



The Neglected Tropical Diseases Trust Fund for Latin America and the Caribbean

Monitoring and Evaluation Guidelines for Projects Funded by the NTD Trust Fund

Prepared by the Mapping, Surveillance and Monitoring and Evaluation
Working Group

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List of abbreviations

BSU	Basic sampling unit
CRS	Clustered random sampling
DALY	Disability-adjusted life years
ELISA	Enzyme-linked immunosorbent assay
Global Network	The Global Network for Neglected Tropical Diseases
Hb	Hemoglobin
HIS	Health information systems
ICT	Immunochromatographic test
IDB	The Inter American Development Bank
KAP	Knowledge, attitudes and practices
LAC	Latin America and the Caribbean
M&E	Monitoring and Evaluation
MDA	Mass Drug Administration
NTDs	The Neglected Tropical Diseases and certain other neglected infectious diseases
PAHO	The Pan American Health Organization
PBPS	Population-based prevalence survey
PCT	Preventive Chemotherapy
PPS	Probability proportional to size
SAEs	Severe adverse reactions
SI	Sampling interval
SSU	Second stage sampling unit
STH	Soil-Transmitted Helminthiasis
TF	Trachomatous inflammation, follicular
TI	Trachomatous inflammation, intense
TT	Trachomatous trichiasis
UIG	Ultimate intervention goal
WHO	The World Health Organization
WISC	Wechsler Intelligence Scale for Children

1. Executive summary

Neglected Tropical Diseases (NTDs) have a debilitating effect on social and economic development. They cause chronic illness and disabling or disfiguring sequelae which can lower worker productivity, decrease wage-earning capacity, cause stigma and create an extra burden on already strained health systems. Recognizing the achievability of elimination and control of NTDs in the Americas, the Global Network, IDB and PAHO have entered into a partnership to establish an initiative to provide technical and financial support for the control and elimination of NTDs in Latin American and the Caribbean. The partnership has developed criteria for proposals including robust monitoring and evaluation (M&E) guidelines for projects supported by the Initiative. In this document we set out these M&E guidelines, presenting the specific data, information and tools that the Initiative requires of its projects for inclusion in their M&E plans and focusing in this initial stage on the 'tool ready' NTDs - those that can be effectively targeted by preventive chemotherapy (PCT) and other proven public health interventions. For lymphatic filariasis and onchocerciasis, we refer users of the guidelines to the relevant WHO guidelines. For trachoma, STH and schistosomiasis, we depart slightly from the standard guidelines, partly in order to encourage more epidemiological rigor in the evaluation assessments, and partly because the Initiative wishes for its projects to target all vulnerable groups including pre-school age children, a group that are often left out of previous published guidelines. This document also sets out the methodological requirements and defines the indicators for monitoring and evaluation, and provides a number of bibliographies and annexes for further guidance on such issues as methodologies for multi-stage cluster sampling, designing and implementing knowledge attitudes and practices (KAP) surveys and developing process indicators for integrated NTD control programs and project-specific indicators of behavior change.

2. Purpose and Use of the Guidelines

At the global level Neglected Tropical Disease (NTD) programs are growing rapidly in number based on the increasing recognition of the enormous public health burden that these diseases represent as well as the availability of inexpensive or donated drugs and low cost delivery strategies (\$0.05 - \$0.75 per person per year). According to analyses carried out by the Disease Control Priorities Project, for example, preventive chemotherapy for intestinal helminthiasis (PCT) is the single most cost-effective public health intervention, making NTD programs the “best buy” in public health.¹ Within the Americas, NTDs are an especially attractive target for public health programs because several of them are candidates for elimination at the country or regional level. To develop NTD programs within the region, the Inter American Development Bank (IDB), the Pan American Health Organization (PAHO) and the Global Network for Neglected Tropical Diseases (Global Network) have formed a partnership to establish an Initiative for NTDs in Latin America and the Caribbean (LAC) that will include a Trust Fund to support the development of integrated approaches to control and eliminate NTDs within the region.

To facilitate the development and implementation of NTD programs with support from an NTD Trust Fund, the partnership has developed criteria for proposals and a transparent review mechanism to guarantee that the distribution of resources will be fair and equitable. As part of this process, it is also important to establish robust monitoring and evaluation (M&E) guidelines for projects supported by the Trust Fund in order to document that they are providing the anticipated public health benefit, both in terms of the populations reached and the impact on health outcomes. This information is critical for maintaining donor support and a flow of resources into the Trust Fund and to demonstrate with evidence, to the partners and governments, that it is possible to implement interventions with measurable impacts. This in turn will encourage governments to extend the measures beyond the funding of the Trust Fund and sustainably incorporate NTDs within their national strategies.

These guidelines are aimed at those individuals involved in developing proposals for funding for the initiative and for those who would be in charge of the baseline mapping and M&E activities in such projects. In developing these M&E guidelines for the NTD Trust Fund, we have relied on disease-specific World Health Organization (WHO) guidelines where available. These guidelines are summarized in tables in this document and links are provided to the original WHO publications as an additional source of reference material. In some cases, we have supplied enhanced or more stringent guidelines where these were appropriate to support the Trust Fund objectives. However, the partners are aware that considerable extra costs may be incurred by programs in meeting these more demanding requirements, compared with complying with the WHO guidelines. Therefore, the Initiative is willing to allocate additional resources (financial, technical support etc,) to successful applicants to cover the extra cost of upholding these high standards.

For the present, this document focuses on what are often referred to as the ‘tool ready’ NTDs, those that can be effectively targeted by preventive chemotherapy (PCT) and other proven public health interventions; however, as the NTD Initiative matures and expands its portfolio of projects in future

¹ (Jamison et al. 2006)

years – and as new monitoring tools become available - we expect the document to expand to incorporate recommendations specific to other NTDs such as Chagas disease and leishmaniasis.

For more information, including templates for project M&E plans and for data reporting, project managers should contact the LAC NTD Initiative's M&E working group.

3. Background

3.1. Regional NTD Burden

The Neglected Tropical Diseases and certain other neglected infectious diseases (which will be referred to as NTDs) are a sub-set of infectious diseases which disproportionately affect poor and marginalized groups and contribute to people's inability to escape the downward spiral of poverty. In this way, NTDs exacerbate existing disparities in health both between and within countries. However, PCT to combat the five most prevalent NTDs is among the most cost-effective global health interventions, in terms of cost per disability-adjusted life years (DALYs) averted. It has been estimated that the economic rates of return on controlling the NTDs are in the order of 15-30%.² It is thought that in LAC, hundreds of millions of people are at risk of certain NTD infections such as Soil-transmitted Helminthiasis (STH). The NTDs caused an estimated 1,220,000 DALYs lost in LAC in 2002, accounting for 1.5 percent of the total burden of disease for countries in the region. In terms of mortality, the disease group contributed around 20,000 deaths in LAC in that same year, accounting for 0.8 percent of total deaths.³ In its *Global Plan to Combat Neglected Tropical Diseases 2008-2015*, the WHO singles out 14 NTDs as the initial focus for intensified elimination and control efforts.⁴ In addition, each of the WHO's regional offices is developing its own complementary list of NTDs of regional epidemiological significance. Under the approach of PAHO – the regional office for the Americas – outlined in resolution CD49.R19 (2009), the NTDs of regional importance to LAC are divided into two groups according to their potential for elimination:⁵

Group 1-Towards elimination: Those diseases that have the greatest potential for being eliminated from LAC using existing, cost-effective interventions. For several such diseases, elimination is defined as a reduction to zero in the incidence of transmission, including:

- Onchocerciasis (river-blindness)
- Human rabies transmitted by dogs
- Malaria - elimination of transmission in Hispaniola and in Mexico and Central America

For other group 1 diseases, elimination as a public health problem is the goal:⁶

- Chagas' disease (elimination of transmission by vector and by blood-transfusion)
- Congenital syphilis
- Lymphatic filariasis (LF)
- Neonatal tetanus

² (Perera et al. 2007)

³ (Bitran et al. 2009), (Bitrán et al. 2009)

⁴ Along with "other zoonoses" (World Health Organization 2007a)

⁵ (Pan American Health Organization 2009b)

⁶ The exact definition of "elimination as a public health problem" varies by disease.

