics).

3. Test ALL children aged 4-8 (inclusive) by ICT AND read strictly at 10 minutes (Appendix 4.1).

4. If a 4-8 year old child is ICT positive – retest immediately by ICT with strict attention to testing protocol (Appendix 4.1).

[2] It is recommended that districts/provinces are not used, as the area is too large.

5. If a 4-8 year old child is positive on repeat testing by ICT – follow protocol for "LF case" and perform Close Contact Testing (refer to protocol outlined above in CTS and Appendix 2).

Interpretation of Results:

If a "Hot Spot" is found to have **>2 ICT positive children** who are ≤ 8 years old, the WHO/SP office should be notified immediately for assistance. The village/community may be considered for Targeted MDA instead of Close Contact Testing (unless >2 ICT positive children are from the same *household*).

Only results from School Year 1 children or 5 year olds who participate in the "Hot Spot" survey should be included with the CTS results for the same year (i.e. only those children who would have been targeted in the CTS should be used for the CTS results).

If a "Hot Spot" survey has been performed in a village/community and **NO children** between 4-8 years are found to be ICT positive, the village/community should **no longer be considered a "Hot Spot"**. Future testing at such villages should be only as part of the routine CTS surveillance.

3. Secondary Surveillance: Border Detection

Aim: Prevent reintroduction of LF from outside the country by *detecting* and *eliminating* any possible sources of infection in new arrivals to the country.

Status: These surveillance strategies are currently under development, as the actual threat that this poses is NOT KNOWN. Once developed, the WHO/SP office will assist those countries that are interested in Border Detection to set up a suitable surveillance system.

Migrants and Returning Nationals

Border Detection surveillance after the cessation of LF transmission will need to detect the reintroduction of the organism into a country or area. One obvious source of reintroduction is the arrival of a migrant from an endemic country. Another source is the return of a former resident who was absent from their country during some or all of the MDAs. Border Detection surveillance needs to consider the risk posed by these groups of people for reintroducing infection. It has been suggested that screening of such people needs to occur, either at country ports of entry or once they are within the country.

It is generally accepted that LF transmission requires several inoculations by infected mosquitoes. Thus, for a new arrival or former resident who returns and is a potential source, they may pose a limited risk for reintroduction if their stay is brief. It may be more cost effective to test those individuals who plan to stay for a longer period that is arbitrarily set (i.e. at six months). The exact length of time that poses a risk for reintroduction from a single source needs to be decided, as do the practical methods that might be used to test for reintroduction.

For a country to test migrants or returning residents at their border, a testing station would need to be operational at every international air and sea port. It may be more feasible to make LF testing a condition of certain visa or permanent resident applications. An alternative may be to provide information to migrants or returning residents at the borders and make free testing voluntary through the medical clinic system although this does not guarantee testing will occur.

Two of the questions that need to be answered to stop reintroduction of LF:

1. Do PICTs Nationals living in another country pose a risk if they come home to the PICTs?

2. Do migrants from LF endemic countries (or previously endemic countries) pose a risk of reintroduction to PICTs?

For countries that are interested in this type of surveillance, the WHO/SP office will assist in the implementation of trial surveillance systems. A surveillance plan that is tailored to the specific country is recommended.

Control Measures

A. Control Measure I: Targeted MDA

Aim: To decrease community reservoir of LF by providing MDA to a "target group"

Definition of a "target group":

A population group, defined by geographical area, gender, occupation, age or other identifiable characteristic for which there is evidence from a recent prevalence survey that there is a high prevalence of ICT positive individuals within that group.

When to use this Optional Control Measure:

When a population has a high prevalence of ICT positive people, as determined by:

C survey ≥ 1%
D survey or CTS ≥ 0.1%

How to identify a "target group":

From C survey: A single geographical cluster with a rate ≥ 1%

From C survey: A population group (eg males or all adults aged 30-40), with a rate ≥ 1%

From CTS: A Primary School found to have >5 ICT positive children (from different villages) that are ≤ 8 years old
OR
A single village has >2 ICT positive children ≤ 8 years old (not in the same household)
OR
A single village has >2 MF positive people >8 years old (not in the same household)

Note: It may not always be possible to identify a "target group". If a C survey finds a rate of ≥1% is in several areas across the country, whole country MDA may be considered instead of Targeted MDA. This decision should be made on a "case-by-case" basis in consultation with WHO/SP office.

Method for Targeted MDA:

1. It is important to discuss this Control Measure with the WHO/SP office and seek their assistance in identifying the "target group" and providing MDA to them. The WHO/SP office may recommend that **social science research** is conducted within the community to determine barriers to further MDA, prior to the commencement of Targeted MDA. This is particularly relevant where there is evidence of previous poor coverage or compliance. If it is anticipated that Targeted MDA may gain poor community support, a method of mass testing and treatment should be considered (i.e. test all community members and treat only the positives).

2. Targeted MDA is provided to all people with the “target group” characteristics, i.e. they live in the same place, or they are of the same gender, occupation, age or other identifiable characteristic.

3. Targeted MDA should be with Albendazole and DEC (See Appendix 5.3).

4. Targeted MDA must be **observed therapy**.

5. Targeted MDA Coverage must be **>80% of the target population**.

6. Targeted MDA should continue yearly for 5 years (unless a different method is discussed with the WHO/SP office).

7. During the Targeted MDA period, surveillance by CTS SHOULD continue (i.e. perform next CTS at the time at which it is due).

B. Control Measure II: Vector Control

Aim: To decrease community prevalence of LF by conducting mosquito control programs

When to use this Control Measure:

Vector control is appropriate in ALL countries where *Culex sp*. or *Anopheles sp*. are the primary LF vectors.

However, it is very important that a country considers increasing its vector control efforts when a population has a high prevalence of ICT positive people, as determined by:

C survey ≥1%
OR
CTS ≥ 0.1%
AND
If the mosquito vector that *PRIMARILY* transmits LF is *Culex sp*. or *Anopheles sp.*

Method:

1. The addition of vector control is only appropriate for the dusk to dawn biting vector mosquitoes of the *Anopheles sp* and *Culex sp*.

2. Mosquito control methods could include the following (as detailed in PacMAN book):

    i. Insecticide impregnated bed nets and curtains
    ii. Breeding source reduction of domestic containers
    iii. Polystyrene beads in pit latrines
    iv. *Bacillus sphaericus* in polluted water
    v. Drainage of permanent water sources
    vi. Repellents and mosquito coils
    vii. Screening houses

The choice of which methods to use are dependant on the vector and its breeding, feeding and resting characteristics. These methods should be discussed with the WHO/SP office and/or relevant vector experts prior to implementation.

Appendix 1: Rationale

Primary Surveillance

Endpoints

The goals of this surveillance program are in keeping with the goals proposed by the Global Programme for Elimination of Lymphatic Filariasis (1), being:

1. Cessation of transmission of LF (the primary surveillance objective)
2. Decrease of burden of disease caused by LF

The second goal of the Global Programme forms a separate pillar of the WHO/SP LF elimination program and as such, is dealt with elsewhere.

To confidently state that cessation of transmission has occurred and is likely to be sustained in the long term, concentrated surveillance activity needs to occur over a reasonable period of time. Ideally, surveillance should occur over the lifetime of an adult worm. If no transmission has been found during that time period, it can safely be assumed that new transmission after this time is unlikely to occur (as all the adult worms would be dead). When planning this surveillance system, the compromise that was reached was that surveillance should occur for a minimum of 4 years (for endemic countries and areas). The reason for this period is that by the time countries do their final CTS, it will be approximately seven years since they had their last round of MDA. If transmission has not occurred within those seven years, future transmission is unlikely, as the adult worms would be dead or past their reproductive capabilities.

The aim of the CTS is that < 0.1% of School Year 1 or 5 year old children are found to be ICT positive. The approximate number of children that this rate (of <0.1%) represents for each country is shown in Table 1. It is recommended that the 95% confidence limits be used to judge the success or otherwise of the CTS. In calculating the number of children, an assumption has been made that the CTS has sampled approximately 2.5% of the total population. It is believed that this would be achieved by either method described for the CTS (i.e. Primary School Method or Community Method).

The aim of the T&T strategy is that all antigenemia positive cases in a defined population are treated until they are negative. Mass screening of population's ≤10,000 people has already been shown to be feasible in the Pacific Program to Eliminate LF. Most countries and regions or islands within countries have ICT prevalence rates between 1% and 10%. Based on this, it is estimated that most countries using this strategy will be required to actively follow up and treat 100 to 1000 people every 3 months in the first year of T&T following mass screening. This number of LF cases is highly manageable and can be made even more so by integrating the T&T strategy into the local health services.

Given that the ultimate goal for the PICTs is elimination of LF this surveillance strategy aims to be extremely rigorous in its approach. It was felt that there is now, more than ever before, a necessity to have a systematic and thorough approach to uncovering ongoing transmission and discovering sources of infection. In addition, treatment and follow-up of individuals would also need to be intensive. It is believed that such an approach is particularly warranted in

areas where *Aedes sp* are the primary LF transmitting mosquito vector, as they are known to be more efficient transmitters of infection. It is hoped that the final endpoint of 0.1% of children is adequate for transmission to cease permanently; however, it must be acknowledged that this is, as yet, unproven.

Testing

Testing for LF infection can be done using one of several testing modalities. The attributes of various tests have been summarised in Table 2. The relative advantages and disadvantages of using each test in the Pacific Region were considered.

Given that LF is becoming increasingly rare in the PICTs, there is a need to use a very sensitive and specific test. Although the ICT is believed to be extremely specific, it is not sensitive enough to use on its own, without fear that some infections will be missed. It can be anticipated that this may be an issue for case-reporting, as occasionally an individual with infection will be missed. For this reason the surveillance strategy recommends repeated testing in the same geographic area every two years.

It is acknowledged that occasionally the ICT can read as a “false positive”. This is thought to be due to operator error, such as holding the test card vertically or waiting longer than 10 minutes before reading. It is hoped that this error will be overcome if the same child is retested by ICT and ACTION is only based on the outcome of a second test (in the same child) being positive.

As was noted in the General Principles section of this document, the current recommendation for the CTS is to test Year 1 children at school or 5 year old children in the community. However, research is currently underway to compare the results of testing children of different age groups. It may be that there is a difference in accuracy of the tests (ICT and Bm14 Antibody) between age groups that makes it advantageous to use children of a different age group to the one recommended here. As such, when the research findings are known, the age group recommended for the CTS may change to reflect those research findings.

The age selected represents expert consensus that a positive ICT test is likely to provide the best indicator of new transmission, as the targeted children were born after the MDAs commenced.

Sampling

A major challenge for the surveillance of a disease that occurs at very low prevalence is deciding on the best type of sampling method. For previous LF surveys, several sampling techniques have been proposed and some of these have been trialled.

Cluster surveys, such as the Multiple Indicator Cluster Survey (MICS), have the advantage of using small cluster sizes and therefore, inconveniencing a smaller number of people, while still providing an estimate of prevalence within the population. Lot Quality Assurance Surveys (LQAS) have been proposed as useful when trying to determine if a rare event exists and where resources are scarce, as testing can cease once an unacceptable number of positive results have been found.

The usefulness of both of these surveys is limited by the geographical heterogeneity of Lymphatic Filariasis. It can be argued that both surveys can only be certain to find foci of infection if the "cluster" or "lot" size is reduced to the "village" level. However, once such surveys are reduced to village level, the advantages are likely to be outweighed by the disadvantages, as the procedures are relatively complicated, involving randomisation of participants.

The role of sampling only "high risk" individuals within the population of PICTs is still to be determined. Thus far, no high risk groups have been consistently identified. There is some anecdotal evidence from the PICTs that some groups may be at higher risk of carrying LF, as a result of their lack of participation in the MDAs or possibly due to higher baseline prevalence.

