

HSD/CD/M/002-11 ISBN: 978-92-75-33041-8

GUIDE FOR THE REORIENTATION OF MALARIA CONTROL PROGRAMS WITH A VIEW TOWARD ELIMINATION OF THE DISEASE

REGIONAL MALARIA PROGRAM COMMUNICABLE DISEASE PREVENTION AND CONTROL HEALTH SURVEILLANCE AND DISEASE PREVENTION AND CONTROL PAN AMERICAN HEALTH ORGANIZATION ISBN: 978-92-75-32960-3 Printed matter

Introduction

In recent years the number of malaria cases has fallen substantially in several of the 21 endemic countries in the Americas. According to information reported to the Pan American Health Organization by its Member States in 2009, during the period in question there were no cases of *Plasmodium falciparum* at all in some countries and only low numbers of focalized cases in others. *P. vivax* also declined considerably in a number of countries, where slide positivity rates were lower than 1% and incidence rates reported by first- and second-level administrative units (municipalities, cantons, or districts) were much lower than 1 case per 1,000 population.

When it comes to shifting the programs' emphasis from controlling malaria to eliminating it, WHO proposes that the first program reorientation should be initiated when the rate of positive slides (or rapid tests) falls below 5% based on information that is representative of the entire endemic area. However, this rule of thumb may not apply in all the countries: what is essential is that the disease burden is sufficiently low to allow for individual monitoring of each malaria patient. This is the fundamental change that needs to take place in those malaria programs that have the potential to eliminate the disease. A program's ability to achieve this status will depend on the capacity of the health system, access to services, communication facilities, infrastructure, and availability of transportation. It would be very difficult for a program to meet the criteria for elimination with a slide positivity rate of more than 5% or an annual incidence of more than 5 cases per 1,000 inhabitants.

This first reorientation phase will have been reached when autochthonous cases are limited to only clearly defined foci and the following conditions have been met: ¹

- All cases are being confirmed microscopically and treated in accordance with national policy;
- There is a fully functioning diagnosis quality management system in place;
- All cases are being reported, investigated epidemiologically, and registered at the central level;
- The malarious areas are clearly delimited and an inventory of transmission foci has been completed;
- Database management and geographic information systems have been created containing information on cases, interventions, and parasite and vector behavior patterns.

In its technical documents on malaria elimination, the World Health Organization refers to transmission focus in the following terms: "Interventions during pre-elimination and elimination programs are based on the concept of a malaria focus, assuming that transmission is focalized and no longer homogeneous across the country. A focus is a defined and circumscribed locality situated in a currently or formerly malarious area and containing the continuous or intermittent epidemiological factors necessary for malaria transmission. Examples are a town, village or other defined geographical area in which there are *Anopheles* breeding sites, feeding and resting places, and people exposed to biting by the vectors."¹

Several countries of the Region now have a panorama that is favorable for advancing toward the elimination of malaria in the near term. It is therefore time to start working with the countries on a review of the technical concepts involved and to initiate internal discussions about adapting current programs and strategies. The concepts described above need to be brought down to a more operational level, taking into account the characteristics of the programs and health services in the Region.

The present Guide focuses on the criteria to be considered in deciding whether the countries have achieved the level of "first program reorientation." The aim is to provide elements with which to make operational changes so that they can transition through a "pre-elimination" phase, consolidating the achievements of recent years, and advance toward the elimination of locally acquired infection.

¹ World Health Organization. 2007. Malaria elimination: a field manual for low and moderate endemic countries. Geneva. ISBN 978 92 4 159608 4

Conceptual Framework

WHO has identified the following levels of malaria control:²

- Control: reducing the disease burden to a level at which it is no longer a public health problem.
- *Elimination:* interrupting local mosquito-borne malaria transmission in a defined geographical area, i.e. zero incidence of locally contracted cases, although imported cases will continue to occur. Continued intervention measures are required.
- *Eradication*: permanent reduction to zero of the worldwide incidence of malaria infection.

As it can be seen, the concept of *elimination* does not require the elimination of disease vectors or a total absence of cases in the country: imported cases will continue to be detected because of international travel, and occasional cases may be introduced in which the infection is a first generation of local transmission subsequent to imported cases.¹

The phases transitioned by malaria programs on the path from control to elimination are: ¹

- <u>First program reorientation / pre-elimination program</u>: This first step toward reorientation is initiated in areas where: i) health facility data that are representative of the entire target area/country indicate that the monthly slide or rapid diagnostic test (RDT) positivity rate among febrile patients with suspected malaria is consistently lower than 5% throughout the year, which indicates that malaria case loads are becoming manageable; and ii) population-based surveys in the peak transmission season confirm a malaria parasite rate lower than 5% among people of all ages with current fever or a history of fever.
- <u>Elimination Program</u>: This phase is initiated in areas where the first program reorientation has been achieved, and where health facility data show malaria incidence at lower than 1 case* per 1,000 persons at risk per year. The goal of the elimination program is to halt local transmission area- or countrywide, clear up malaria foci, and reduce the number of locally acquired cases to zero.
- <u>Second program reorientation</u>: The second program reorientation is initiated in areas where: i) adequate surveillance shows complete or nearly complete interruption of local transmission; ii) there have been no cases, or very few sporadic cases, of local transmission in recent years; and iii) the overwhelming majority of malaria cases can be clearly identified as being of imported origin.
- <u>Prevention of reintroduction</u>: When there is clear and convincing evidence that there have been no locally acquired cases for at least three consecutive years, the process for requesting WHO certification of malaria elimination can be initiated.