- Trachoma
- Leprosy (at the national and first subnational level)
- Plague

Group 2 - Drastic reduction of the burden: Those diseases for which the burden can be reduced drastically using available tools are:

- Schistosomiasis
- STH

For other infectious diseases, such as leishmaniasis and leptospirosis, the burden in LAC needs to be further assessed, tools need to be developed, and methods and strategies for achieving cost-effective control need to be established. For these diseases and for others that have epidemiological relevance to some of the region's countries, more operational research needs to be conducted, new tools need to be assessed, and surveillance systems need to be improved, mainly in terms of the current technical capacity in the region's research centers.

NTDs have a debilitating effect on social and economic development. They cause chronic illness and disabling or disfiguring sequelae which can lower worker productivity, decrease wage-earning capacity, cause stigma and create an extra burden on already strained health systems. In addition, several NTDs impede physical and mental development in children, causing severe anemia, organ damage, and blindness and increase the chances of poor birth outcomes and maternal morbidity. There is overwhelming evidence that a reduction in the incidence of parasitic infections not only improves children's health (by reducing diarrhea and anemia) but also significantly increases cognitive development, school participation and adult welfare.⁷ In fact, while in other regions such as Sub-Saharan Africa, the NTDs exhibit widespread endemicity and considerable geographical overlap, in LAC, the distribution of many NTDs is highly focalized in ecological niches with unique conditions conducive to the survival and transmission of the infectious agents.⁸ Eleven such sub-regions or "hotspots" have been identified (see Table 1), all of which are characterized by the poor housing and lack of access to water and basic sanitation of their populations. Consequently, social and economic factors further entrench the NTD burden within these foci. Furthermore, the diseases "...predominantly affect people of African descent and indigenous groups, as well as other vulnerable groups such as women and children."⁹ The presence of certain diseases in the region has been partially attributed to a "legacy of slavery",¹⁰ as at least 3 of the present-day tropical diseases within the LAC region arrived by means of the Atlantic slave trade.¹¹ Today, in areas with populations of predominantly African descent, especially in the Caribbean, Central America and Brazil, the NTD burden remains particularly high. In more rural areas, especially in Bolivia, Colombia, Ecuador, Guatemala, Mexico and Peru – home to 80% of the region's indigenous citizens – elevated NTD rates also prevail.

⁷ (Cattaneo et al. 2007)

⁸ (Hotez et al. 2008)

⁹ (Hohlfelder 2008)

¹⁰ (Lammie et al.)

¹¹ These being onchocerciasis, lymphatic filariasis and schistosomiasis (Hotez 2008)

A preliminary study that analyzed the situation of 10 selected neglected diseases in the region, found that in every LAC country at least one NTD is present. The most prevalent is STH with an estimated 26 million school-age children at risk (and large numbers of individuals in other risk groups such as pre-school age children and pregnant women), followed by schistosomiasis (36 million at risk) and lymphatic filariasis (8.9 million). The study also concluded that there is a considerable amount of information available for most of the neglected diseases, although additional baseline studies that use standardized criteria are still needed;¹² mapping or re-mapping of some NTDs is also needed. Although no gender-sensitive research has been conducted, some studies point out that women suffer a higher burden of NTDs. The cultural distribution of work and duties result in a higher prevalence due to a greater exposure to risk factors, barriers in access to health care or preventive services result in increased severity of the disease, while stigma and discrimination often impact more on women.¹³ More information is needed on how NTDs differentially affect other vulnerable populations.

In September 2009, the PAHO 49th Annual Directing Council meeting, PAHO Member States approved the first ever resolution to address NTDs in the Americas. The resolution clearly demonstrates that political will and leadership on integrated NTD control and elimination is building in the Americas. PAHO Member States have now pledged to strengthen ongoing efforts to eliminate LF, onchocerciasis and trachoma, as well as reduce the burden of schistosomiasis and STH by the year 2015.

3.2. Description of the Aims of the Partnership

Recognizing the achievability of elimination and control of NTDs in the Americas, the Global Network, IDB and PAHO have entered into a partnership to establish an initiative to provide technical and financial support for the control and elimination of NTDs in LAC. The aim of this partnership is to support projects that employ an integrated, community-based methodology that goes beyond short-term curative measures such as MDA of PCT, to include longer-term solutions that tackle the social and environmental determinants of disease transmission and contribute to the strengthening of epidemiological surveillance and health systems. The partnership aims to coordinate and support country ownership and capacity building to address the burden of NTDs in the region. Targeted at national governments, national NTD programs, and non-governmental organizations (NGOs), the partnership aims to promote the integration of NTD prevention, control and elimination activities into existing systems and efforts, such as primary care, clean water and improved sanitation initiatives, conditional cash transfer programs and housing initiatives. It will act as a regional hub to facilitate the development of an NTD agenda for LAC, while developing priorities for integrated disease control, project implementation, advocacy and resource mobilization. Priorities include a collaborative effort to address the treatment gap for pre-school age and school-age children in need of PCT in the Americas, as well as targeted regional elimination efforts for certain NTDs.

¹² (Pan American Health Organization 2009a)

¹³ (Velez et al. 2001), (Hartigan 2001), (Courtright and West 2004)

Table 1: Summary of global and regional burden of NTDs¹⁴

		NTDs										
		Parasitic diseases							Bacterial diseases		Viral disease	
		Helminthiases				Protozoan parasites						
		Soil-transmitted helminthiases	Vector-transmitted ¹⁵					Leishmaniasis		Trachoma ¹⁶	Leprosy	Dog-transmitted Rabies
			Schisto-somiasis	Lymphatic filariasis	Oncho-cerciasis	Chagas Disease	Visceral					
Distribution		Widespread	Focal	Focal	Focal	Widespread	Focal	Focal	Focal	Widespread	Focal	
Global strategy		Control	Control	Elimination	Elimination	Control	Control	Control	Elimination	Elimination	Elimination ¹⁷	
Global burden ¹⁸	Cases (000s)	807,000	207,000	120,000	ND	ND	ND		84,000	ND	55	
	DALYs (000s)	1,600-22,100	4,500	5,800	500	667	2,100		2,300	200	ND	
	Incidence of morbidity (000s)	ND	5,733	1,564	38	217	534	1,157	437	175	55	
	Prevalence of morbidity (000s)	59,999	248,248	38,137	349	10,137	1,508	1,257	2,936	903	NA	
	Deaths (000s)	9	15	0	0	14	51		0	6	55	
	Cases (000s)	50,000-100,000	1,800	720	ND ¹⁹	9,000 ²⁰	5	62	1,100	47,612	0.01	
LAC burden	DALYs (000s)	124.8-1,923	36	34.8	2 ²¹	662	44		23.2	18	ND	
	Population at risk (000s)	345,000-523,000	25,000 ²²	8,900	529 ²³	25,000-90,000	ND		50,000	ND	94,850	
	% infected	8.9%-17.8%	0.3%	0.1%	<0.1%	1.6%	ND		<0.1%	<0.1%	NA	
	% of poor infected	23.5%-46.9%	0.8%	0.3%	<0.1%	4.1%	ND		<0.1%	<0.1%	NA	
	% of global burden in LAC	8.7%-16.6%	0.9%	0.6%	0.3%	99.8%	ND		1.31% ²⁴	11.40%	NA	
	Sub-region	Southern Cone	-	-	-	-	✓	✓		✓ ²⁵	-	✓
		Chaco	✓	-	-	-	✓	✓		-	-	✓
		Andean Region	✓	-	-	-	✓	✓		-	-	✓
		Amazonian Basin	✓	✓ ²⁶	-	✓	✓	✓		✓	✓	✓
		Eastern Brazil	✓	✓	✓	-	✓	✓		✓	✓	-
		N. Pacific of S. America	✓	-	-	✓	-	✓		-	-	-
		Caribbean Basin	✓	✓	✓	-	-	-		-	✓	✓
		Central America	✓	-	-	✓	✓	✓		-	-	✓
		S. and Central Mexico	✓	-	-	✓	✓	✓		✓	-	✓
Northern Mexico	✓	-	-	-	✓	✓		-	-	-		

¹⁴ Data taken from (Hotez et al. 2008)and (Mathers, Ezzati, and Lopez)unless otherwise stated. ND = No data.