In theory, to identify recent transmission within a population, the most useful sample is children born after the commencement of MDAs. One would expect that such children have not been infected with LF and if found positive by any of the available testing techniques, this would indicate relatively recent transmission. Various methods of sampling children are possible; however, the best way of managing sampling limitations is by testing all children of a certain age group, particularly if attempting to determine remaining geographical pockets or 'foci' of infection. It is for this reason that the current surveillance strategy focuses on testing children in School Year 1 (who would normally be aged 5-6 years) or 5 year old children. It is assumed that such a sample will represent approximately 2.5% of the total population. In addition, Year 1 children generally have good school enrolment and attendance rates and may already be the subject of other health screening or treatment initiatives that the LF surveillance program could partner.

ACTION to follow the finding of a positive child

Finding an ICT positive School Year 1 or 5 year old child indicates recent transmission and therefore a geographical area in which there is a source of infection. The actions that follow this finding aim to find and eliminate the source of the child's infection.

The Primary School and Close Contact Testing described is based on an understanding of the behaviour of common mosquito LF vectors in the Pacific. It is beyond the scope of this document to describe in detail vector behaviours and these details are provided elsewhere. It is likely that the mosquito that infected the child would have been infected from a human reservoir in the relatively close vicinity of the child. As this age child spends the majority of their time at school or home, the infectious human reservoir is likely to have been in or close to one of these environments.

Thus following the finding of an ICT positive School Year 1 or 5 year old child, every child and adult in the school (if they attend) needs to be tested, as well as a number of people within their community. Testing within the community includes all household members from the child's home and the closest houses to the child's home. Ideally, the household members in all the houses within a distance of approximately 200m from the child's home need to be tested. Where it is anticipated that a distance of 200m will be difficult for the testing team to judge, the closest 24 houses are recommended to be tested. An important point to make is that that number of 24 households has been selected arbitrarily. This has been judged as likely to cover an area of 50-100 metres around the child's house, and the nearest 100-150 people. Importantly, the use of 24 households will ensure that mosquitoes

living within the area will have adequate “blood meals” to feed upon, and are likely to remain within such an area.

It is worthwhile conducting Close Contact Testing for all children ≤ 8 years old who are found to be ICT positive during any of the testing performed. Infection in these children probably represents transmission since the start of the MDAs, and may lead to detection of residual sources of infection within the community.

Where only one or two children are found to be ICT or antibody positive by the CTS, the source of that infection is likely to be found by testing all people that are living close-by those children. Where it is found that larger numbers of children are infected (i.e. >5 children aged ≤ 8 years old), not only would it be unfeasible to test all the people living close to them, it may not be an adequate public health response to ensure transmission is contained. For this reason, limits have been recommended as points at which advice should be sought from the WHO/SP office and Targeted MDA may be considered.

Test & Treat action with LF cases

The Test & Treat strategy essentially commences following mass screening of a country or region or island with a population ≤10,000 people. All LF cases identified during mass screening should be entered into the T&T register for recording quarterly treatment and follow up testing. As ICT prevalence is the elimination indicator in the Pacific Program to Eliminate LF, a more aggressive treatment of LF cases compared to normal yearly MDA is recommended due to the impact of the drugs on the adult worm. This aggressiveness has to be balanced with practicality, and therefore quarterly treatment using 6mg/kg DEC and 400mg Albendazole has been recommended. The demands placed by T&T on National Programs is expected to reduce significantly after the first year of quarterly treatment, as more LF cases test negative.

Primary Surveillance II: “Hot Spot” Survey

The “Hot Spot” Survey is a surveillance method devised to increase the sampling performed in an area of suspected high prevalence (assumed to be a “high risk area”). It uses recent historical records (since 1999) to identify geographical areas where there may be residual sources of infection within the population. This method assumes that if a village or small area demonstrated a relatively high prevalence in the recent past, it is still likely to be an area of higher prevalence than other areas in the country. It is hoped that this additional survey leads to more children that are ICT positive being detected (increasing the detection of ongoing transmission), which is improving the detection rate of the overall surveillance system.

Secondary Surveillance: Border Detection

Surveillance after the cessation of LF transmission may need to detect the reintroduction of the organism into a country or area. One obvious source of reintroduction is the arrival of a migrant from an endemic country. Another source is the return of a former resident who was absent from their country during MDAs. Ongoing LF surveillance needs to consider the risk posed by these groups of people for reintroducing infection. As the importance of this mode of reintroduction to a country is unknown, two research questions have been proposed.

It is generally accepted that LF transmission requires several inoculations by infected mosquitoes. Thus, for a new arrival or former resident who returns and is a potential source, they may pose a limited risk for reintroduction if their stay is brief. It may be more cost effective to test those individuals who plan to stay for a longer period. The exact length of time that poses a risk for reintroduction from a single source is not known. Therefore, this decision will need to be made arbitrarily (i.e. at six months) until direct evidence is available.

For a country to test migrants or returning residents at their border, a testing station would need to be operational at every international air and sea port. It may be more feasible to make LF testing a condition of certain visa or permanent resident applications. An alternative may be to provide information to migrants or returning residents at the borders and make free testing voluntary through the medical clinic system, although, this does not guarantee that testing will occur.

Decisions about whom, when and how to test can be made by individual countries that wish to participate in this form of surveillance. It may be more acceptable to smaller countries that are non-endemic or recently endemic. It is recommended that some countries participate in this form of surveillance as part of a research project, as the findings will be useful for their country and all of the PICTs in the future to ensure the PICTs remain LF free.

Control Measure I: Targeted MDA

The Targeted MDA is proposed to be used when there is evidence that there is a group within the population that has a high prevalence. This is likely to be a group residing in a small geographical area that is defined by the primary school catchment area. It may also be found that there is a population group within a country that has missed out on the previous rounds of MDA and are therefore, more likely to be sources of infection.

The decision to use Targeted MDA should be made by the country LF Manager in consultation with the WHO/SP office. It is recommended that social science research is conducted prior to commencement of any further MDAs to establish if there are barriers to the successful implementation of MDA.

Control Measure II: Vector Control

It has been suggested that MDA alone will not be enough to achieve cessation of transmission of LF, particularly for some countries. The ubiquitous nature of *Aedes sp.* means that current vector control programs will have limited success in areas where they are the primary vector for LF. However, for countries in which *Anopheles sp.* or *Culex sp.* are the primary vectors, vector control might be a useful additional measure in response to surveillance findings. Therefore, this has been recommended for those countries with *Anopheles sp* or *Culex sp* as the primary LF vector, to be considered if surveillance targets are not being met.

A Regional Approach

This LF Surveillance Strategy provides a generic template from which all PICTs can plan their ongoing LF surveillance. By necessity, it requires all countries to be vigilant in their approach to identification of LF transmission, and thorough in their efforts to find and eliminate all remaining sources of LF infection.

Although the PICTs are at different stages of their elimination program and will continue to be at different stages of surveillance, the time is drawing nearer when all PICTs will reach the final goal. Although Papua New Guinea is likely to be the last country that finishes MDA, the updated plan from PNG shows that the final rounds of MDA are due for completion in 2013. This means that after 2013, all countries in the Pacific will have entered into a phase of ongoing surveillance, which will be a great achievement.

For the Pacific region to be declared “LF free”, the records of ALL countries will need to be reviewed, by external expert auditors. It may be that surveillance will need to continue to some extent, for all PICTs, until world-wide elimination has been achieved; however, such surveillance is likely to be less intense than that which is required now. For now, it is hoped that each of the individual PICTs can continue LF surveillance until the region is certified as “LF free” and deemed to be safe from reintroduction.

Table 1: PICTs total population, estimated primary school population and estimated CTS target group population

Country	Population size (SPC estimate, 2008)	Estimated Number of Primary School Children (15% of total population)	CTS Target Group Population: Estimated number of School Year 1 Children or 5 year olds (2.5% of total population)	Number of School Year 1 or 5 year old children expected to be ICT positive if no LF transmission is occurring (maximum number *)
American Samoa	66,107	9,615	1,602	1 (4)
Cook Islands	15,537	2,705	468	0 (2)
Fed States Micronesia	110,443	17,715	2,953	2 (7)
Fiji	839,324	123,705	20,617	20 (29)
French Polynesia	263,267	34,950	5,825	5 (11)
Guam	178,980	22,230	3,705	3 (8)
Kiribati	97,231	13,605	2,267	2 (5)
Marshall Is	53,236	7,770	1,295	1 (4)
Nauru	10,163	1,725	287	0 (2)
New Caledonia	246,614	31,905	5,317	5 (10)
Niue	1549	285	47	0 (1)
Northern Mariana Is	62,969	11,505	1,917	1 (5)
Palau	20,279	2,865	477	0 (2)
PNG	6,473,910	718,620	119,770	119 (135)
Pitcairn Is	66	7	0-2	0 (n/a)
Samoa	179,645	25,380	4,230	4 (8)
Solomon Is	517,455	67,185	11,197	11 (17)
Tokelau	1,500	225	37	0 (1)
Tonga	102,724	15,030	2,505	2 (6)
Tuvalu	9,729	1,485	247	0 (1)
Vanuatu	233,026	29,970	4,995	4 (9)
Wallis & Futuna	15,472	2,190	365	0 (2)

* Upper limit of 95% Confidence Interval

Table 2. Comparisons between tests available for diagnosing LF infection

Test name	Stage of parasite detected by test	Sensitivity	Specificity	Time after infection test reads positive	Time after death of worm, test reads negative	Operator considerations	Use in 5 year old children
MF thick blood film	Microfilariae	Poor. Reduced with low prevalence and low density (<20mf/ml)	100% - only with a trained microscopist	>1 year	Days	Needs significant training of operator	Limited – few children are MF+ following MDA
Og_4C_3 Antigen test	Adult worm	High (>95%) Reduced with low prevalence and low density[2]	99-100%[2]	Months - years	Months - years[2]	Sophisticated laboratory equipment	Has detected Ag in children <4 years, although limited experience
Antibody Test (IgG_4 antibody to Bm14)	Microfilariae or adult worm; possibly also L3 exposure	91%[7] for MF+ persons	Low in areas with L.loa and O. volvulus [7]	Likely within months after L3 infection	Months - years	Sophisticated laboratory equipment; blood collection stable on filter paper	Have identified Ab in 3 year olds, but likely depends on transmission intensity
ICT card NB: Should use Og_4C_3 for QA on 10% of ICT cards	Adult worm	High (>95%)[5,6] Reduced with low prevalence and low density[2]	100%[5,6] NB: No cross reactivity with immune markers[4]	Months - depends on intensity of transmission	Months - years	Relatively easy to use field test[3,5,6] Potential problems: If read >10mins or held vertically: false positive (reader error) If card kept at >8degC: reads false negative If card is expired: reads false negative	Has been positive in children as young as 2 years old in PICTs data collected so far
Blood Elisa PCR	Microfilariae	Still experimental, results unknown					
Vector PCR	MF, L1, L2, L3	High	100%	Immediate	N/A	Not feasible for general field use in PICTs setting currently	NA
Vector microscopy	Not feasible in PICTs setting currently						

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Appendix 2 : CTS Flowcharts and Close Contact Testing Maps

2.1 CTS Flowchart – Primary School Method

2.2 CTS Flowchart – Community Method

2.3 Close Contact Testing Procedure

2.4 Map 1: Close Contact Testing by 200m rule: Village

2.5 Map 2: Close Contact Testing by 200m rule: Town/City

2.6 Map 3: Close Contact Testing by 24HH rule: Village

2.7 Map 4: Close Contact Testing by 24HH rule: Town/City

2.1 CTS Flowchart – Primary School Method

Primary School

Test all Year 1 children by ICT

Follow protocol for reading ICT test

ICT -

No Further Action for this school

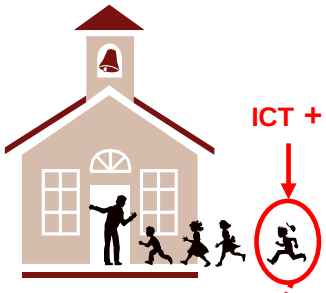
ICT +

Repeat ICT

ICT -

ICT +

"LF CASE"



ICT +

ICT +
Each person that is considered to be an "LF Case" MUST be treated and their name recorded for follow-up

Every child ≤ 8 years old represents NEW transmission.

