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Cook Islands Program for the Elimination of Lymphatic Filariasis 2013-2014

1. Transmission Assessment Survey (TAS)

Background

Lymphatic filariasis (LF) is a parasitic disease transmitted by mosquitoes that can cause significant morbidity in humans. In 1997, the World Health Assembly resolved to eliminate lymphatic filariasis (LF) as a public health problem by the year 2020. Shortly thereafter, the Pacific Program for the Elimination of Lymphatic Filariasis (PacELF) was established to eliminate the disease in the Pacific Region in 1999. After the recent regional Neglected Tropical Diseases meeting in May 2011, a commitment to LF elimination was refined with a goal of 10 countries achieving elimination by 2016 and the remaining 12 by 2020.

Objectives

1) To assess prevalence of LF, whether it is lower than a level where transmission can no longer be sustained in Rarotonga, Mangaia, Atiu, Mauke, Manihiki, Rakahanga, Penrhyn and Palmeston islands.
2) To assess whether LF transmission has been ceased and sustained in other 9 islands
3) To provide anti-LF treatment for any LF antigenemia positive cases

Methods

This survey will follow current WHO guidelines for LF program evaluation (WHO, 2011) but will be adapted to the country situation accordingly.

Survey Timeline

The team will conduct the survey between March and June in 2014.

Survey Area

The evaluation units (EU) for the survey are Rarotonga, Mangaia, Atiu, Mauke, Manihiki, Rakahanga, Penrhyn and Palmeston.

Sample size and Sampling

For Rarotonga the team will conduct the survey targeting all students from grade 1 and 2 (those who were born after the initiation of the first MDA) in primary schools. Also all residents on Mangaia, Atiu, Mauke, Manihiki, Rakahanga, Penrhyn and Palmeston islands who are older than 2 year old up to 80 years old will be tested due to their small population sizes and the history of being hot spots.

For other 9 inhabited islands, as the school attendance rate in Cook Islands is higher than 75%, the survey will be conducted in primary schools. Every grade 1 and grade 2 students will be targeted in primary schools in these islands. Data in 2011 census showed there are 1,506 children in the age group of 5-9 therefore it is estimated that around 550 students enrolled in grade 1 and grade 2 in primary schools in 8 island.

Site Selection

The names of all primary schools in each island will be listed and provided to the surveyors.

Critical Cutoff Criteria and follow up strategy

To have the proportion of antigenemia positive participants tested is no more than 1%, the number of positive participants should not be above the critical cutoff value, which is defined to be the first integer less than 0.01*totals sample size obtained. For example, if there are a total of 600 primary and secondary graders in 9 inhabited islands' elementary schools and all of them are tested, then the critical cut off 0.01*600=6>5. If the number of positive participants is not above the critical cutoff value, we can conclude that there is no endemicity in the EU or transmission has been ceased in the EU.
All positive individuals will be treated annually and be followed up by ICT test after at least 6 months from treatment.

Data collection

All data will be collected and managed in a computer. Only survey staff and LF program coordinators will have access to personal identifiers. Information will be kept private as allowed by law. Personal identifiers will not appear in any reports that come from this survey. The data will be collected by the survey teams that are trained in blood collection and using ICT cards and include nurses/laboratory technicians/health workers to obtain blood and provide medication if needed.

Blood Collection and Examination

The student will be provided with the information session on the disease itself, objective of the survey, and the procedure of blood collection before they are requested to proceed.

The survey will utilize the Immunochromatographic Card Test (Binax, Scarborough, ME), which has been shown to be a useful and sensitive tool for the detection of *W. bancrofti* antigen. Prior to using the cards, 2 ICT cards from each Lot will be tested with filarial antigen to ensure that the sensitivity has remained high during shipment and storage. Outlines of the procedure for testing the cards with the filarial antigen will be provided to the surveyors.

A total of 0.1ml (100µl) of blood will be collected into a capillary tube from each participant using a finger prick with a lancet and will be placed directly onto an ICT card. The cards will be read exactly at 10 minutes and marked as either positive or negative according to manufacturer's instructions. Detailed instructions from the manufacturer on how to interpret the results will be provided to the surveyors. The cards will be kept for the duration of the survey in a secure place for quality control purposes and disposed at the end of the survey.

If a participant has a positive ICT test result, tablets of albendazole and DEC against *W. bancrofti* will be given to him/her. The surveyors will be provided on how to administer the tablets including dosages.