¹⁵ Technically, schistosomiasis is not a vector-transmitted disease as it does not transmit the parasite directly to the subsequent hosts; however the schistosome parasite does rely on the snail to complete its lifecycle. (Hotez et al. 2008)

¹⁶ Sub regional distribution comes from (Pan American Health Organization 2009a)

¹⁷ Elimination is the strategy for the Americas

¹⁸ "Cases" refers to population currently infected. For onchocerciasis and trachoma, prevalence and incidence of morbidity refer to blindness only, for lymphatic filariasis, they refer to hydrocele

¹⁹ 64 new cases of onchocerciasis in 2004 (Hotez et al. 2008)

²⁰ (Remme et al. 2006)

²¹ (World Health Organization 2004)

²² (Pan American Health Organization 2009a)

²³ (OEPA)

²⁴ Calculations by IDB staff

²⁵ Trachoma present in Southern Brazil (Pan American Health Organization 2009a)

²⁶ (Pan American Health Organization 2009a)

Table 2: Approaches to NTD control in LAC

		Trichuriasis	Ascariasis	Hookworm infection	Schisto-somiasis	Lymphatic filariasis ²⁷	Oncho-cerciasis ²⁸	Chagas Disease ²⁹	Leish-maniasis ³⁰	Trachoma ³¹	Leprosy ³²
Mass Drug Administration³³	Albendazole	✓	✓	✓	-	✓	-	-	-	-	-
	Mebendazole	✓	✓	✓	-	-	-	-	-	-	-
	Diethylcarbamazine	-	-	-	-	✓	-	-	-	-	-
	Ivermectin	(✓)	(✓)	-	-	- ³⁴	✓	-	-	-	-
	Praziquantel	-	-	-	✓	-	-	-	-	-	-
	Levamisole	(✓) ³⁵	✓	✓	-	-	-	-	-	-	-
	Pyrantel	(✓)	✓	✓	-	-	-	-	-	-	-
	Azithromycin	-	-	-	-	-	-	-	-	✓ ³⁶	-
Transmission control	Vector control/integrated vector management	-	-	-	✓	✓	- ³⁷	✓	✓	-	-
	Individual case treatment and morbidity management	-	-	-	✓	✓	✓	✓	✓	✓	✓
	Housing Improvements ³⁸	✓	✓	✓	-	✓ ³⁹	-	✓ ⁴⁰	✓	-	-
	Water/Sanitation Improvements ⁴¹	✓	✓	✓	✓	✓	-	-	-	✓	-
	Animal reservoir control	-	-	-	-	-	-	✓	✓	-	-
	Health education for behavior change	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Improved case detection and management		-	-	-	-	-	-	✓	✓	✓	✓
Drug resistance monitoring		No information					-	-	-	-	✓

²⁷ (Remme et al. 2006)

²⁸ (Remme et al. 2006)

²⁹ (Remme et al. 2006)

³⁰ (Cattand et al. 2006)

³¹ (World Health Organization 2006a)

³² (Remme et al. 2006)

³³ (✓) indicates drugs that are not recommended for treatment but that have a (suboptimal) effect against the disease (World Health Organization 2006a)

³⁴ Ivermectin is only used for lymphatic filariasis control in situations where the disease is co-endemic with onchocerciasis. There are no such situations in LAC.

³⁵ Limited effect except when used in combination with Oxantel

³⁶ Tetracycline is to be used for infants under 12months and for pregnant women.

³⁷ Vector control for onchocerciasis control is carried out in Africa but not in LAC.

³⁸ (Cattaneo et al. 2007)

³⁹ Screens, closed doors, closed eaves

⁴⁰ (Campbell-Lendrum et al. 2007)

⁴¹ (Cattaneo et al. 2007)

Table 3: Key features of methodologies for mapping geographical areas in which may need interventions for the tool-ready NTDs in LAC

		Onchocerciasis		Lymphatic filariasis	Trachoma	Schisto- somiasis	STH
Administrative level		Village	Village or sentinel community	Implementation Unit	District or community	Community	District or Community
Mapping	Baseline	Prevalence of infection	<ul style="list-style-type: none"> • Skin snip (microfilaremia) • Serology, • Presence of nodules or ocular affections • Infectivity rate in black flies 	<ul style="list-style-type: none"> • Prevalence of infection (microfilaremia or antigenemia) • Density of microfilaremia • Prevalence of clinical manifestations (lymphedema and hydrocele) 	Prevalence of TF and TT	Prevalence and intensity of infection	Prevalence and intensity of infection
	Follow up						
Tested population	Baseline	Adults (≥ 15 years)	<ul style="list-style-type: none"> • Children under 5 years (serology and presence of nodules), • Adults ≥10 years old (ocular affections) • At least 10,000 female black flies 	School age children (5-14 years) and adults (≥15 years old)	Children (1-9 years old) for TF and adults (≥15 years old) for TT	School age children (5 to 14 years)	Pre-school age children (1-4 years old) and School age children (5 to 14 years)
	Follow up	Population at risk aged ≥ 1					
Procedure	Baseline	Skin snip (microfilaria)	Skin snip (microfilaria)	Blood test (microfilaremia or antigen detection -ICT)	Eye exam (TF/TI/TT)	Stool exam, serology (ELISA), CCA Antigen	Stool exam
	Follow up		<ul style="list-style-type: none"> • PCR for DNA of black flies • ELISA for antibodies against OV16 				

	Onchocerciasis		Lymphatic filariasis	Trachoma	Schisto- somiasis	STH
Threshold for starting MDA	Evidence of transmission	NA	≥1% prevalence of infection	≥10% TF among 1-9 year old children at district and community level	≥10% prevalence	≥20% prevalence
Criteria for stopping MDA	0% infection	Less than 1 infective fly/2,000 flies tested	<1% prevalence of infection	< 5% TF among 1-9 year old children at community level	<10% prevalence	<20% prevalence
Existing guidelines⁴²	(World Health Organization 2000) <ul style="list-style-type: none"> ○ English ○ Español 		(World Health Organization 2005), (World Health Organization Forthcoming)	(World Health Organization 2006b)	(World Health Organization 2006a)	

⁴² The existing publication for lymphatic filariasis, Trachoma, Schistosomiasis and STH are being revised by the WHO. The Trust Fund Monitoring and Evaluation guidelines will be updated when this happens.

4. Guidelines for M&E of projects supported by the LAC NTD Initiative

In the remainder of the document, we set out the specific data, information and tools that the Initiative requires of its projects for inclusion in their M&E plan.

4.1. Mapping and Baseline Data

4.1.1. Demographic and Socioeconomic Data

Part of the rationale for the development of NTD programs is based on an understanding that the poorest populations are disproportionately affected by these diseases (see Table 1) and that NTDs contribute to the cycle of poverty by inducing disability and affecting growth and cognitive development. In addition, in LAC, lymphatic filariasis, onchocerciasis and schistosomiasis represent a living legacy of the slave trade, continuing to exact a toll on Afro-descendant and marginalized populations. The NTD Trust Fund was established with the aim of assisting countries in providing equitable access to health interventions and to help redress these historical grievances. Consequently, we consider it important that project proposals present information on the socioeconomic status of program beneficiaries. In most cases, government data will be adequate for describing the characteristics of the target population. In particular, proposals should present the most up to date data available and disaggregated to the lowest administrative level possible relating to the following indicators (subnational data at the first or second administrative level -e.g. departmental and municipal - will be preferable, but where unavailable, national level data will suffice):

- **Demographic data:** size of target population (by age groups, sex, urban/rural etc.), fertility and mortality indicators, life expectancy at birth, and years of life lost to communicable diseases
- **Socioeconomic indicators:** These may include the population or proportion of population living below the poverty line; gross national income per capita; adult literacy rate; net primary school enrolment ratio (disaggregated for males and females); population with sustainable access to improved drinking water source (total, rural, urban); population with sustainable access to improved sanitation (total, rural, urban)
- **Morbidity and mortality statistics:** Deaths reported, hospitalization, outpatient treatments, rates of malnutrition, anemia etc.
- **Data on schools (proposals for school-based MDA only,):** Size of school-age population; Number of schools and teachers by administrative unit and ecological zone included in the project; school enrollment rates; number and size of schools in implementation area; Number of teachers; school calendar.

Proposals should also provide information on health system capacity, resources and coverage in the target area, where such data is available. These may include such indicators as:

- **Infrastructure**
 - The existence of health centers and posts in the targeted areas
 - The availability of essential equipment and drugs for basic diagnostics, treatment and referral at the Primary Care level
 - The existence of laboratories and reference laboratories for diagnosis and diagnostic quality control
 - The existence of health education resources – training and health education materials available or in use in schools/MDA distribution points etc.
- **Routine surveillance:**
 - Description of the national and local surveillance system with respect to targeted diseases
 - The level of disaggregation of routinely reported data (e.g. by geographical level, population group etc.)
 - Whether, according to national policy, the NTDs are of compulsory notification, and if so with what frequency.