In one school, how many children ≤ 8 years old are ICT positive?

> 5

≤ 5

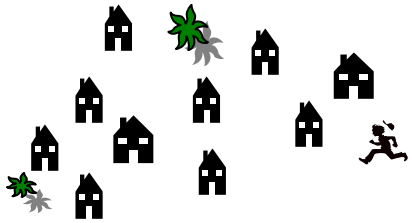
ACTION:

ALERT WHO/SP office immediately

Do "Close Contact Testing" for all children ≤ 8 years old:
1. Test all household members
2. Test everyone in nearest houses

(See Maps next pages)

2.2 CTS Flowchart – Community Method



Village or Community

Test all **5 year old** children by ICT

Follow protocol for reading ICT test

ICT -

ICT +

No Further Action for this village/community

ICT -

Repeat ICT

ICT +

"LF CASE"

ICT +
Each person that is considered to be an "LF Case" MUST be treated and their name recorded for follow-up

Every child ≤ 8 years old represents NEW transmission.

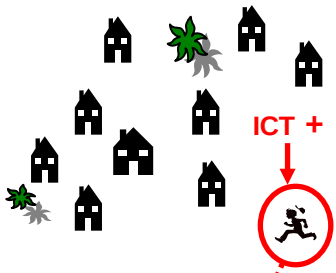
In one village, how many children ≤ 8 years old are ICT positive?

> 2

≤ 2

ACTION:

ALERT WHO/SP office immediately



Do "Close Contact Testing" for all children ≤ 8 years old:
1. Test all household members
2. Test everyone in nearest houses

(See Maps next page)

2.3 Close Contact Testing Procedure

STEP 1. For every child ≤ 8 years old test ALL people living within the child's home (as source may be within their home).

STEP 2. For every child ≤ 8 years old test ALL people living within 200m from that child's home (see Map 1 and 2)

OR

ALL people living in the closest 24 surrounding households (HH) to the child's home (see Map 3 and 4)
(as the "source" may be from nearby their home).

A decision about which method to use must be made by the Country LF Manager prior to survey implementation

NOTE: Testing for children ≤ 8 years should be by ICT alone
(refer Appendix 5.1)
Testing for people > 8 years should be by ICT and MF slide
(refer Appendix 5.2)

STEP 3. Additionally, for every child ≤ 8 years old who is found to be ICT positive, their parent/carer should be asked if that child visits another home/household daily.

If they visit another house daily, that is >200m from their own home, then the other house could be where (or near) the source of infection.

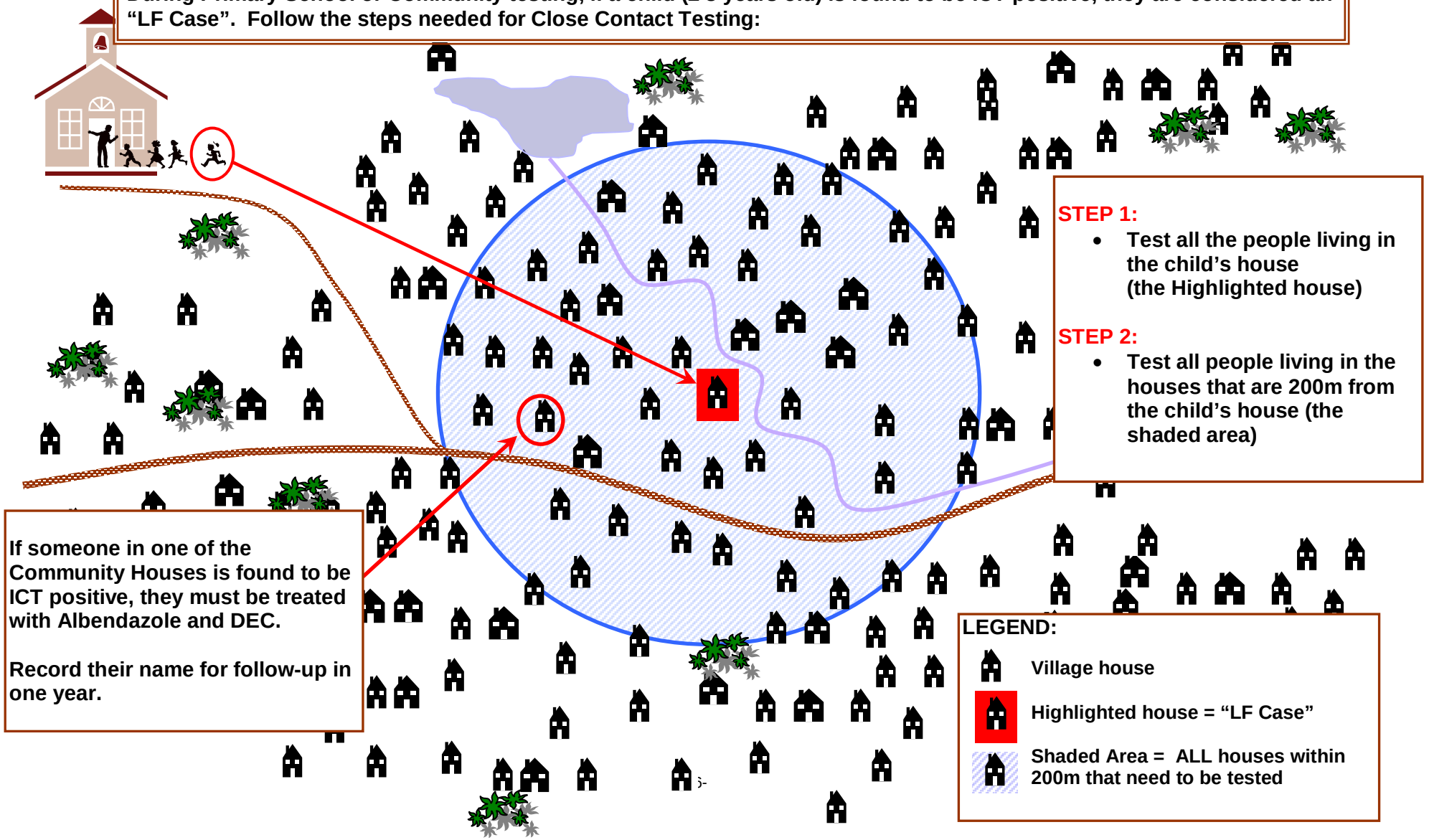
This second house should also be treated as the "child's home" and Close Contact Testing for this home should be completed by the same method as for the Child's home (i.e. test all members of the household and all members of the houses that are 200m around it).

STEP 4. Everyone who is found to be ICT positive must be treated with the recommended doses of Albendazole and DEC (refer Appendix 5) and their name recorded for follow-up.

STEP 5. Follow up needs to be performed on EVERYONE who has a positive test result, depending on their age and the test.

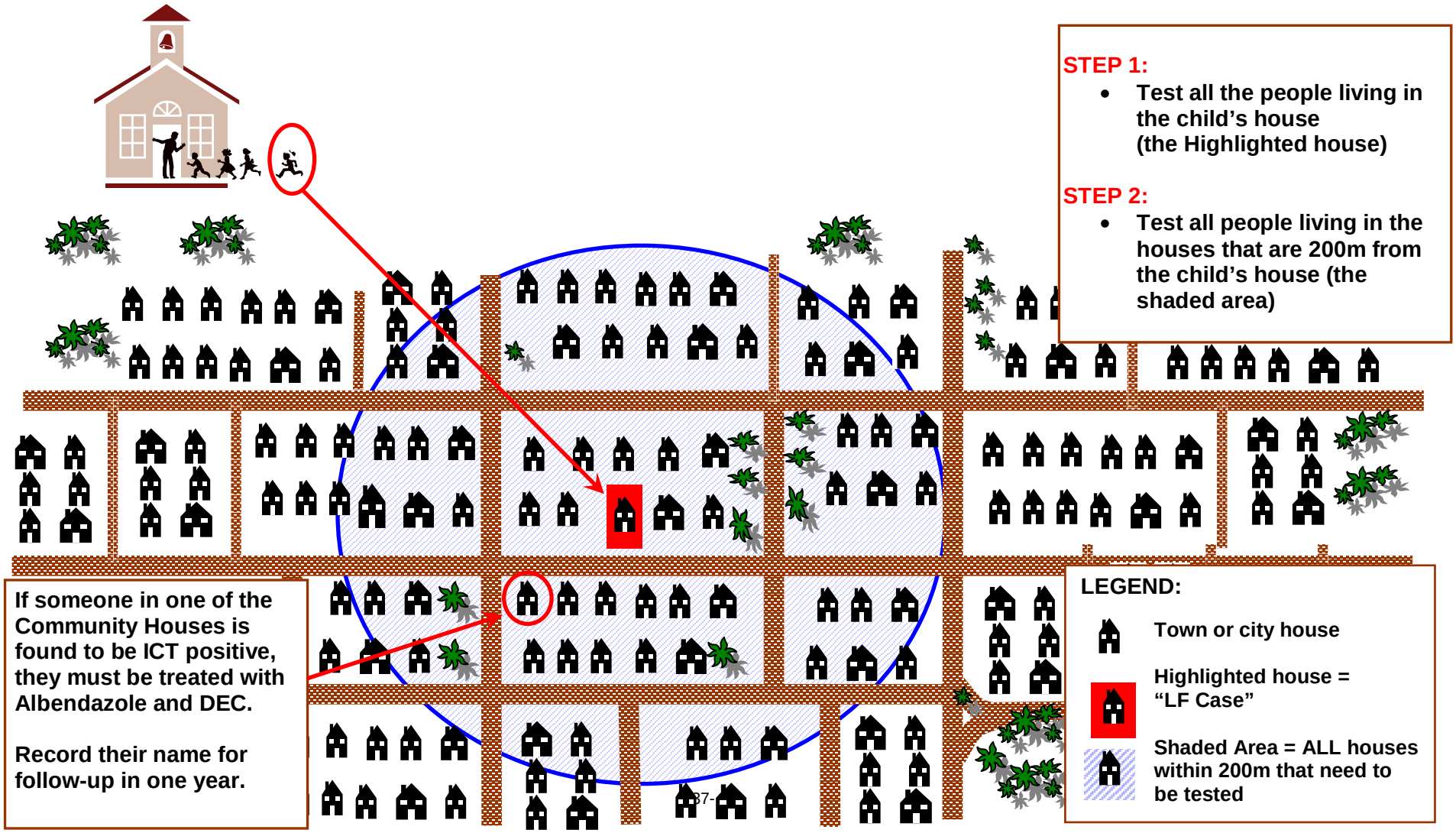
2.4 Map 1: Close Contact Testing by 200m rule: Village

During Primary School or Community testing, if a child (≤ 8 years old) is found to be ICT positive, they are considered an "LF Case". Follow the steps needed for Close Contact Testing:



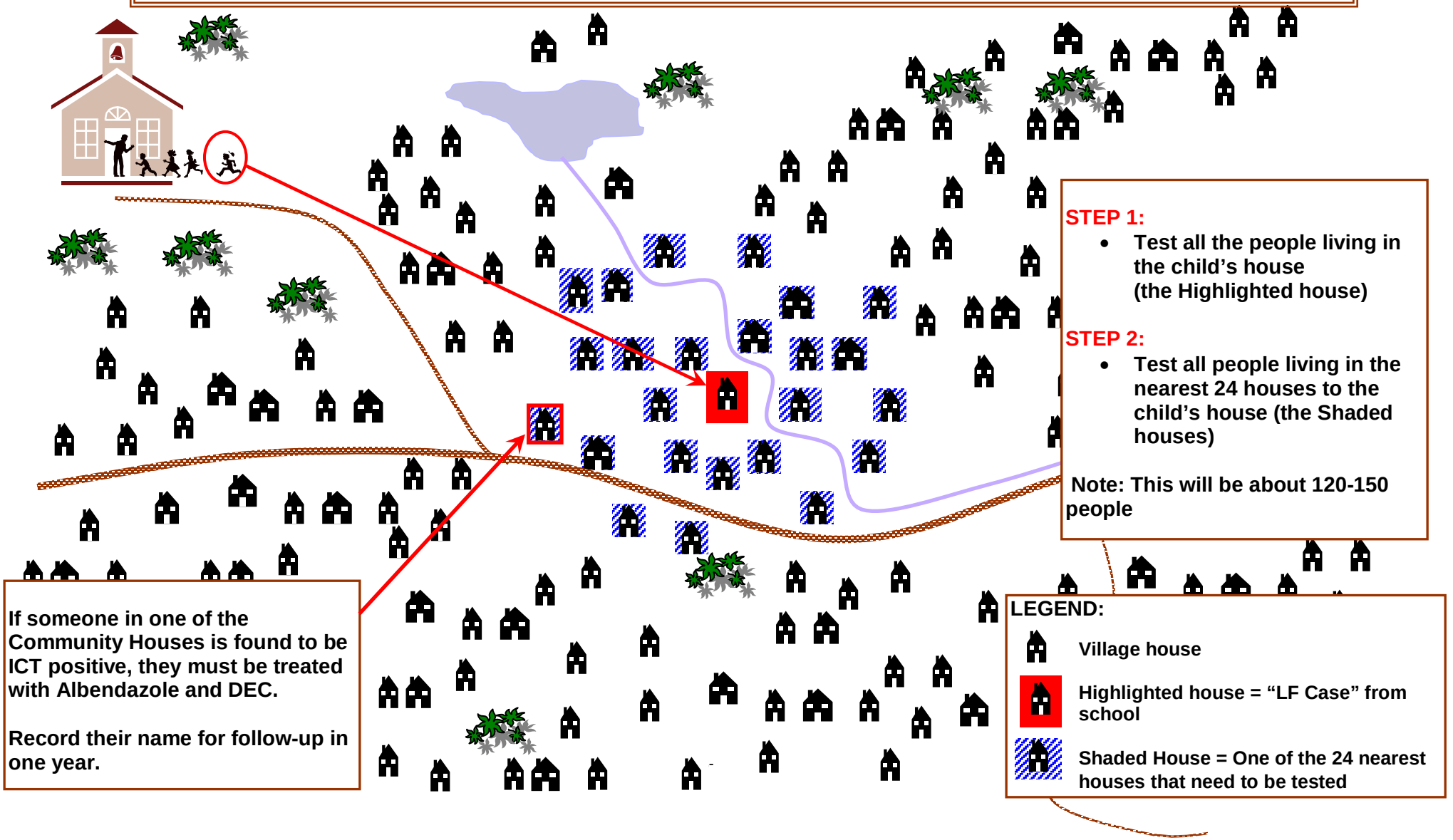
2.5 Map 2: Close Contact Testing by 200m rule: Town/City

During Primary School or Community testing, if a child (≤ 8 years old) is found to be ICT positive, they are considered an "LF Case". Follow the steps needed for Close Contact Testing:



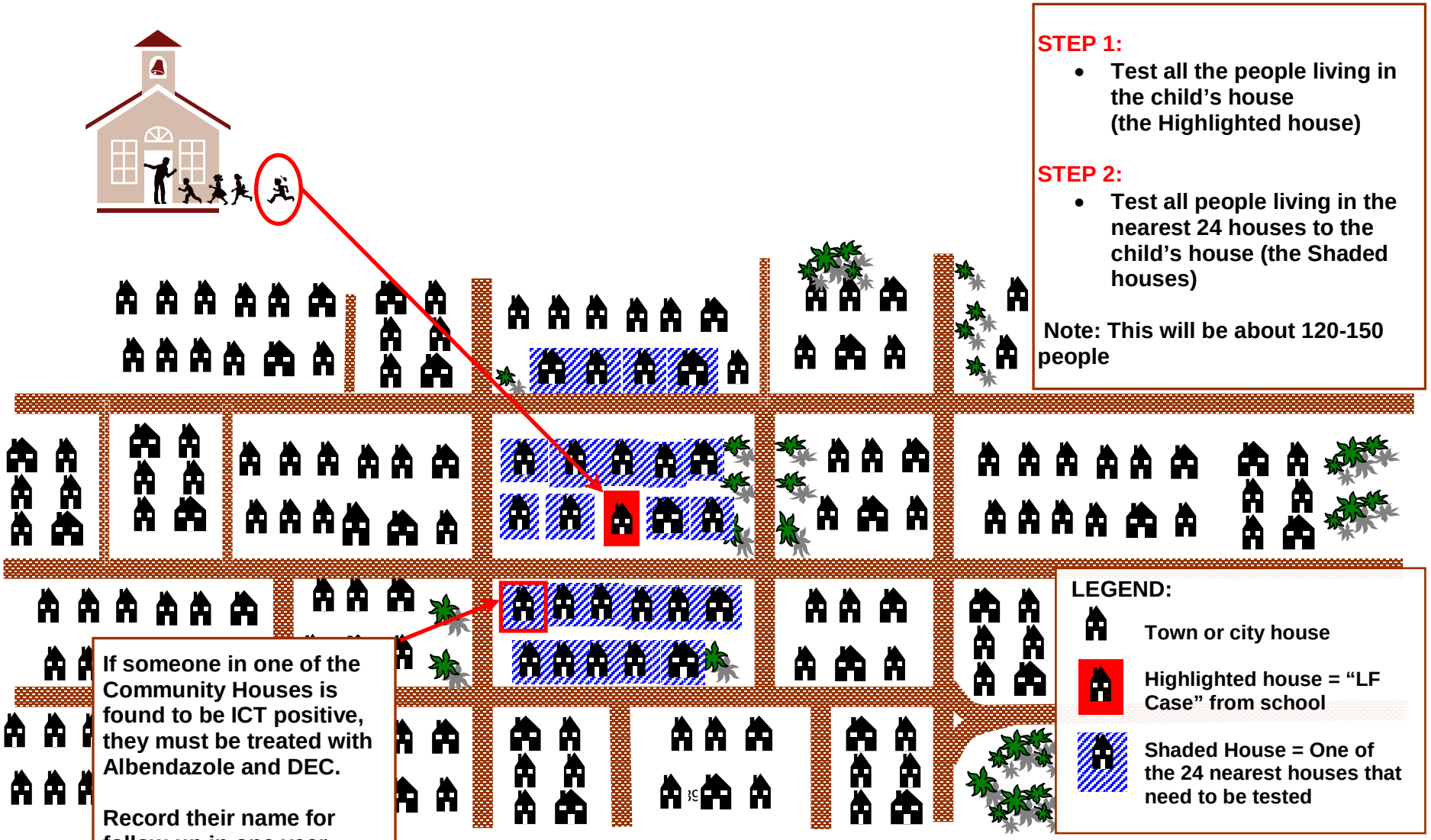
2.6 Map 3: Close Contact Testing by 24HH rule: Village

During Primary School or Community testing, if a child (≤ 8 years old) is found to be ICT positive, they are considered an "LF Case". Follow the steps needed for Close Contact Testing:



2.7 Map 4: Close Contact Testing by 24HH rule: Town/City

During Primary School or Community testing, if a child (≤ 8 years old) is found to be ICT positive, they are considered an "LF Case". Follow the steps needed for Close Contact Testing:

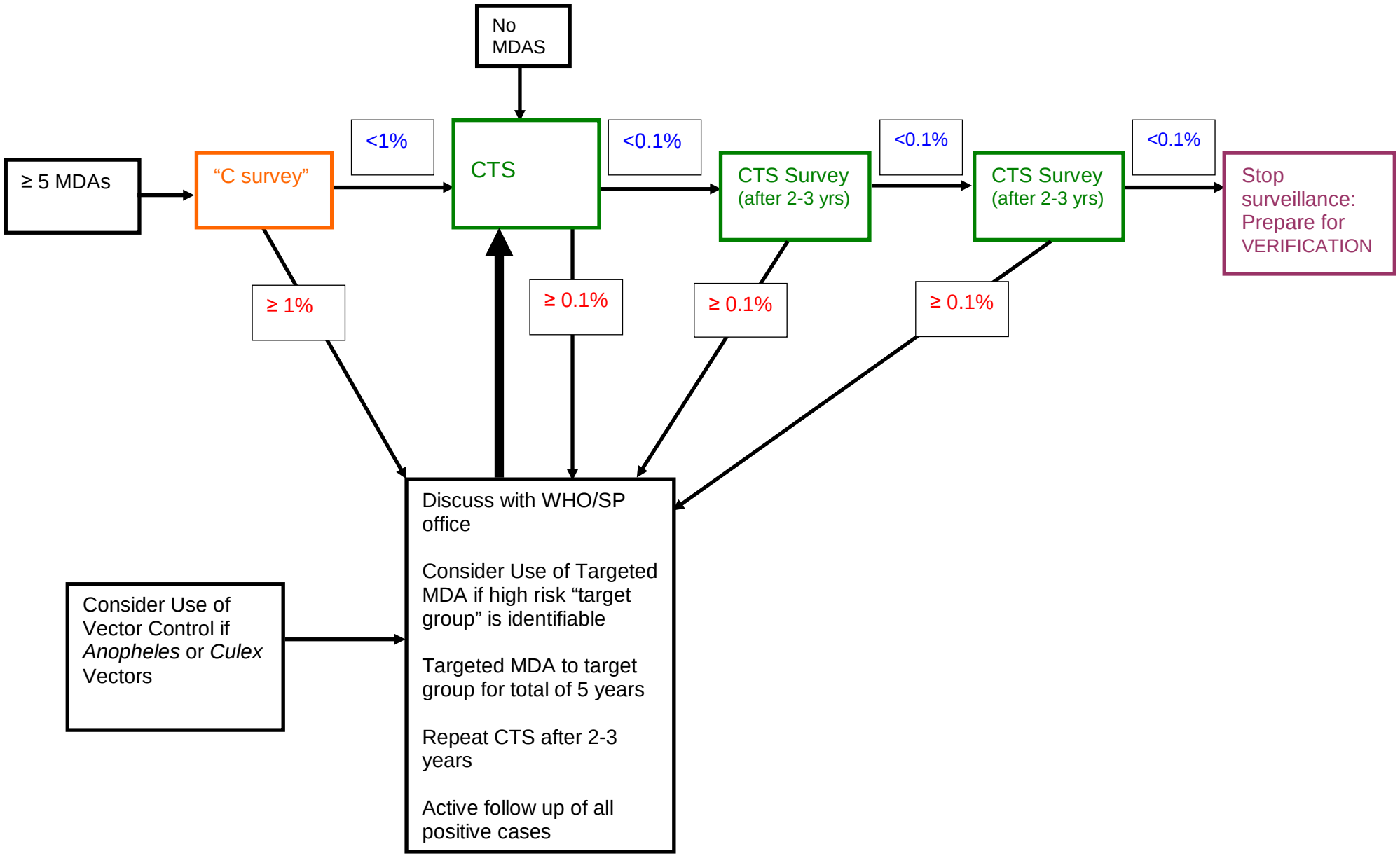


Appendix 3 : LF Surveillance Algorithms

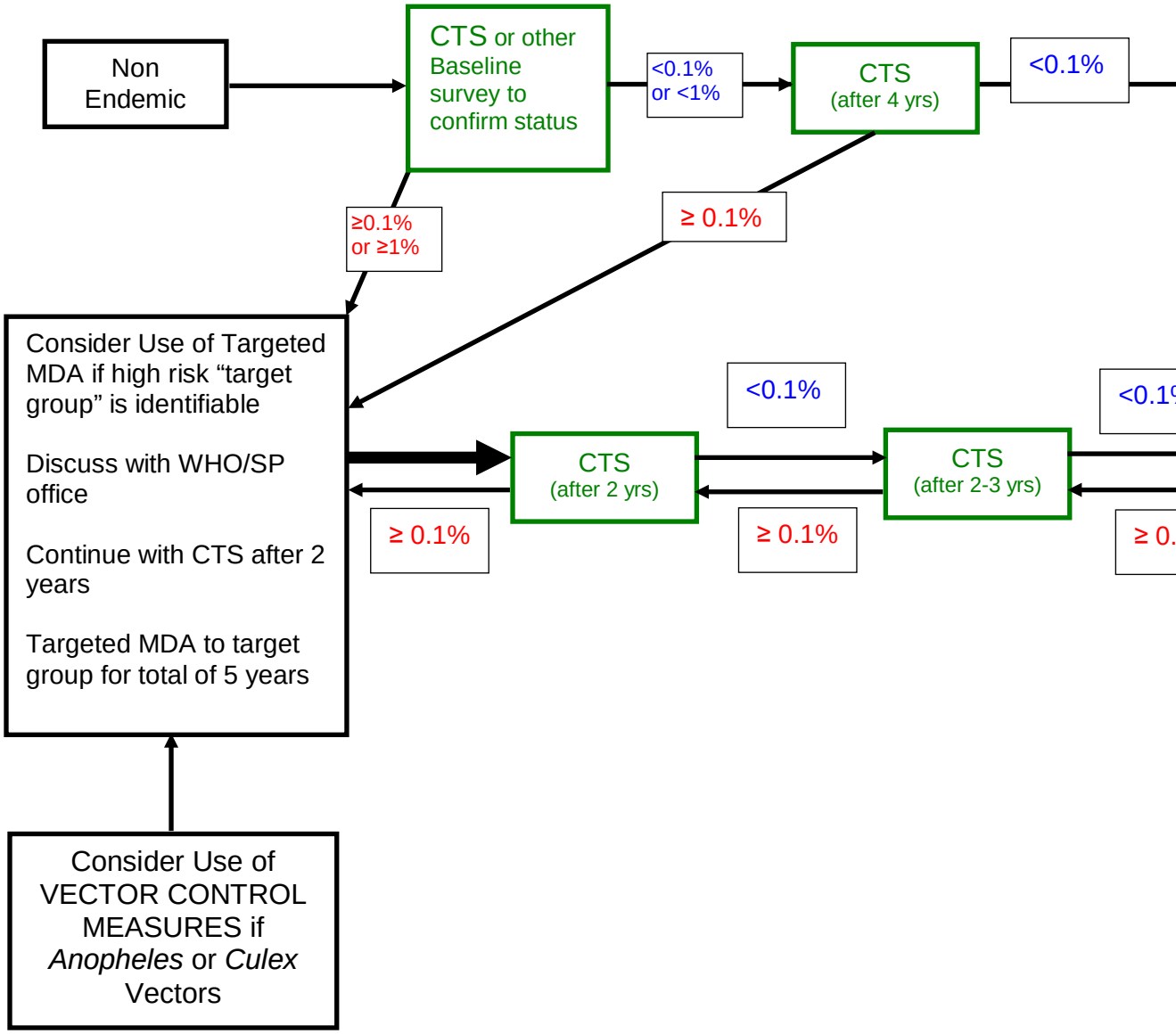
3.1 ALGORITHM FOR ENDEMIC and PARTIALLY ENDEMIC COUNTRIES

3.2 ALGORITHM FOR NON ENDEMIC COUNTRIES

3.1 ALGORITHM FOR ENDEMIC and PARTIALLY ENDEMIC COUNTRIES



3.2 ALGORITHM FOR NON ENDEMIC COUNTRIES



Appendix 4: Testing Protocols

4.1 ICT testing protocol

4.2 MF testing protocol

4.3 MF blood collection times

4.4 Collecting Blood Spots for Antibody Test

4.1 ICT testing protocol[3]

Materials

ICT kit contains these materials

- ☐ ICT test card
- ☐ Gloves
- ☐ Sterile blood lancets
- ☐ 100ul heparin coated capillary tubes
- ☐ Alcohol wipes
- ☐ Clean cotton wool
- ☐ Sharps container
- ☐ Yellow plastic bag for collecting biohazardous material
- ☐ Pen
- ☐ Timer or watch

Procedure

1. Collect all materials (supplied with the card) necessary for the test and prepare your working area.

2. Remove the card from the silver pouch just before use.

3. Write the name of person who will be examined and the date of test on the front of test card (use a pen).

4. Open the test card and lay it flat.

5. Wear gloves.

6. Collect blood sample by finger prick into the 100ul capillary tube (**full**).

7. Add all the blood in the capillary tube **onto the top (white area)** of the pink and white pad on the left hand side of the test card. **Slowly** drop by drop. The tip of the tube can touch the pad.

8. **Wait until the blood has reached into the pink area**. This may take one minute or so. If you do not wait, the test may not work.

9. Remove the adhesive tape on the right hand side of the card and close the card.

10. Press firmly along the window of the card from right to left and the top to the bottom.

11. **Start timing for 10 min**.

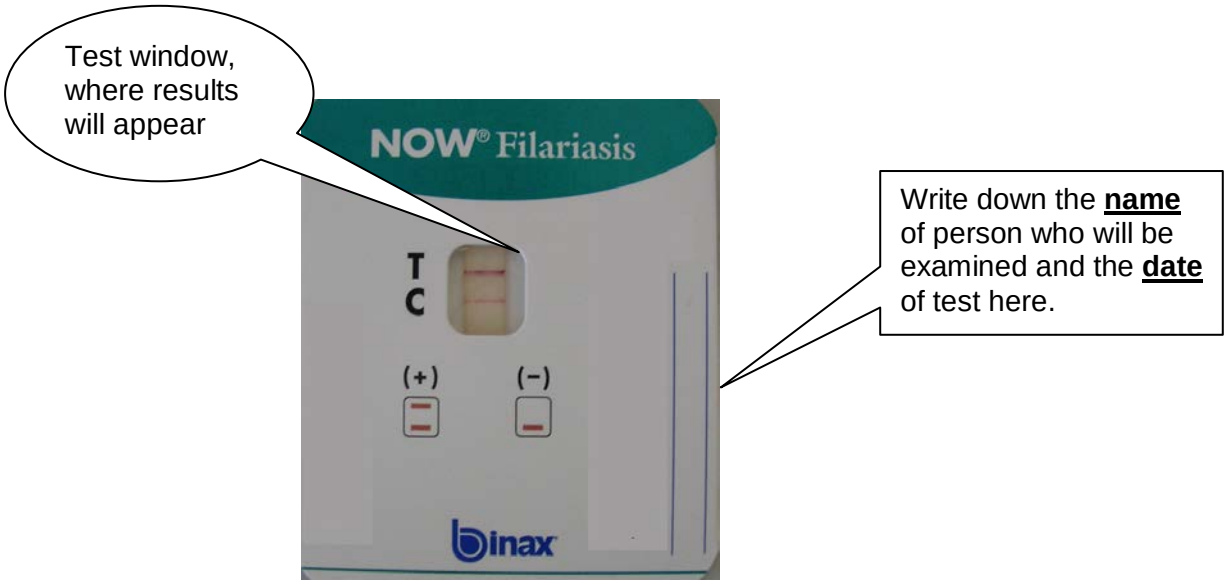
12. Read the result through the window **at exactly 10 minutes**. You must read the result at 10 min to ensure the test works.

13. Record the result on the card and on the appropriate form (Appendix 6).

[3] Source: Adapted from Standard Operating Procedures, Mataika House and PacELF Office, Suva, Fiji.

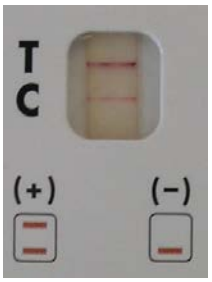
14. Discard the used capillary tube and lancet into the sharp container. The rest should be collected in the yellow plastic bag.

15. Keep the test card in an appropriate container and inform the person who was tested of their result.



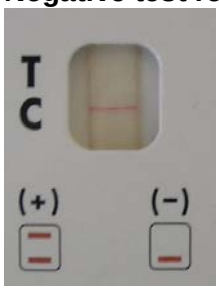
Interpretation of results

Positive test result



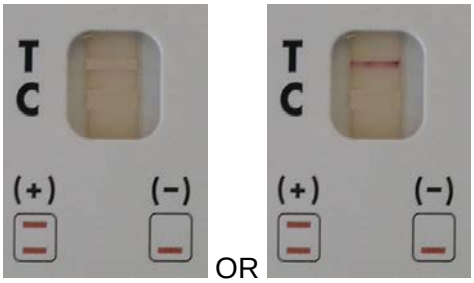
When two lines (both T and C) are observed in the window of the card at 10 min, the test is positive. Even if the top line (T) is only slightly visible, the test is considered as positive.

Negative test result



If only the bottom line (C) appears at 10 min, the test is negative.

Invalid test result



The test is invalid, if the bottom line (C) does not appear at 10 min (e.g. only the T line or no lines). The test needs to be repeated with a new card.

Manufacturer
Binax, INC.
Portland, ME, USA
Product name
NOW® ICT FILARIASIS
A rapid immunochromatographic test for the quantitative detection of *Wuchereria bancrofti* antigen

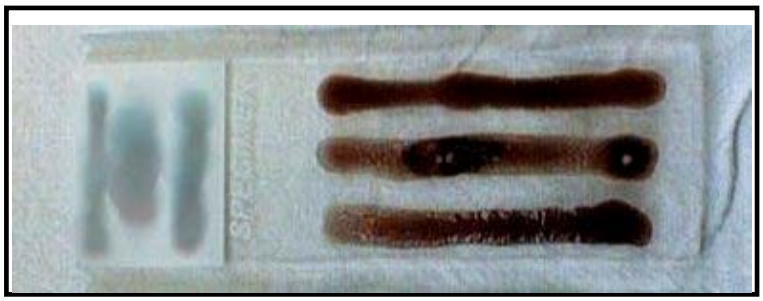
4.2 MF slide testing protocol

Three line method – for MF blood smear[4]

Purpose
To ensure proper preparation of 3 line blood smear for microscopic examination of microfilariae of *Wuchereria bancrofti*.

Notes

- 60ul of whole blood is required for the preparation of the slide.
- The sample should be collected between the ideal times, depending on the primary mosquito vector (refer Appendix 4.3, next page).
- Specimen (blood) should be collected in a heparin coated container (test tube, capillary etc) according to one of the following methods:
- Finger prick blood collection: the sample should be collected in a 100ul capillary tube supplied with the ICT kit. The sample should be used immediately.
- Venous blood collection by any standard venipuncture method in a heparin coated tube. The blood can be stored at 2 to 8 °C for three days



Materials
Single use gloves
Clean glass microscope slides
Sterile blood lancets
Cotton wool
Alcohol wipe
Capillary tube
Pencil
Sharps container
Tissue/paper and box to wrap slides for transport to laboratory

Procedure

1. Prepare all necessary materials.
2. Wear gloves.
3. Write the name of test subject and the date of test on the slide (frosted end) using a pencil.
4. Collect blood sample by finger prick or standard venipuncture. The sample should be collected in (or transferred to) a heparin coated capillary tube up to 60ul line or the two thirds of the 100ul tube.
5. With the filled capillary tube using all the blood in the tube, draw three lines of equal width (3mm) and length onto the microscope slide.
6. Allow the blood slide to dry in a flat position protected from insects, dust and heat. Minimum drying time is 30minutes, but drying may take several hours.
7. Discard the used materials in appropriate containers (i.e. lancet and capillary tube in sharps container; other items in the yellow plastic bag).
8. Pack prepared slides appropriately to transport to laboratory.