Blood Collection Protocol:

1. Clean the finger to be pricked with an alcohol swab.
2. Allow the finger to dry.
3. Prick the internal side of the finger using a sterile lancet
4. Discard the lancet into a sharp's container.
5. Collect blood into a calibrated capillary tube according to the needs of each test as outlined below.

Blood Collection for Antigen Test Using ICT Binax Cards:

1. The ICT card is labeled with the participant's unique ID.
2. The blood sample (100µl) is taken directly from the participant's finger and collected using an EDTA-coated, 100µl calibrated capillary tube.
3. The blood is then placed on the test kit card, as stated by manufacturer.
4. The results of each test will be read and recorded according to manufacturer's instructions. Test results will be shared with each tested subject.
5. The cards will not be discarded but will be packed and kept in a secure place for quality control purposes until the end of the survey.

Supply List

The following list of supplies will need to be procured to complete the survey:

- ICT Filarial antigen card kits (Binax)
- Lancets
- Cotton
- Alcohol swabs
- Gloves
- Biohazard waste and Sharps disposal container
- Trash bags
- Pens/pencils
- Clipboards
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Data Entry, Management, and Analysis Software

All data will be entered into a data management system (Excel or Epidata). All survey participants will be assigned a unique identification number. Data analysis will be conducted by LF program coordinator. Analysis may be carried out by sex and sub-

geographical areas to detect any specific LF focus. The Departments of Public Health will keep all personal identifying information at their respective office. Data will be appropriately archived with the National Program for Elimination of Lymphatic Filariasis to allow for easy retrieval if needed at later stages of the program.

Roles and Responsibilities

The National Program for Elimination of Lymphatic Filariasis will direct this survey. All data will remain the property of the National Program for Elimination of Lymphatic Filariasis and the Public Health Departments.

Ethical Considerations

This study presents low risk to the participants. The finger stick for blood draw is of minimal risk, but may result in anxiety and discomfort, and rarely, infection or bleeding for some individuals. Results of testing will be kept confidential and only shared with the study participant. If the results of the survey do not warrant another MDA, participants who are ICT positive will be followed up and appropriately treated according to the LF treatment guidelines. Any unanticipated problems involving risks to subjects or others will be reported immediately to the Public Health Department in accordance with institutional policies and will be referred to the nearest health facilities for medical care if needed.

Informed Consent

Written informed consent will be obtained from the participant or his/her parent or guardian. In addition, verbal assent will be sought prior to testing. A sample written consent is provided (Appendix 2). This form will be translated into the local language(s) accordingly.

Justification for Designation as Non-Research

The purpose of the surveys is to assist LF elimination programs with the collection of data to make critical programmatic decisions, i.e., whether to resume MDA or continue surveillance or the country can be classified as non-endemic. We believe that these activities constitute a public health evaluation and not research. Our belief is based on the following points:

1) Survey is recommended in order to make a decision to stop MDA or not to resume MDA.

2) The proposed work is an evaluation of on-going activities of a public health program.

3) This evaluation will assist the program in decision-making about the final steps in the filariasis elimination program.

1. Budget Proposal 2014 – 2015 (US Dollars)

	Activities	**Amount US$**
1	Personal Daily perdiume ($50.00/day) Subtotal	 $5000.00
2	Supplies/Stationeries/Freight Subtotal	 $3000.00
3	Travel from Rarotonga to all of the outer islands Fare (Mangaia/Atiu/Mauke/Manihiki/Rakahanga/Penrhyn Subtotal	 $10000.00
4	Accommodation Subtotal	 $5000.00
5	Cost of dissemination of results Subtotal	 $2000.00
6	Venue hire Subtotal	 $2500.00
7	Miscellaneous expenses Subtotal	 $2500.00
8	**Grand total**	**$30,000.00**

2. Cook Islands - TAS Estimation of ICT for 2014

	Island	Population	ICT required	Albendazole	DEC
A	**Primary School/Year 5-9**			**100**	**1000**
1	**Rarotonga**				
	Nikao School	15	25		
	Papaaroa School	22	25		
	Rutaki School	8	25		
	Arorangi School	30	50		
	Titikaveka School	14	25		
	Takitumu School	16	25		
	Avarua Scool	122	150		
	Avatea School	68	100		
	Total	**295**	**425**	**100**	**1000**
B	**Whole island**				
2	Mangaia	573	575		
3	Atiu	481	475		
4	Mauke-	307	300		
5	Penrhyn	203	200		
6	Rakahanga	77	75		
7	Palmeston	60	75		
8	Manihiki	243	250		
	Total	**1996**	**2375**	**200**	**2000**

Thank you maata

Mr. Charlie Ave
Cook Islands Lf Program Manager