Proposals must state clear and complete information about any control and elimination activities that are being or have been carried out for the diseases in question over the last three years, whether by the national programs themselves, or by non-governmental entities. This should include the timing and coverage achieved by these interventions where this information is available. Furthermore, proposals for support for MDA activities should also report on other mass, population-based public health activities (such as vaccination campaigns, child health weeks etc.) that might serve as potential distribution channels with which to integrate NTD activities. Finally, opportunities for social mobilization should be considered and presented, such as information about the possibility of mass media advertising campaigns.

4.1.2. Baseline Disease Burden Data

All projects under the initiative will be required to conduct baseline surveys to determine the burden of the disease in question (in terms of prevalence and intensity of infection etc.) in the intervention area prior to the project's implementation. It may be possible to make exceptions to this in cases where such assessments have already been carried out so recently as to make it unnecessarily costly to repeat the exercise. Existing disease burden data may be used as a baseline as long as it is recent and meets certain requirements and if a document can be provided that fully explains the methodology by which the data was obtained. These exceptions will be judged on a case by case basis. All other proposals, however, must clearly indicate the methodology by which they will carry out the mapping and baseline assessment of disease prevalence.

4.1.2.1. Lymphatic filariasis and Onchocerciasis

For those diseases for which mapping and baseline are already complete, it will be necessary to present the most detailed and up-to-date information available. For example in the Americas, the mapping of lymphatic filariasis and onchocerciasis is close to completion; consequently proposals seeking support

for elimination efforts targeting these diseases should submit information from annual reports to WHO, including maps, the size of the at risk population, assessments of baseline infection levels in sentinel sites, and current infection levels if known. A summary of existing mapping guidelines is provided in Table 3 along with links to the appropriate WHO reference documents. The guidelines for LF are in the process of being updated by the WHO and will be published some time in 2011. Until this happens, proposals for LF control and elimination projects should consult the existing guidelines (2005), and applicants should make contact with members of the LAC NTD Initiative M&E working group for an overview of the main changes between the 2005 and 2011 editions.

Regarding lymphatic filariasis, there are a number of diagnostic tests for identifying infected individuals. The M&E Working Group strongly recommends using the ICT (Immunochromatographic test cards) antigen detection technique in order to determine the prevalence of LF. The alternative microfilaremia test using night-blood surveys can be used in addition to confirm the diagnosis of individuals that test positive by the ICT method, and to measure the density of microfilaria among infected individuals. However, due to its lack of sensitivity and greater logistical demands, it is recommended that night-blood surveys only be used as the principal screening method in situations where it is not possible to procure ICT cards in a timely manner. WHO guidelines do recommend monitoring of microfilaremia in sentinel sites to document program impact and as a precursor to surveys to stop MDA.

4.1.2.2. Trachoma

The four components of the WHO-endorsed and globally agreed strategy for trachoma elimination – the ‘SAFE’ strategy – are: **S**urgery to correct trichiasis (TT); treatment with **A**ntibiotics to treat ocular Chlamydia infection using either mass drug administration (MDA) or the family/individual approach; the promotion of **F**acial cleanliness and personal hygiene to reduce transmission; and **E**nvironmental improvements to reduce incidence by interrupting the cycle of infection.⁴³ In keeping with the Trust Fund’s commitment to an integrated approach to tackling NTDs, proposals for trachoma projects submitted to the fund must address each of these four components. Applications will not be accepted unless they propose interventions in the ‘F’ and ‘E’ components as well as the ‘S’ and ‘A’.

The Global WHO Program for the Elimination of Blinding Trachoma has developed rigorous guidelines for defining the distribution of infections as well as the baseline prevalence within targeted communities. These guidelines should serve as the basis for any funding request for mapping or implementation activities targeting trachoma. According to these guidelines, the burden of trachoma is to be measured by determining the prevalence of follicular trachoma (TF) in children aged 1-9. Therefore, for baseline and follow-up prevalence assessments, samples must be defined in such a way as to make it possible to estimate prevalence in the 1-9 year age group to an acceptable degree of certainty (even if the target population includes a wider age range). This is to ensure the comparability of estimates across different settings. The prevalence of Trachomatous trichiasis (TT) in persons aged 15 and over should also be assessed and reported although a lower level of precision for this estimate will

⁴³ (Bitran et al. 2009), (Bitrán et al. 2009)

be tolerated and is to be expected given that it is a rarer manifestation.⁴⁴ This is an important indicator because TT is a more stringent sign of risk of blindness or visual impairment and its prevalence can be used to determine the need for surgical services and as a proxy indicator for the awareness of patients regarding the importance of seeking timely care.⁴⁵

The WHO recommends estimating prevalence of active trachoma at implementation unit level, meaning the district or municipality – the second subnational level corresponding to administrative units with populations of around 100,000. Given the highly focalized distribution of trachoma in LAC, even within endemic municipalities, we expect proposals to present a strategy for assessing prevalence at *community*-level (the third subnational administrative level or similar) in known trachoma hotspots.

The “gold standard” method for reliably estimating the burden of trachoma is the cross-sectional population-based prevalence surveys (PBPS) with clustered random sample (CRS) design. An outline of the protocol for conducting such an assessment is presented in annex 2. Alternative tools exist for determining whether a given community is endemic for trachoma (the Trachoma Rapid Assessment tools – TRA) and for classifying communities as high or low prevalence. These have been designed to aid operational decision-making in resource-limited settings and are not based on probabilistic sampling. The NTD Trust Fund partners have therefore decided that all trachoma projects financed under the fund must propose the measurement of baseline prevalence and of impact based on PBPS with CRS and preferably, probability proportional to cluster size (PPS). Alternative methodologies may be used during monitoring activities to determine whether a given community continues to be eligible for treatment, but for baseline and impact assessments, proposals must commit to the more rigorous methodology. The proposed sampling methodologies should take into account an estimated design-effect of 4-5 for active trachoma and 1.5-2 for trichiasis. The Ultimate Intervention Goal (UIG) of Trachoma according to the WHO is TF prevalence of lower than 5% and all TT cases having been either operated on or approached with an offer of surgery. As the implementation unit reaches the UIG, programs need to start planning for surveillance. A relevant WHO guideline manual for carrying out the surveillance is currently being finalized for publication in the first quarter of 2011.

4.1.2.3. *STH and schistosomiasis*

The WHO has published numerous guidelines dealing with the monitoring and evaluation of soil-transmitted helminthiasis and schistosomiasis.⁴⁶ Methods for the rapid assessment of infection prevalence at community level are laid out in these guidelines and are based on convenience sampling of 250 school-children per administrative region or ecologic zone. However, the assumptions underlying the rapid assessment methodology are that the conservation of resources is to be prioritized over statistical precision. The aim of the rapid assessment is to provide an approximation of the burden of disease in resource-limited settings for programmatic purposes – to inform decision-makers regarding the optimum treatment schedule for the community under assessment. The NTD Trust Fund partners have taken the decision to demand higher standards of epidemiological rigor in the surveillance of STH

⁴⁴ (World Health Organization 2006b)

⁴⁵ (World Health Organization 2006b)

⁴⁶ (Montresor et al. 1998), (Montresor et al. 1999), (Montresor et al. 2002), (World Health Organization 2006a), (World Health Organization 2007b), (World Health Organization 2010), (World Health Organization Forthcoming)

and schistosomiasis and in the monitoring and evaluation of projects funded. In this way the activities of the Trust Fund can contribute reliable and valid data toward the overall mapping of STH and schistosomiasis prevalence within the region. To this end, proposals for STH and schistosomiasis will be judged, in part, according to the quality and epidemiological rigor of the baseline mapping methodology that they propose. As previously mentioned in section 1, successful applicants will receive additional resources, commensurate with upholding these high standards.