[4] Adapted from: Protocol used for Mataika House and PacELF Office, Suva, Fiji.

4.3 MF blood collection times[5]

Recommended times for collection of blood specimens for testing for *Wuchereria bancrofti* microfilariae in the South Pacific

Type	Recommended collection time
Diurnally sub-periodic	15:00 – 17:00 (peak 16:00)
Nocturnally periodic	22:00 – 01:00 (peak 24:00, midnight)

By country

Country/region	Filaria type	Primary vector	Recommended collection time
American Samoa	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Cook Islands	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Fiji	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
French Polynesia	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Kiribati	Nocturnally periodic	Culex quinquefasciatus	22:00 – 01:00 (peak 24:00, midnight)
Niue	Diurnally sub periodic	Aedes cooki	15:00 – 17:00 (peak 16:00)
Papua New Guinea	Nocturnally periodic	Anopheles	22:00 – 01:00 (peak 24:00, midnight)
Samoa	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Tonga	Diurnally sub periodic	Aedes tabu	15:00 – 17:00 (peak 16:00)
Tuvalu	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Vanuatu	Nocturnally periodic	Anopheles	22:00 – 01:00 (peak 24:00, midnight)
Wallis and Futuna	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
FSM	Diurnally sub periodic	Culex annulirostris s.l.	15:00 – 17:00 (peak 16:00)
Marshall	Diurnally sub periodic	Culex quinquefasciatus	15:00 – 17:00 (peak 16:00)
Palau	Nocturnally periodic	Culex quinquefasciatus	22:00 – 01:00 (peak 24:00, midnight)
Guam	Nocturnally periodic	Culex quinquefasciatus	22:00 – 01:00 (peak 24:00, midnight)

[5] **References**:
Monitoring and epidemiological assessment of the programme to eliminate lymphatic filariasis at implementation unit level. World Health Organization, 2005.
PacELF Data Book 2006. Pacific programme to Eliminate Lymphatic Filariasis, 2006.

Nauru	Nocturnally periodic	Culex quinquefasciatus	22:00 – 01:00 (peak 24:00, midnight)
New Caledonia	Diurnally sub periodic	Aedes vigilax	15:00 – 17:00 (peak 16:00)
NMI	Nocturnally periodic	Culex quinquefasciatus	22:00 – 01:00 (peak 24:00, midnight)
Pitcairn	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)
Solomon	Nocturnally periodic	Anopheles	22:00 – 01:00 (peak 24:00, midnight)
Tokelau	Diurnally sub periodic	Aedes polynesiensis	15:00 – 17:00 (peak 16:00)

4.4 Collecting Blood Spots for Antibody Test (at same time as ICT testing)[6]

Note: This will be used only by some countries, after consultation with WHO/SP office and LF Coordinating Centre, JCU, Townsville, Aust.

Additional Materials Needed

- ☐ Filter paper "disk" from laboratory for antibody testing
- ☐ Freezer bags ("zip-lock" bags)
- ☐ Pencil or pen

Procedure

1. Use one disk for each person. Each disk has 6 "ears."

2. Push out the disk from the card (Figure 1).

3. Remove the smaller disk from the centre to leave a hole.

4. Write the person's name and registration number on the disk.

5. After collecting blood for the ICT test either use the same capillary tube to put blood on to the "ears" or touch the ears to the finger. Fill all 6 ears.

6. Push a pencil through the centre hole in the disk. You can put many disks on to the same pencil but leave room between them so then don't touch each other. Alternatively, push each filter paper through a metal spike, making sure that they do not touch while they dry (Figure 2).

7. Leave the disks on the pencil until completely dry – usually about four hours.

8. After they are dry, put disks into plastic bags in groups of 100. It would be helpful to the lab if they were grouped 1 to 100, 101-200, etc.

9. Place the bags in the freezer.

[6] Source of information: Dr Wayne Melrose, LF Coordinating Centre, James Cook University, Townsville, Aust. Photos: Dr Corinne Capuano

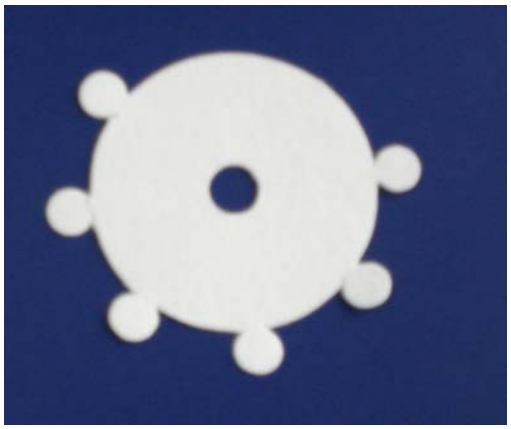


Figure 1: Filter paper “disk” ready for use

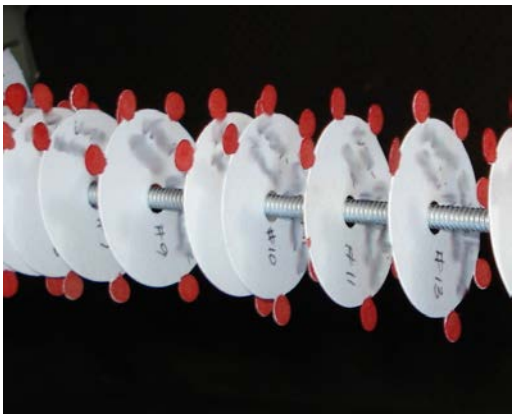


Figure 2: Filter papers drying on metal spike

Appendix 5: Treatment Protocols

5.1 Treatment protocol: ICT positive case

5.2 Treatment protocol: MF positive case

5.3 Targeted MDA dosing schedule

5.1 Treatment protocol: ICT positive case

For people found to be ICT positive, treatment is as follows[7]:

Single dose of Albendazole and single dose of DEC (6mg/kg) every 3 months

Dosage:
Doses for DEC must be given by WEIGHT, using the table on the following pages (Refer to Appendix *5.4: Doses by weight for DEC and Albendazole tablets*)

Young Children:
Drug Administrators should be advised to take special care in administering tablets to young children. The tablets should be always administered to children under the supervision of the drug distributor or a responsible adult. Do not leave tablets unattended where children can reach them.

The albendazole tablet is relatively large. The Albendazole has a pleasant taste and can be chewed by the child (or crushed and given). In no circumstances should small children be forced to swallow the tablet, as it may obstruct the airway resulting in breathing problems. Crying and/or distressed children should be calmed before the administration of tablets.

Exclusion[7]:
For DEC and Albendazole co-administration, the following groups should be excluded from treatment:

- Sick individuals
- Children less than 2 years of age
- Pregnant women

Side Effects[7]:
DEC and Albendazole are both safe and well-tolerated drugs.

General reactions, in decreasing order of frequency, are: headache, body ache, fever, dizziness, decreased appetite, malaise, nausea, urticaria, vomiting and sometimes bronchial asthma. General reactions and fever are positively associated with the prevalence and intensity of microfilaraemia. Reactions occur early during the treatment and generally do not last more than 3 days.

Local reactions are most commonly scrotal nodules due to death of the adult worm. Others include lymphadenitis (inflamed lymph node), funiculitis ("boil"), epididymitis , orchalgia (painful testicles), and lymphangitis. Rarely, abscess formation, ulceration or transient lymphoedema have been reported. They tend to occur later (1-3 weeks after treatment) and last longer.

[7] **Source:** Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis
World Health Organization. Geneva, Switzerland. 1999.
Document Ref: WHO/CDS/CPE/2000.15

5.2 Treatment protocol: MF positive case

For people found to be MF positive, treatment is as follows[8]:

Single dose of Albendazole and single dose of DEC (6mg/kg)

Dosage:
Doses for DEC must be given by WEIGHT, using the table on the following pages (Refer to Appendix *5.4: Doses by weight for DEC and Albendazole tablets*)

Young Children:
Drug Administrators should be advised to take special care when administering tablets to young children. The tablets should be always administered to children under the supervision of the drug distributor or a responsible adult. Do not leave tablets unattended where children can reach them.

The albendazole tablet is relatively large. The Albendazole has a pleasant taste and can be chewed by the child (or crushed and given). In no circumstances should small children be forced to swallow the tablet, as it may obstruct the airway resulting in breathing problems. Crying and/or distressed children should be calmed before the administration of tablets.

Exclusion[8]:
For DEC and Albendazole co-administration, the following groups should be excluded from treatment:

- Sick individuals
- Children less than 2 years of age
- Pregnant women

Side Effects[8]:
DEC and Albendazole are both safe and well-tolerated drugs.

General reactions, in decreasing order of frequency, are: headache, body ache, fever, dizziness, decreased appetite, malaise, nausea, urticaria, vomiting and sometimes bronchial asthma. General reactions and fever are positively associated with the prevalence and intensity of microfilaraemia. Reactions occur early during the treatment and generally do not last more than 3 days.

Local reactions are most commonly scrotal nodules due to death of the adult worm. Others include lymphadenitis (inflamed lymph node), funiculitis ("boil"), epididymitis , orchalgia (painful testicles), and lymphangitis. Rarely, abscess formation, ulceration or transient lymphoedema have been reported. They tend to occur later (1-3 weeks after treatment) and last longer.

[8] **Source:** Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis
World Health Organization. Geneva, Switzerland. 1999. Page 17.
Document Ref: WHO/CDS/CPE/2000.15

5.3 Targeted MDA dosing schedule

During Targeted MDA, Treatment is as follows:

Single dose of Albendazole and single dose of DEC (6mg/kg)

Must be given **every 12 months**

Must be given to **>80% of the target population**

Give for **5 consecutive years**

Dosage:
Doses for DEC must be given by WEIGHT, using the table on the following pages
(Refer: *5.4 Doses by weight for DEC and Albendazole tablets*)

Young Children:
Drug Administrators should be advised to take special care when administering tablets to young children. The tablets should be always administered to children under the supervision of the drug distributor or a responsible adult. Do not leave tablets unattended where children can reach them.

The albendazole tablet is relatively large. The Albendazole has a pleasant taste and can be chewed by the child (or crushed and given). In no circumstances should small children be forced to swallow the tablet, as it may obstruct the airway resulting in breathing problems. Crying and/or distressed children should be calmed before the administration of tablets.

Exclusion[9]:
For DEC and Albendazole co-administration, the following groups should be excluded from treatment:

- Sick individuals
- Children less than 2 years of age
- Pregnant women

Side Effects[9]:
DEC and Albendazole are both safe and well-tolerated drugs.

General reactions, in decreasing order of frequency, are: headache, body ache, fever, dizziness, decreased appetite, malaise, nausea, urticaria, vomiting and sometimes bronchial asthma. General reactions and fever are positively associated with the prevalence and intensity of microfilaraemia. Reactions occur early during the treatment and generally do not last more than 3 days.

[9] **Source:** Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis
World Health Organization. Geneva, Switzerland. 1999. Page 17.
Document Ref: WHO/CDS/CPE/2000.15

Local reactions are most commonly scrotal nodules due to death of the adult worm. Others include lymphadenitis (inflamed lymph node), funiculitis ("boil"), epididymitis , orchalgia (painful testicles), and lymphangitis. Rarely, abscess formation, ulceration or transient lymphoedema have been reported. They tend to occur later (1-3 weeks after treatment) and last longer.

5.4 Doses by Weight for DEC and Albendazole tablets[10]

Use the tables below to work out the number of tablets needed.
First CHECK which type of DEC tablets the country is using, 50mg or 100mg.