Prevalence assessments at baseline and at follow-up should be based on probabilistic sampling methodologies, using either simple random sampling (in the case of small-scale projects where a sample frame is available and resources permit) or, as with Trachoma, a cross-sectional population- or school-based prevalence surveys with CRS and preferably PPS. A list of publications in which this procedure is described is included in annex 1 and an outline of the protocol for sampling is presented in annex 2. Separate samples must be taken from each ecologically homogenous zone within the implementation area. Parallel sampling should be used when separate estimates are needed from different groups.⁴⁷

4.2. Project Monitoring and Evaluation

All projects should include a plan for monitoring the processes and performance of the program and evaluating its impact. Recognizing the significant costs associated in most cases with measurements of program impact, existing WHO guidelines should be used as the basis for these evaluations; however, for programs targeting STH and schistosomiasis, more scrupulous follow-up is recommended, using the survey methodology described above in paragraph 4.1.2.3. In addition, the Trust Fund partners are interested in supporting operational research in parallel with project implementation to evaluate the impact of NTD treatment in broader societal terms. To this end, we have set out the following criteria, by which applications to the Trust Fund will be judged. We are prepared to commit additional resources – technical support and data collection tools as well as financial resources - to projects that meet these standards in order that they may be upheld. It is our hope that data collected during these projects will contribute towards building a clearer picture of the distribution of the diseases in the LAC region.

⁴⁷ (Davis et al.)

Table 4: Indicators for project evaluation for STH and schistosomiasis.

Data on performance indicators should be recorded and reported following each round of MDA, while epidemiological and other impact indicators should be assessed at baseline, every 2-3 years and at the end of the project.

	Indicator	Numerator	Denominator	Required by Fund
Performance indicators	Program coverage	Number of individuals in area treated by Preventive Chemotherapy (PCT) program	Total number of individuals targeted for treatment with PCT in that area	Yes
	Epidemiological coverage	Number of individuals in area treated by PCT program	Total number of individuals at risk of the disease in that area	Only when reliable data on population at risk is available
	Geographical coverage	Number of endemic administrative units where PCT is implemented	Total number of endemic administrative units that need PCT	Only for national or state-level projects
	School coverage	Number of schools where PCT was delivered	Number of schools, where PCT is needed, in implementation area	Only for school-based PCT
	Coverage of health education/ health promotion activities	Number of schools/classes/ communities where at least one activity was carried out	Number of schools/classes/ communities in the implementation area	No
Epidemiological impact indicators	Cumulative prevalence STH	Number of individuals infected with <u>any</u> species of STH	Number of individuals screened	Yes
	Prevalence of STH by species	(For each helminth species X) Number of individuals infected with X	Number of individuals screened	Yes
	Prevalence of schistosome infection	Number of individuals with schistosome infection	Number of individuals screened	Yes
	Overall prevalence of heavy intensity ⁴⁸ STH infections	Number of individuals with heavy intensity infections with any species of STH	Number of individuals screened	Yes

⁴⁸ For definitions of heavy intensity infections by helminths species, see annex 2.

	Prevalence of heavy intensity infections for each species of STH	Number of individuals with heavy intensity infection with STH species X	Number of individuals screened	Yes
	Prevalence of heavy intensity schistosome infection	Number of individuals with heavy intensity schistosome infection	Number of individuals screened	Yes
Additional impact indicators	Prevalence of stunting	Number of individuals with low height-for-age	Number of individuals assessed	No
	Prevalence of anemia	Number of individuals with Hb <11g/dl	Number of individuals assessed	No
	School participation	Average number of children present on any given day	Number of children enrolled	No
	School performance	-	-	No
	Cognitive function	WISC-III test score	Total number of children assessed	No
	Psychomotor development	-	-	No
	Knowledge, attitudes and practices	-	-	Yes
	Behavioral indicators	-	-	No
Other indicators	Assessment of drug efficacy	-	-	No
	Presence and use of latrines	-	-	No

Table 5: Indicators for project evaluation for Trachoma⁴⁹

	Indicator	Numerator	Denominator	Required by Fund
Performance indicators	Program coverage of surgical intervention ('S' component)	Number of individuals with TT receiving corrective surgery	Number of individuals identified with TT in implementation area	Yes
	Geographic program coverage of surgical intervention	Number of implementation units in which active TT case finding and referral are being carried out	Number of implementation units indicated for inclusion in the program	Yes
	Program coverage of MDA ('A' component)	Number of individuals in area treated by MDA program	Total number of individuals targeted for treatment with MDA in that area	Yes
	Epidemiological coverage of MDA	Number of individuals in area treated by MDA program	Total number of individuals at risk of the disease in that area	Yes
	Geographic program coverage of MDA	Number of endemic communities where MDA is implemented	Total number of endemic communities identified as needing MDA	Yes
	Geographic program coverage of facial cleanliness promotion ('F' component)	Number of endemic communities where facial cleanliness promotion is implemented	Total number of endemic communities identified as needing facial cleanliness promotion	Yes
	Geographic program coverage of environmental improvement interventions ('E' component)	Number of endemic communities where environmental improvement interventions are implemented	Total number of endemic communities identified as needing environmental improvement interventions	Yes
	Cumulative geographic program coverage of A, F and E components	Number of endemic communities where A, F and E components are implemented	Total number of endemic communities identified as requiring A, F and E components	Yes
Epidemiological indicators	Prevalence of TF in children aged 1-9	Number of individuals positive for TF	Total number of individuals aged 1-9 examined for TF	Yes
	Prevalence of TT in persons aged 15 or over	Number of individuals positive for TT	Total number of individuals aged 15 or over examined for TT	Yes

⁴⁹ Taken from (World Health Organization 2006b). TT = Trachomatous trichiasis, a sign of active trachoma. MDA = Mass Drug Administration.

4.2.1. Performance indicators:

Performance indicators are those that are used to assess whether coverage of the program has reached its objective.⁵⁰ Data on performance indicators should be recorded and reported following each round of MDA. Drug coverage is the minimum indicator for assessing and comparing program performance and is common to all programs implementing MDA.⁵¹ Data on coverage must be recorded by direct observation at the point where the drug is ingested by the individual (i.e. the person recording the data must witness the pill being swallowed. This is usually the case in school-based PCT projects where the teacher or school nurse administers the antihelminthic medication and records the event at the same time.) This information should be collected on tally sheets or forms that record the numbers and ages of the persons treated; examples are available in the annexes of the WHO manual Preventive Chemotherapy in Human Helminthiasis.⁵² Reported coverage should be verified independently at least once during the proposed project using a rapid assessment survey.

Monitoring and evaluation systems must report program coverage, geographical coverage and the epidemiological coverage of MDA at each round of treatment. These three indicators are defined as follows:⁵³

4.2.1.1. Program coverage:

The program coverage of a given administrative area is defined as follows:

$$= \frac{\text{Number of individuals in that area treated by PCT program}}{\text{Total number of individuals targeted for treatment by PCT program in that area}} \times 100$$

This represents the proportion of individuals that the program originally expected to reach through the proposed distribution channels that go on to receive treatment as a result of the program. This indicator will be used to monitor and evaluate the effectiveness of the program.

4.2.1.2. Epidemiological coverage:

The epidemiological coverage of a given administrative area is defined as follows:

$$= \frac{\text{Number of individuals in that area treated by PCT program}}{\text{Total number of individuals at risk of the disease in that area}} \times 100$$

This represents the proportion of all members of the particular risk group selected for intervention in the implementation area (regardless of whether they are accessible through the selected distribution channel) that go on to ingest a drug. For example, in a school-based PCT program, the denominator for the program coverage indicator would be the number of children enrolled in schools in the implementation area, whereas for epidemiological coverage, it would be the number of children of school-age (regardless of enrollment status) in the area. Wherever possible, population data should be

⁵⁰ (World Health Organization Forthcoming)

⁵¹ (World Health Organization 2007b)

⁵² (World Health Organization 2006a)

⁵³ (World Health Organization 2007b), (World Health Organization 2010)

updated at each assessment to ensure that the denominator reflects the true population at risk. National programs should report epidemiological coverage at country level.⁵⁴

4.2.1.3. *Geographical coverage:*

The geographical coverage of a program is defined as follows:

$$\frac{\text{Number of endemic administrative units where PCT is implemented}}{\text{Total number of endemic administrative units in the country that need PCT}} \times 100$$

This represents the proportion of endemic districts/administrative units covered with PCT. This is a measure of the completeness of program coverage of administrative entities (such as villages, districts, provinces, and country) where the population-at-risk of the disease resides.

4.2.2. *Treatment costs*

As noted above, maintaining donor support is critical for the development and growth of NTD projects across LAC. An important component of guaranteeing donor support is the appropriate documentation of the cost-effectiveness of the interventions. While detailed cost-benefit analyses would be too costly to incorporate as a standard feature of most projects, such analyses are of interest and would be favorably considered for support. On the other hand, all projects are expected to collect basic data on the cost of the intervention, relative to the number of persons treated. We would encourage all applicants to propose reporting a complete breakdown of program costs to enable subsequent *ex-post* cost-effectiveness analysis of the program. For guidelines on the analysis of costs in primary health care see:

- Creese, Andrew, and David Parker. 1994. Cost analysis in primary health care. Geneva: World Health Organization.

4.2.3. *Epidemiological impact/results indicators:*

Coverage is a process indicator and may not be used as a proxy indicator of impact. The impact of an MDA program must be evaluated by the effect of the program on parasitological, serological or clinical indicators, as appropriate. Currently recommended approaches for monitoring are summarized in Table 3.

Both the prevalence and the intensity of STH/schistosomiasis infections must be reported and assessed at intervals of two to three years and immediately prior to the carrying out of the MDA campaign in those years. Infection intensity should be calculated as the prevalence of infections in each of three classes of intensity (light, moderate and heavy) according to the thresholds based on egg count per gram established by the WHO (see annex 5).⁵⁵ Intensity may also be reported as the mean egg count in the sample as a supplementary indicator. Both prevalence and intensity of infection in the sample must be presented both as cumulative measures (for any worm) and disaggregated by species. Both STH and

⁵⁴ Equivalent to the “national coverage” indicator presented in (World Health Organization 2010)

⁵⁵ (Montresor et al. 1998)

schistosomiasis infections should be diagnosed using the Kato Katz technique although projects that propose using alternative, laboratory-based methods may be accepted if these methods have been adequately validated. Appropriate quality control measures should be carried out to assure consistency of microscopic results.

Follow-up prevalence surveys to determine the impact on epidemiological indicators for STH and/or schistosomiasis (parasitological) and for Trachoma (ophthalmological – TT and TF prevalence) at the end of the program should be based on the same probabilistic sampling methodologies required of baseline assessments. If it is possible for the project to repeat the baseline assessment in the same sample of schools, communities etc for the follow-up assessments so that they might serve as “sentinel sites” to provide longitudinal data, then this is to be encouraged. For trachoma, as with for STH/schistosomiasis, 2-3 years must be allowed to elapse between assessments of prevalence, in order to ensure sufficient time to observe a detectable impact. For the evaluation of LF and onchocerciasis activities, proposals should adhere to the published guidelines listed in table 3.

Between the initial baseline assessment and the final impact evaluation, it is likely to be necessary to monitor the progress of the intervention on based on epidemiological indicators. The forthcoming WHO guidelines on deworming school-age children outlines a low-cost and practical methodology for obtaining parasitological data from “sentinel sites” for monitoring for programmatic purposes.⁵⁶ These guidelines may be followed for MDA programs targeting school-age children through schools, in which cases, the sentinel sites will be schools. If the program is targeting other groups, such as pre-SACs, other methods of monitoring the progress in those groups will need to be specified. The guidelines also give suggestions of threshold prevalence levels for reducing the frequency of MDA distribution. The LAC NTD Initiative endorses these suggestions - which may also be extrapolated to programs targeting other age groups for deworming (e.g. Pre-SACs) - as a strategy for scaling-down long-running, successful programs as long as they are applied following a 5-6 year period of regular, uninterrupted and high coverage (>75%) MDA campaigns (preferably accompanied by improvements in water and sanitation). Until these guidelines are made public, applicants should consult the NTD Initiative’s M&E working group for details of these suggestions.

4.2.4. Other required indicators:

Data on any severe adverse reactions (SAEs) to medication experienced by recipients should be recorded as well as reported to the national regulatory authority and the pharmaceutical company. A standard form for the reporting of SAEs is available from the WHO,⁵⁷ or can be provided by the IDB.

In at least a sub-sample of the individuals sampled for assessment, data on knowledge, attitudes and practices (KAP) relating to the diseases and their risk factors should be collected. The IDB is developing standard KAP questionnaires for this purpose.

⁵⁶ (World Health Organization Forthcoming)

⁵⁷ (World Health Organization 2006a)

Depending on the situation and the diseases existing in each target population, it will be necessary to specify the kind of indicators that will be used for monitoring changes in behaviors. This will be particularly relevant for projects that contain a health education or social mobilization component. In such cases, the specific choice of indicators used for monitoring and evaluating behavioral change will depend on the particular objectives of the strategy set out in the proposal and the actions to be implemented by the project. For an example of how to develop behavioral change indicators based on the objectives of a project, see annex 4. Collecting data for monitoring behavior change is not always straightforward. In many cases it will not be possible to observe the behavior in question (for example hand washing), in which case it may be necessary to identify proxy indicators that are observable such as whether there is soap and a place to wash near the toilet and where food is prepared.⁵⁸ Applicants are advised to consult the following publications:

- Favin, M and others. *Improving Health through Behavior Change: A Process Guide on Hygiene Promotion*. Washington DC: Environmental Health Project / Pan American Health Organization / United States Agency for International Development, 2004.
- Parks, W, and L Lloyd. *Planning Social Mobilization and Communication for Dengue Prevention and Control*. Geneva: World Health Organization, 2004.

4.2.5. Additional indicators

The following indicators are not required. However, proposals that include any of these in their M&E plans will be viewed favorably and given special consideration:

4.2.5.1. Process indicators:

Process indicators are those that are used to determine whether organizational elements of the program are in place and are functioning properly.⁵⁹ These will vary according to the design of the intervention but for MDA programs, they might include the following:⁶⁰

Indicators for monitoring the efficiency of drug procurement and management

- Drug quality – whether a drug of appropriate quality (as determined by a quality control report) was received at least 2 years before the expiration date
- Drug procurement – the proportion of the total drugs needed that were subsequently received. Target 100%
- Drug distribution at peripheral units – the proportion of drug distribution posts (e.g. schools) established by the program that receive the drug supply in time and in appropriate quantity for the drug administration
- Drug storage – Proportion of tablets procured that expire in the central storage facility. Target of <5%.

⁵⁸ (Favin, Nalmoll, and Sherburne 2004)

⁵⁹ (World Health Organization Forthcoming)

⁶⁰ Adapted from (World Health Organization Forthcoming)

Indicators for monitoring the distribution of supporting material

- Presence of supporting material (e.g. Tablet pole or weighing scales for praziquantel administration, reporting forms, health education materials, training materials etc.) – Proportion of implementation units or distribution posts receiving supporting material in time and in appropriate quantity for the campaign

Indicators for monitoring the adequate training of drug distributors

- Number of distributor training sessions
- Number of distributors trained
- Adequacy of training (can be determined using questionnaires conducted pre- and post-training)

In addition it will be important to allow for the reporting of any information that is obtained about the community acceptability of the project (a topic that could be addressed using KAP surveys, see annex 1 for publications on this). For a list of suggested process indicators for PCT programs and for integrated NTD programs see annex 3.

4.2.5.2. Additional indicators of impact/results:

Although not a requirement, preference will be given to those proposals that intend to evaluate the impact of PCT on the morbidity or other negative outcomes associated with STH and schistosomiasis infection. However, the timeframe proposed for measuring these indicators may vary, but should take into account the fact that the impact of MDA on NTD morbidity usually takes several years. Such indicators may include:

- Nutritional indicators – Anemia, stunting, mid-upper arm circumference, appetite etc.
- Cognitive function and psychomotor development-test results.
- Measures of school attendance and test/exam performance
- Frequency of symptoms such as stomach ache or diarrhea

4.2.5.3. Health education/health promotion activities:

Coverage of health education and health promotion activities aimed at reducing the risk of transmission of NTDs can be measured at the level of the community (i.e. geographical coverage – the proportion of targeted communities or schools in which an activity took place). Attendance of health promotion activities may also be reported. The impact of health promotion activities should be measured using a KAP survey.

4.2.6. Monitoring and evaluation for integrated NTD programs

Applications for projects that propose an integrated approach to more than one NTD in co-endemic areas should present an integrated approach to monitoring and evaluation. For guidance on the process for developing integrated monitoring and evaluation tools for multiple NTDs, applicants should consult the WHO's forthcoming *Manual on Approaches to Integrated Control of Neglected Tropical Diseases*.⁶¹

⁶¹ (World Health Organization 2010)

4.2.7. Evaluation of health information system strengthening

Applicants are encouraged to consider how the project will strengthen health information systems (HIS) and discuss how project results will be used to influence government policy and how this will be assessed *ex-post*. Each proposal shall include a strategy for the strengthening of HIS through epidemiological surveys, regular reports of MDA, coverage of interventions and others activities that are relevant to the needs of each administrative level - health care institutions, municipalities, states/departments/provinces, nation, international - and that allow for the disaggregation of information by age, sex, ethnic groups, rural and urban areas etc. In addition, it is likely to be necessary to include the strengthening of human resources not only for the gathering of data but also, to consolidate, analyze and disseminate the information to present to decision-makers and the wider public health community. This is an important requirement for promoting integrated and inter-programmatic approaches to NTDs.