For DEC and Albendazole co-administration, the following groups should be **excluded** from treatment:

- Sick individuals
- Children less than 2 years of age
- Pregnant women

DRUG DOSAGE CHART BY WEIGHT FOR TREATMENT WITH DEC AND ALBENDAZOLE

USING 50mg DEC TABLETS

BODY WEIGHT (kg)	NUMBER OF TABLETS	
	DEC **(50mg)**	Albendazole (400mg)
10-13	1	1
14-22	2	1
23-29	3	1
30-38	4	1
39-46	5	1
47-52	6	1
53-63	7	1
64-71	8	1
72-79	9	1
80+	10	1

DRUG DOSAGE CHART BY WEIGHT FOR TREATMENT WITH DEC AND ALBENDAZOLE

USING 100mg DEC TABLETS

BODY WEIGHT (kg)	NUMBER OF TABLETS	
	DEC **(100mg)**	Albendazole (400mg)

[10] Source: PacELF HandBook. Facts and Methods for Lymphatic Filariasis Elimination in the Pacific. Published by PacELF Home Office, February, 2004.

10-13	½	1
14-22	1	1
23-29	1 ½	1
30-38	2	1
39-46	2 ½	1
47-52	3	1
53-63	3 ½	1
64-71	4	1
72-79	4 ½	1
80+	5	1

Appendix 6: Record Keeping

6.1 CTS – Primary School Method: Form for recording testing by the Primary School Method

6.2 CTS - Community Method: Form for recording testing by the Community Method

6.3 “Close Contact Testing” Form

6.1 CTS – Primary School Method: Form for recording testing in Primary Schools

1. Country: _____ _____
2. State/Region: _____ _____
3. Name of Person performing the testing: _____ ____
4. School Name:_____ _____
5. School Address: _____ _____
6. Date: _____

ID	Name (List all School Year 1 children enrolled at the school)	School year	Age	Gender (M or F)	ICT		If positive, record address of positive person	IF not tested, give reason	Treatment given	
					performed (Y/N)	result (+/-)			DEC (number tablets)	Albend. (number tablets)
001	*Example ONLY:* Ruby Citizen	1	6	F	Y	+	3 Long Lane, Quiet Village, Big Island		2	1

6.2 CTS - Community Method: Form for recording testing in Community/Village

1. Country: _____
2. State/Region: _____
3. Name of Person performing the testing: _____
4. Village/Community Name:_____
5. Date: _____

ID	Name (List all known 5 year old children in the Community/Village)	Age	Gender (M or F)	ICT		If positive, record address of positive person	IF not tested, give reason	Treatment given	
				performed (Y/N)	result (+/-)			DEC (number tablets)	Albend. (number tablets)
021	*Example ONLY:* Danny Citizen	5	M	Y	-				

6.3 "Close Contact Testing": Form for recording the testing in the Community

1. Country: _____
   _____
2. State/Region: _____
   _____
3. Name of Person performing the testing: _____
   ___
4. Village/Community Name:_____
   _____
5. Date: _____

6. **Close Contact Record for : Name:**_____
   Address:_____
   (Name of "index" child for whom the testing is being done)
   (Address of "index" child for whom the testing is being done)
   (NOTE: a separate form must be started for each child for whom Close Contact Testing is being done.)

ID	Name of all Close Contacts (List ALL people in the "index" child's household and ALL their nearest neighbours)	Age	Gender (M or F)	Type of Contact: Household (HH) or Neighbour (N)	ICT		If positive, record address of positive person.	MF slide		IF not tested, give reason	Treatment given	
					performed (Y/N)	result (+/-)		performed (Y/N)	result (+/-)		DEC (number tablets)	Albend. =(number tablets)
031	*Example ONLY:* Paul Citizen	38	M	HH	Y	+	3 Long Lane, Quiet Village, Big Island	Y			8	1

Appendix 7: Test and Treatment Register

Test & Treatment Register - Insert Country Name **Year 1:**

Name	Sex	Age	Village & Island	Date of last ICT test	Date of Treatment				ICT Test		Remarks
					1	2	3	4	Date	Result	

Appendix 8: Patient leaflets and Drugs information

PATIENT CONSENT FORM

BACKGROUND

You have tested positive for the *Wuchereria bancrofti* (also called *W. bancrofti*) parasite worm, which causes the disease called lymphatic filariasis, or LF. The National Filariasis Elimination programme and your doctor would like to give you a single dose of Albendazole (400 mg) with Diethylcarbamazine Citrate (also called DEC) to treat your LF infection.

The adult worms that cause LF are 2-5 inches long very thin and live in the lymphatic vessels of the body. These worms are spread to humans by mosquitoes. These worms can live in the human body for 5-10 years. They can produce millions of tiny baby worms that can be found in the blood.

These worms can damage the lymphatic vessels that help balance the fluid in the body. This damage causes fluid to collect in the tissues. This can cause swelling in parts of the body like the arms and legs. Because the damage gets worse as long as the adult worms are alive, Albendazole and DEC are used to kill the worms.

WHO IS ELIGIBLE TO PARTICIPATE IN THIS TREATMENT PROGRAM?

Before knowing if you are eligible to participate in this treatment program, your doctor needs to know if you:

- Have ever been treated with Albendazole
- Have ever been treated with DEC
- Have any health problems
- Are pregnant

In order to be eligible to participate in this program you must:

- Test positive for infection with the parasite worm *Wuchereria bancrofti* (this test should have already be done)
- Not be pregnant or breast feeding
- Be older than two years of age
- Not have allergies to or have other reasons for not taking Albendazole
- Not have had past problems with taking Albendazole
- Not have allergies to or have other reasons for not taking DEC
- Not have had past problems with taking DEC

WHAT WILL HAPPEN TO ME DURING THIS PROGRAM?

If you meet the eligibility criteria, you will be given a single dose of Albendazole (one 400 mg Tablet) and DEC. You will be given a copy of this informed consent form to keep.
You may be asked to stay at the clinic for a while after receiving treatment for observation.

ARE THERE BENEFITS?

There is a good chance that the treatment provided will kill many of the adult worms. Although some people require only one dose of Albendazole and DEC, it is usually necessary to be treated more than once to ensure that all the adult worms have been killed. Taking these drugs helps prevent some of the long-term health effects from LF. If you have LF symptoms right now, they may get better. Also, the treatment will lower the chance that mosquitoes that bite you will give the worm to someone else.

ARE THERE RISKS?

Some patients who take Albendazole and DEC have side effects. These side effects can be worse if there are many of the tiny baby worms in the blood. For example, you could:

- Feel dizzy.
- Feel queasy or throw up.
- Get a fever and a headache.
- Feel weak.
- Have aches in your muscles or joints.

Also, about 40% of men with this worm get painful lumps in their scrotum. This is caused by death of the adult worm and should go away on its own.

WHAT IF I AM OR MIGHT BE/BECOME PREGNANT?

Please tell the doctor now, before starting treatment with Albendazole and DEC. In the normal treatment doses given for this worm, both Albendazole and DEC may not be safe for pregnant women.

WHAT HAPPENS IF I AM HARMED?

If you think that the Albendazole and DEC treatment given to you caused harm, please contact your doctor, Dr. _____ (print name). The doctor will see you or will refer you to another doctor to decide if you need care. WHO/PacELF and the Ministry of Health does not pay the expenses for people harmed from being in a program like this one. Being in this program does not change your legal rights.

VOLUNTARY PARTICIPATION

It is up to you to decide if you will get the single-dose Albendazole and DEC through this program. Even if you decide to take part, you can change your mind at any time and choose to not take the drugs. But, please know that the chance of getting better without treatment is very low.

WHAT ABOUT PRIVACY?

We will keep all information about you as private as the law allows. People who work for the Ministry of Health, WHO/PacELF may look at your records. Your name and personal information will not be used or listed in any report.

WHO CAN I CALL IF I (MY CHILD) HAVE PROBLEMS OR QUESTIONS?

If you have any questions about the program or if you think you got side effects or were harmed, please call your doctor, Dr. _____ (print name) at phone number _____. If you have questions about your rights as a participant in this program, please call **Dr Corinne Capuano** at the World Health Organization (WHO) office in Suva Fiji on **+679 3323346** Please leave a brief message with your name and phone number. Someone will return your call as soon as possible.

CONSENT STATEMENT

I have read the form or it has been read to me. I have been given a chance to ask questions and my questions have been answered. **I agree to take single-dose albendazole with DEC**.

Patient's name (print): _____ Date: _____

Patient's signature: _____

NOTE: If patient is unable to sign, legally authorized representative may sign.

Name: _____ Date: _____

Witness Signature

I _____(print name) observed the process of consent. The participant read this form, was given a chance to ask questions, appeared to accept the answers, and signed for treatment with single-dose DEC.

Witness signature: _____.

Translator Signature (If applicable)

I have translated this form into the _____language.

Translator's signature: _____ Date: _____

Translator's name (print): _____

Diethylcarbamazine Citrate (DEC)

Commonly used brand name(s): Hetrazan.

Category: Anthelmintic (systemic)

Indications

Accepted

- *Filariasis*, Bancroft's (treatment): Diethylcarbamazine is indicated as a primary agent in the treatment of Bancroft's filariasis caused by *Wuchereria bancrofti* .
- *Loiasis* (treatment): Diethylcarbamazine is indicated as a primary agent in the treatment of loiasis caused by *Loa loa* .
- *Onchocerciasis* (treatment): Diethylcarbamazine is indicated as a secondary agent in the curative treatment, given before and after suramin therapy, of onchocerciasis (river blindness) caused by *Onchocerca volvulus* .Ivermectin is considered to be the primary agent in the treatment of onchocerciasis.
- *Tropical eosinophilia* (treatment): Diethylcarbamazine is indicated as a primary agent in the treatment of tropical eosinophilia (eosinophilic lung; tropical pulmonary eosinophilia).

Unaccepted

Diethylcarbamazine has been used for the treatment of ascariasis. However, in the opinion of most experts, it has been superseded by newer, safer, and more effective anthelmintics.

Pharmacology/Pharmacokinetics

Mechanism of action/Effect:

- *Filariasis*, *loiasis*: Microfilaricidal and macrofilaricidal.
- *Onchocerciasis*: Microfilaricidal; diethylcarbamazine reduces the number of intrauterine Onchocerca volvulus microfilariae by inhibiting the rate of embryogenesis; this agent also increases the rate of loss of *O. volvulus* microfilariae from nematodes and nodules; diethylcarbamazine has no sterilizing effect on adult worms.

Absorption: Readily absorbed following oral administration.
Distribution: Widely distributed throughout all body compartments except adipose tissue.
Biotransformation: Partially metabolized to diethylcarbamazine N-oxide.
Half-life: Approximately 8 hours.
Time to peak serum concentration: 1 to 2 hours.
Peak serum concentration: 80 to 200 nanograms per ml after a single 50-mg dose.
Elimination:

- Renal: excreted in urine, largely unchanged and as N-oxide metabolite, within 48 hours.
- Fecal: Approximately 4 to 5% eliminated in feces.

Precautions to Consider

Pregnancy/Reproduction

Treatment of pregnant patients with diethylcarbamazine should be deferred until after delivery. However, problems in humans have not been documented.

Breast-feeding

It is not known whether diethylcarbamazine is distributed into breast milk. However, problems in humans have not been documented.

Pediatrics

Appropriate studies on the relationship of age to the effects of diethylcarbamazine have not been performed in the pediatric population. However, no pediatrics-specific problems have been documented to date.

Geriatrics

No information is available on the relationship of age to the effects of diethylcarbamazine in geriatric patients.

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate), not necessarily inclusive (» = major clinical significance).

Risk-benefit should be considered when the following medical problem exists : Hypersensitivity to diethylcarbamazine.