Proposals should present a methodology for collecting and analyzing the correlation between socioeconomic variables and the prevalence of NTDs and for defining the socio-economic indicators to be monitored and evaluated during project implementation. It will be important to demonstrate how the intersectoral approach to the coordination of the work will be incorporated in the context of the proposal.

The Trust Fund is committed to supporting proposals that include strategies and actions to strengthen HIS at local as well as national level. This issue is important for guaranteeing the process of M&E. In the absence of a strong information system it is possible that data relating to baseline prevalence, health services, surveillance etc, will not be available for ensuring the production, analysis, dissemination and use of reliable and timely information on NTDs. Strong HISs are also necessary for monitoring and evaluating progress towards objectives presented in integrated plans for NTDs.

Some actions to strengthen the HIS include:⁶²

1. Strengthening personnel capacity, skills and procedures and acquiring appropriate equipment to facilitate or improve the generation of data
2. Compiling, analyzing or synthesizing these data into strategic information
3. Using, disseminating and communicating health information

Data relating to NTDs may include such topics as:

- Surveillance systems: prevalence and incidence by age group, gender, ethnic group, area (rural or urban), administrative level, etc.
- Drug coverage and supply systems
- Interventions for control and elimination. Morbidity management
- Demographic and socio-economic indicators
- Environmental information
- Health services delivery

⁶² (The Global Fund to Fight AIDS, TB and Malaria 2009)

4.2.8. Evaluation of data generation and reporting capacity

1. Number of staff members trained in M&E (per level)⁶³

Capacity-building through training health personnel in M&E enables trained individuals to generate relevant high-quality data, analyze them and use these data to improve program planning and decision-making, thus improving health systems and health status. This indicator therefore provides information on the pool of staff members whose capacity is being built in M&E.

$$\frac{\text{Number of staff / volunteers trained in M\&E}}{\text{Total number of staff who are working in M\&E}} \times 100$$

“Training” here refers to in-service training programs for current M&E officers or staff members with M&E responsibilities to refresh skills and knowledge or add new material and examples of best practice needed to fulfill their current or emerging M&E responsibilities. The training can occur through structured learning and follow-up activities or through less structured means to solve problems or fill identified performance gaps. It can consist of short non-degree technical courses in academic or in other settings, non-academic seminars, workshops, on-the-job learning experiences, observational study tours or distance-learning exercises or interventions.

2. Number and percentage of health institutions or volunteers using standard data collection formats according to national/subnational guidelines

The indicator measures the number of health institutions or volunteers with standardized data collection tools. This includes manual primary source documents and registers, data collection and reporting formats and both manual and electronic databases for data collection.

$$\frac{\text{Number of health facilities with mechanisms and tools for data collection and analysis}}{\text{Total number of health facilities providing NTD services in unit of implementation}} \times 100$$

3. Number and percentage of unit of implementation submitting timely, complete and accurate reports to their corresponding administrative level

National and subnational programs managing the national plan to NTDs need accurate program information on a timely basis from all facilities. By tracking this indicator, national and subnational programs will be able to identify health facilities that may need support to report accurately and on time.

$$\frac{\text{Number of implementation units with timely, complete and accurate reporting of key data}}{\text{Total number of implementation units}} \times 100$$

⁶³ (The Global Fund to Fight AIDS, TB and Malaria 2009)

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Annex 1: List of publications

On multi-stage cluster sampling

- Bennett, S, T Woods, W M Liyanage, and D L Smith. 1991. "A simplified general method for cluster-sample surveys of health in developing countries." *World Health Statistics Quarterly*. Rapport Trimestriel De Statistiques Sanitaires Mondiales 44 (3): 98-106.
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On Knowledge, Attitudes and Practices Surveys

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On monitoring behavior change

- Favin, Michael, Gail Naimoli, and Lisa Sherburne. 2004. *Improving Health through Behaviour Change: A Process Guide on Hygiene Promotion*. Environmental Health Project/Pan American Health Organization/United States Agency for International Development, August.
- Parks, W, and L Lloyd. 2004. *Planning Social Mobilization and Communication for Dengue Prevention and Control*. Geneva: World Health Organization. <http://apps.who.int/tdr/svc/publications/training-guideline-publications/planning-social-mobilization-dengue-fever>.

Annex 2: Summary of protocol for multi-stage cluster sampling for assessing disease prevalence

Usually, in large-scale prevalence assessments, it is unfeasible to draw a simple random sample from the whole study population because a sampling frame may be unavailable or because the population is dispersed over too large an area. A solution to this problem is to use a multi-stage sample that takes advantage of existing groupings or “clusters” within the population (such as villages, school-districts etc.). Using this method it’s possible to derive a prevalence estimate of comparable accuracy as with simple random sampling, in a way that is not prohibitively demanding in terms of costs and time.

The following is a basic protocol for selecting a self-weighting, multi-stage sample by the equal probability selection method. It deals with two stage samples, though the method may be adapted for additional stages. For a more detailed methodology, applicants are advised to see the publications listed in annex 1. According to the methodology presented here, clusters are sampled with probability proportional to their population size. This ensures that each individual in the study area has a known probability of being included in the sample, and therefore that prevalence of the disease can be estimated to a known degree of precision. This methodology assumes that it is possible to obtain a reliable sampling frame giving the population size (or relative population size) of each primary sampling unit. In situations where a sampling frame of this kind not available, other methods will need to be employed. Table 6 defines the key concepts referred to in this protocol as they apply to the NTDs, for which baseline mapping will need to be carried out.

Table 6: Definitions of sampling units for STH, schistosomiasis and trachoma

	STH and schistosomiasis		Trachoma
	School-based	Community-based	
Level of prevalence estimate/ study area	Ecological zone	Ecological zone	District / municipality
Primary sampling unit/cluster	School district / municipality	Community	Community
Second stage unit	School	Household	Household
Basic sampling unit	<ul style="list-style-type: none"> School aged children (5-14) 	<ul style="list-style-type: none"> School age children Pre-school age children (1-4) 	<ul style="list-style-type: none"> Children (TF) aged 1-9 Adults aged 15+ (TT)

The steps for selecting the sample are as follows:

Step 1: Determine the required size of the sample and the number of clusters in the study design based on:

- The available resources
- The estimated prevalence of the disease
- The desired level of precision of the estimate
- The design effect

The decision regarding the number of clusters to be selected and the number of SSUs sampled from each will affect the precision of the estimate. Estimates made from a survey will be more precise with larger samples. However, for the same overall total sample size, an assessment in which a large number of clusters are selected with few units selected from each will give more precise estimates than one in which a larger number of units are selected in each of a smaller number of clusters. For example, a survey in which 300 individuals are screened will give more precise results than one in which 200 are screened, but if the 300 individuals are distributed as 50 clusters of size six, they will give better estimates than if they were distributed as 30 clusters of size 10. However, more clusters will lead to increases in travel costs, time and administration.

Step 2: Obtain a sampling frame that lists the number of second stage units (SSUs) - the population size - in every cluster in the study area (e.g. a list of households in the community, a list of schools in the district). Suppose we were to select the clusters using simple random sampling and then select an equal number of SSUs from each one, also by simple random sampling. This would mean that SSUs from clusters with fewer SSUs would be more likely to be selected than those in larger clusters. The sample would not be “self-weighting”. For it to be self-weighting we would need every BSU in the study population to have an equal chance of being included in the sample. In order to make the sample self-weighting with probability proportional to the size of the cluster, we must take the following steps:

Create a list of the cumulative population sizes of the clusters. “Population size” here does not refer to the entire population but to the size of the particular risk group for whom the prevalence estimate is to be determined (defined by age, sex or school-enrolment status etc.), in other words, the total number of potential basic sampling units (BSUs) in the cluster.

Example:

Table 7: Sampling frame with example

Primary sampling unit/cluster	Population size	Cumulative population size	Example		
			Community	Population aged 5-14	Cumulative population size
1	A	A	1	1,000	1,000
2	B	A+B	2	400	1,400
3	C	A+B+C	3	200	1,600
4	D	A+B+C+D	4	300	1,900
5	E	A+B+C+D+E	5	1,200	3,100
6	F	A+B+C+D+E+F	6	1,000	4,100
7	G	T=(A+B+C+D+E+F+G)	7	700	4,800

Step 3: Divide the total population of all the clusters (T) by the number of clusters to be selected to obtain the sampling interval (SI)

Example: If three clusters are needed for the sample, $SI = (4,800 \div 3) = 1,600$.

Step 4: Generate a random number (R) between 1 and the SI.. A random number can be generated by typing the following formula into a cell in an Excel spreadsheet =randbetween(1,1600).

Example: $R = 1,218$

Step 5: Identify the first cluster to be included in the sample by fitting R into its position in the list of cumulative population size i.e. select the cluster that contains the Rth individual.

Example: 1,218 lies between 1,000 and 1,400, therefore cluster 2 contains the Rth individual and is therefore the first cluster to be included.

Step 6: Add the SI to R and fit it into its position in the list of cumulative population size (in the same way as step 3) to select the second cluster to be included in the sample i.e. select the cluster that contains the (SI + R)th individual.

Example: $1,600 + 1,218 = 2,818$. Therefore (SI + R) lies between 1,900 and 3,100 and so cluster 5 contains the (SI + R)th individual and is the second cluster to be included in the sample.

Step 7: Add the SI again to select the next cluster – the one that contains the c individual.

Example: $2,818 + 1,600 = 4,418$. Therefore $((SI + R) + SI)$ lies between 4,100 and 4,800 and so cluster 7 contains the $((SI + R) + SI)$ and is the third cluster to be included in the sample.

Step 8+: Keep adding the SI and selecting the corresponding cluster (repeat step 5), until the desired number of clusters is obtained.

Step 9: Select the second-stage sampling units. Using the sampling frames for the selected clusters, choose the same number of SSUs from within each cluster by simple random sampling. Assessors will then visit every randomly selected SSU and screen every BSU in each until the desired number of BSUs for the cluster is obtained. The same number of BSUs should be screened from each cluster.

Annex 3: Suggested Process indicators for integrated NTD control programs⁶⁴

Planning

- Coordination/steering committee formed and operational
- Neglected diseases included in the National Plan
- Annual Ministry of Health Policy statement to Parliament
- Integrated control of neglected diseases included in national and state level health plans
- Integrated plan of action for control of neglected diseases available at national level
- Number of districts with mapping of disease distribution.
- Number of district health plans that include integrated control of neglected diseases or their vectors
- Number of integration planning meetings held at the various levels and participation

Finances

- Funds allocated and released in sufficient amounts for integrated plan of action
- Proportion of funds released by partners towards the implementation of the integrated plan

Health education and promotion

- Availability of IEC materials and their utilization/consumption
- Frequency of Radio and TV programs on integration
- Number of health education meetings held
- Assess knowledge of service providers and targeted communities

Advocacy and resource mobilization

- Political commitment through policy statements and documents
- Budgetary allocation at all levels

Training

- Training targets achieved at all levels e.g. number of trained teachers and health workers.
- Quality of training assessed (e.g. management of adverse events, proper record keeping, proper dosing, etc)

Supervision

- Availability of integrated supervisory check lists
- Number of targeted supervisory visits undertaken
- Integrated supervisory reports available

Integrated logistics

- Availability of functional vehicles/motor cycles and other equipment such as computers used
- Availability of integrated delivery documents
- Integrated database and data management
- Integrated monitoring tools, registers, training manuals, etc

⁶⁴ (Parks and Lloyd 2004)

Human resources

- Number of trained personnel on integration
- Personnel integrating activities as outlined in the plan of action

Drugs procurement/supplies

- Integrated application for drug procurement where applicable
- Timely procurement of drugs in good quality and sufficient amounts
- Integrated delivery of drugs to districts and health units
- Availability of adequate community drug registers
- Timely delivery to primary care units

1.1 Annex 4: How to develop project-specific indicators of behavior change

As an example consider an STH control program that proposes a health education component to encourage hygiene-promoting behaviors. In this case, the health impact indicator is the prevalence and intensity of infection for soil-transmitted helminths – the health outcome that the hygiene promotion activity seeks to improve. One might decide that the objective of the hygiene promotion activity is to promote the following behaviors:⁶⁵

1. Washing hands properly with soap (or a local alternative) at critical times (includes the availability of essential supplies for hand washing, especially soap)
2. Dispose of all feces safely – especially those of young children who cannot easily use a toilet
3. Practice safe drinking water management in the household and/or school (this includes the use of an improved water source, safe water storage, and possibly, water treatment at the point-of-use)
4. Practice safe food management in the household

In this case, one might develop the indicators for monitoring behavior change as follows:⁶⁶

1.1.1.1 Access to Hardware

Priority Indicator: Percentage of households that use improved sanitation facilities

Sanitation and Solid Waste

- Percentage of households that have child-friendly feces disposal facility
- Percentage of households that have a hygienic solid waste disposal system

Household Technologies and Materials

- Percentage of households that have soap
- Percentage of households that have water-treatment supplies
- Percentage of households that use a safe method for transferring drinking water from a container
- Percentage of households that use covered and narrow-neck water storage containers

1.1.1.2 Hygiene Promotion

- Priority Indicator: Percentage of caregivers who report having used soap for hand washing at least at two critical times during past 24 hours

Knowledge and Attitude

- Percentage of caregivers who know at least two ways to prevent diarrhea
- Percentage of caregivers who know at least two danger signs of diarrhea
- Percentage of schoolchildren who know at least two ways to prevent diarrhea
- Percentage of caregivers who know how to treat drinking water
- Percentage of caregivers who know at least two reasons why it is important to wash hands with soap

⁶⁵(Favin, Nalmoll, and Sherburne 2004), see also (Parks and Lloyd 2004)

⁶⁶Adapted from (Favin, Nalmoll, and Sherburne 2004)

- Percentage of caregivers who say that the community can do something together to prevent diarrhea

Reported Behavior

- Percentage of caregivers who know critical times for hand washing
- Percentage of households using a properly cleaned sanitation facility
- Percentage of caregivers who clean their water storage containers at least once per week
- Percentage of caregivers who had contact with health experts about water, sanitation or hygiene during past month
- Percentage of respondents who report using the following behaviors in order to protect themselves or their family from getting sick:
 - i. Washing their hands with soap/ash after going to the latrine
 - ii. Washing their hands with soap/ash before eating
 - iii. Drinking clean water (or boil the water)
 - iv. Keeping food and household water clean/ safe
 - v. Washing fruit and vegetables in clean water before eating
 - vi. Cooking meat properly
 - vii. Wearing shoes
 - viii. Using latrine
 - ix. Keeping latrines/ the area around the toilets clean
 - x. Keeping fingernails clean
 - xi. Keeping fingernails short
 - xii. Encouraging family and friends to treat worm infection
 - xiii. Avoiding swimming in/contact with contaminated rivers, lakes, ponds etc.
 - xiv. Encouraging children/ family members to take medicine for worm infection

Communication

- Percentage of caregivers who have heard hygiene promotion activities
- Percentage of caregivers who report that messages are understood and useful

1.1.1.3 Enabling Environment

- Percentage of households that know whom to contact about hygiene
- Percentage of households that know of committee dealing with hygiene
- Percentage of households that participate in committee
- Percentage of households involved in water/sanitation/hygiene problem-identification and problem-solving exercises

Collecting data for monitoring behavior change is not always straightforward. In many cases it won't be possible to observe the behavior in question (for example hand washing), in which case it may be necessary to identify proxy indicators that are observable such as whether there is soap and a place to wash near the toilet and where food is prepared.⁶⁷ Applicants are advised to consult the list of publications in annex 1.

⁶⁷ (Favin, Nalmoll, and Sherburne 2004)

1.2 Annex 5: Definitions of STH and Schistosomiasis infection intensity categories⁶⁸

Helminth Species	Intensity category		
	Light	Moderate	Heavy
<i>A. lumbricoides</i>	1-4,999 epg	5,000-49,000 epg	≥50,000 epg
<i>T. trichiura</i>	1-999 epg	1,000-9,999 epg	≥10,000 epg
Hookworms	1-1,999 epg	2,000-3,999 epg	≥4,000 epg
<i>S. mansoni</i>	1-99 epg	100-399 epg	≥400 epg

Table 8: Definitions of STH and Schistosomiasis infection intensity categories

⁶⁸ (World Health Organization 2006a) “epg” = eggs per gram