Note: In ocular onchocerciasis, prolonged administration of diethylcarbamazine may result in inflammation and subsequent degenerative changes in the optic disc and retina.

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):

For Bancroft's filariasis and loiasis

Microfilarial blood concentrations (may be required prior to and periodically during therapy with diethylcarbamazine; in loiasis, retinal hemorrhage and encephalopathy may occur with very high microfilarial blood concentrations).

For onchocerciasis

» Ophthalmologic examinations, including examinations for visual acuity, visual fields, and ophthalmoscopy (ophthalmologic examinations for visual acuity and visual fields may be required routinely prior to and periodically during therapy with diethylcarbamazine; slit-lamp examinations may be required prior to, periodically during, and following treatment with diethylcarbamazine to assess the number of intraocular microfilariae and adverse reactions such as iridocyclitis)

» Skin snips (may be required prior to and every 6 to 12 months following treatment with diethylcarbamazine to assess the number of intradermal microfilariae)

Side/Adverse Effects

Note: In heavily infected patients with onchocerciasis, severe reactions may occur following a single dose of diethylcarbamazine. The Mazzotti reaction, a complex, acute inflammatory response characterized by fever, tachycardia, hypotension, adenitis, and an ocular inflammatory response, usually results from the death of microfilariae. The intensity of the reaction depends on the dose and the microfilarial load. However, it is sometimes difficult to determine whether these reactions are caused by the death of microfilariae or by diethylcarbamazine itself. In very heavily

infected patients with loiasis, encephalopathy and retinal hemorrhage may occur following treatment with diethylcarbamazine.
The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate). Not necessarily inclusive:

Those indicating need for medical attention
Incidence more frequent
Itching and swelling of face, especially eyes
Incidence less frequent
Fever, lymphadenopathy (painful and tender glands in neck, armpits, or groin), skin rash
With prolonged use in onchocerciasis
Visual disturbances (loss of vision; night blindness; tunnel vision)

Those indicating need for medical attention only if they continue or are bothersome
Incidence more frequent
Arthralgia (joint pain), headache, malaise (unusual tiredness or weakness)
Incidence less frequent
Dizziness, nausea or vomiting

Patient Consultation
In providing consultation, consider emphasizing the following selected information (» = major clinical significance):
Before using this medication
» Conditions affecting use, especially:
Pregnancy: Treatment of pregnant patients should be deferred until after delivery. However, problems in humans have not been documented
Proper use of this medication: taking immediately after meals
» Compliance with full course of therapy; second course may be required in some patients
» Proper dosing
Missed dose: Taking as soon as possible; not taking if almost time for next dose; not doubling doses
» Proper storage
Precautions while using this medication
Checking with physician if no improvement within a few days

For river blindness
Regular visits to physician to check progress, as well as ophthalmologic examinations
» Caution if dizziness, loss of vision, night blindness, or tunnel vision occurs
Concurrent administration with systemic corticosteroids to reduce inflammatory response to death of microfilariae
Side/adverse effects
Signs of potential side effects, especially itching and swelling of face, particularly eyes; fever; lymphadenopathy; skin rash; and visual disturbances
General Dosing Information

Diethylcarbamazine should be taken immediately after meals.
Diethylcarbamazine should be administered with caution (e.g., gradually increasing doses) to prevent or minimize allergic reactions. Most side effects of Diethylcarbamazine are not serious and do not generally require discontinuation of therapy. However, it may be necessary to discontinue therapy if severe allergic reactions, in conjunction with skin rash, occur.
Patients who are more heavily infected may require more prolonged treatment.

For Bancroft's filariasis, loiasis, or onchocerciasis
In the acute and chronic stages of these infections, treatment should be continued for 2 to 4 weeks. Recurrences require retreatment.
In *Bancroft's filariasis, treatment* should preferably be given before irreparable damage is done to the lymphatic system and its valves.
In the *curative treatment of onchocerciasis*, diethylcarbamazine is administered before and after suramin therapy. Diethylcarbamazine is recommended in low initial doses concurrently with systemic corticosteroids to suppress the inflammatory response to the death of microfilariae caused by diethylcarbamazine, especially in moderate to heavy infections with ocular involvement.
In *severe onchocerciasis*, severe allergic reactions may develop following the administration of a single dose of diethylcarbamazine. Gradually increasing doses are recommended as follows: 25 mg daily, gradually increased to the usual maintenance dose over a period of 7 to 14 days. If very severe allergic reactions occur, Diethylcarbamazine should be discontinued and corticosteroids should be given. If severe allergic reactions occur again, diethylcarbamazine should not be used in these patients.
In the *suppressive treatment of onchocerciasis*, diethylcarbamazine is recommended in low, intermittent doses to preserve eyesight and to relieve pruritus by reducing the microfilarial load.

For treatment of adverse effects
Recommended treatment consists of the following:
Systemic corticosteroids for very severe allergic reactions.

Oral Dosage Forms: DIETHYLCARBAMAZINE CITRATE TABLETS USP
Usual adult dose
Bancroft's filariasis; or Loiasis; or Onchocerciasis
Oral, 2 to 3 mg per kg of body weight three times a day.
Tropical eosinophilia
Oral, 6 mg per kg of body weight once a day for four to seven days.
Usual adult prescribing limits
Onchocerciasis: Up to 9 mg per kg of body weight a day.
Tropical eosinophilia: up to 13 mg per kg of body weight a day.
Usual pediatric dose
Dosage has not been established in the treatment of Bancroft's filariasis, loiasis, onchocerciasis, or tropical eosinophilia. However, doses of 50 mg to 250 mg daily, based on the patient's age, have been used in children between the ages of 1 and 15 years of age.
Packaging and storage:

Store below 40 °C, preferably between 15 and 30 °C, unless otherwise specified by manufacturer. Store in a tight container.

Auxiliary labeling:

- Take immediately after meals.
- May cause dizziness or vision problems.
- Continue medication for full time of treatment.

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Albendazole (ALB)

PATIENT LEAFLET

Read all of this leaflet carefully before you start taking this medicine.
- ✓ Keep this leaflet. You may need to read it again.
- ✓ If you have further questions, please ask your doctor or your pharmacist.
- ✓ This medicine has been prescribed for you personally (or your child†), and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

† Only applicable if a parent or guardian is administering the medicine.

TITLE: ALBENDAZOLE
SCOPE
Trade Name(s) of the product: *ZENTEL*™
Formulation, strength and device * (*if appropriate)
Tablets:
Albendazole 400 mg chewable tablets.
Each tablet contains 400 mg albendazole.
The other ingredients are:
Tablet core:
Lactose
Maize starch
Polyvidone
Sodium lauryl sulphate
Sodium starch glycolate
Cellulose microcrystalline
Sodium saccharin
Magnesium stearate
Flavouring.

WHAT ALBENDAZOLE IS AND WHAT IT IS USED FOR

Albendazole is supplied to you as film coated tablets, to be taken by mouth. The tablets are provided in packs. Albendazole belongs to the benzimidazole carbamate class of anthelmintic and anti-parasitic compounds. Albendazole is used to treat a wide range of intestinal conditions caused by worms or parasites. Albendazole is effective against threadworm or pinworm, roundworm, Albendazole is also effective in a number of different systemic conditions caused by parasites including hydatid disease and neurocysticercosis.
Albendazole is thought to clear worms or parasites by causing them to starve and killing them. The eggs, larvae and adult parasites are all affected.

BEFORE YOU TAKE/USE ALBENDAZOLE

Do not take Albendazole
- ➢ if you are hypersensitive (allergic) to albendazole or any of the other ingredients, listed above
- ➢ if you know, or suspect you are pregnant, or intend to become pregnant.

Special warnings and precautions for use
Pregnancy
Tell your doctor before you start to take this medicine:
- if you are planning to become pregnant
- if you are pregnant or think you might be pregnant
- if you are breast-feeding.

Avoid taking Albendazole during early pregnancy, by starting the medication only during the first week of having your period or only after a negative pregnancy test. Tell your doctor if you become pregnant while taking Albendazole.
If you are unsure if you are pregnant, the doctor may wish to do a pregnancy test.
Pregnancy must be avoided (use effective contraception) while you take this medicine and for one month after you have stopped taking it.

Breast-feeding

Tell your doctor if you are breast-feeding or if you are planning to breast feed your baby. Your doctor will decide if this medicine is suitable for you.

Taking Albendazole with food and drink

Systemic helminth infections

Take your medicine with meals.

Intestinal infections and cutaneous larva migrans

Your medicine may be taken with or after a meal or on an empty stomach.

Driving and using machines

This medicine should not affect your ability to drive or operate machinery. However, be careful when driving or operating machinery until you know how you react to Albendazole.

Taking other medicines

You can generally continue to take other medicines while you are being treated with Albendazole except for praziquantel, another anthelmintic medicine.
Always tell your doctor or pharmacist which medicines you are taking, including those you have bought yourself.

HOW TO USE ALBENDAZOLE

Take Albendazole exactly as you have been prescribed. Read the direction label carefully. If you have any concerns about how to take this medicine talk to a doctor or a pharmacist.
Your doctor will advise how many tablets of Albendazole are needed each day, and for how long you will need to take Albendazole. The dose will depend on your weight or age, and the type and severity of your infection.
For intestinal infections, the usual dose for adults and children older than 2 years of age, is one Albendazole 400 mg tablets, once a day, for up to three days.
The usual dose for children 1 to 2 years of age, is one Albendazole 200 mg tablet once a day
Your tablets or suspension may be taken with or after a meal or on an empty stomach.
Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water, alternatively tablets may be crushed.
For other infections, the dose prescribed by your doctor may be different. You may also be told to take your medicine with meals.
You should take the full course of medicine, and not just stop when you feel better.
If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.
Follow your doctors instructions about how and when to take your medicine otherwise you will not fully benefit from your medicine. It is best to take the tablets or suspension at the same time each day.
Your doctor may need to see you two to three weeks after taking the prescribed dose or course. This is to make sure that Albendazole has worked. A second dose or course of Albendazole is sometimes needed.
Do not take more medicine than your doctor has recommended.

ONCE YOU HAVE STARTED USING ALBENDAZOLE

If you take more Albendazole than you should

If you take more Albendazole than you should, or if someone else has taken your medicine, tell a doctor or pharmacist immediately. Show them the package or bottle containing the

tablets or suspension. Do this even if there are no signs of discomfort or poisoning. There are unlikely to be any serious problems following an overdose of Albendazole.

If you forget to take Albendazole

Take your medicine as soon as you remember. Take your next dose at the usual time but do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

Like all medicines, Albendazole can have side effects.

Most side effects with Albendazole are mild, and usually disappear without having to stop taking Albendazole. However, some side effects may need medical treatment. If you develop any unusual discomfort tell your doctor as soon as possible.

Tell the doctor about any effect, which is troublesome or ongoing such as the following:

- headache or dizziness
- vomiting or feeling sick, stomach pains or diarrhoea
- itchiness.

Albendazole may cause an increase in liver enzyme levels in the blood so, if you or your child are having a blood test done, tell your doctor about the Albendazole treatment.

Stop taking Albendazole and contact a doctor immediately, or go to the emergency department of your nearest hospital, if you notice any of the following:

- swelling of limbs, face, mouth or throat
- shortness of breath or breathing difficulties
- skin rash. This could be severe, and widespread over your body, and you may experience blistering of the skin, mouth or eyes.

These maybe signs of a severe skin or allergic reaction. Albendazole rarely causes these side effects..

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING ALBENDAZOLE

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the pack.

Store in the original package.

Do not store above 25°C.

If your doctor stops your medicine, do not keep any leftover medicine unless your doctor tells you to. Return any unused medicine to your pharmacist who will discard it safely.

Appendix 9. Data Analysis: A Summary of *PICTs LF Elimination Program Data 1999 - June 2007*