* Although the recommended incidence level is 1 case per 1,000 inhabitants at risk, it should be noted that the WHO Expert Committee on Malaria in its Eighth Report (Technical Report Series 205) cited experience indicating that 0.5 cases per 1,000 inhabitants is the maximum level at which active and passive detection systems are effective. Furthermore, in its Tenth Report (Technical Report Series 272) the Committee went on to say that the level of 0.5 cases per 1,000 may be too high and suggested that it should not exceed 0.1 case per 1,000. The Committee also pointed out that this indicator by itself is not sufficient: it should be considered within the complete epidemiological context. Taking all this into account, it is felt that studies should place less emphasis on the indicator alone and look at the foci in terms of their shared epidemiological characteristics, geographic location, resources available for case-finding and analysis, and most appropriate response in the circumstances.³

Epidemiological Situation in the Americas and Prospect for Elimination

In 2009, a total of 524,123 cases of malaria were reported in the Americas, or 56% fewer than the Member States reported to the Pan American Health Organization in 2000. Since 2005, the Region has experienced a significant decline in transmission of this disease, which disables people and compromises

² World Health Organization. 2008. Global malaria control and elimination: report of a technical review. Geneva.

³ José A. Nájera, personal communication.

quality of life for a sizable percentage of its population. Since the 1970s, endemic malaria transmission has continued to persist in 21 countries of the Americas: Argentina, Belize, Bolivia, Brazil, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Guyana, French Guiana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, and Venezuela. The recent trend, however, makes it possible to consider that some countries (Argentina, El Salvador, Mexico, and Paraguay) have definite potential to advance toward elimination of the disease in the coming years.⁴ Moreover, between 2000 and 2009 the number of cases detected has fallen by more than 50% in Argentina, Belize, Bolivia, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Mexico, Nicaragua, Paraguay, and Suriname—progress that may inspire these countries to start working toward elimination.⁵

Analysis of the malaria situation in the Region may begin by grouping the countries into three subregions that share certain ecoepidemiological characteristics and social determinants in common. Of these, the Amazon region has the largest number of cases and accounted for 87% of the Hemisphere's total disease burden in 2009. Efficacy studies conducted in all the Amazon countries revealed treatment and parasitological gaps with 4-aminoquinoline, and as a result these countries are now using artemisininbased combination therapy (ACT) for P. falciparum infections. Of the countries in this group, Brazil has the most cases, or 54% of all the cases in the Americas. The countries of Central America and Mexico form another subregion, which has lower levels of transmission and a strong predominance of P. vivax (93%) with strains of P. falciparum that are sensitive to 4-aminoquinoline. Colombia has ranked second in number of malaria cases in the Region for a number of years. Much of its national territory offers environmental and social conditions that are propitious for malaria transmission. Moreover, it is a land bridge between the two subregions. The island of Hispaniola (Haiti and the Dominican Republic) is the third most important group in the Region and the only territory in the Caribbean where malaria transmission persists. With 100% of the cases caused by P. falciparum, it is a severe public health problem that impacts negatively on the island's tourism industry and threatens reintroduction of the disease in transmission-free countries elsewhere in the Caribbean. Finally, Argentina and Paraguay in the south would constitute yet another group, with *P. vivax* transmission in focalized areas.³

The Region as a whole has seen a significant drop in the number of cases relative to 2000-2009. The downward trend got started after 2005, when several countries saw peaks in transmission (Brazil, Costa Rica, Dominican Republic, Guatemala, Guyana, and Haiti). That year Brazil saw an increase of more than 138,000 cases over the previous period. However, since 2005 there has been steady decline. Because of the large numbers in question, this progress in Brazil is reflected in a major drop at the regional level. Within the Region, most of the countries saw significant reductions as well. The country with the largest percentage of reduction between 2009 and 2000 was Paraguay (98%), followed by El Salvador, Ecuador, and Suriname, with 97%, 96%, and 89% respectively. In 2009 malaria increased in the Dominican Republic, Haiti, and Venezuela.

At the Regional level, 74% the cases reported in 2009 were due to *P. vivax*, 26% to *P. falciparum*, and <0.1% to *P. malariae* (reported in Brazil, French Guiana, Guyana, Suriname, and Venezuela).

Although the reduction of malaria in recent years is an event of great public health importance in the Region, with notable improvements in indicators at the country level, a significant portion of the population in the Americas continues to live at risk of acquiring the disease, and at the local level there are still communities in which the incidence is very high. In 2009, the second-level administrative units (municipalities, districts, or cantons) with the highest annual parasite incidence (API) were in Brazil. The municipality of Anajás, in Brazil, where transmission is related to harvesting hearts of palm, the API in

⁴ Pan American Health Organization. 2009. 49th Directing Council. Elimination of neglected diseases and other poverty-related infections. Washington, DC. Document CD49/9. Available at: <u>http://new.paho.org/hq/dmdocuments/2009/CD49-09-e.pdf</u>

⁵ Annual country reports on the status of malaria. Pan American Health Organization.. http://new.paho.org/hq/index.php?option=com_content&task=view&id=2155&Itemid=1912

2009 was 951 cases per 1,000 population. There were municipalities with APIs of at least 100 cases per 1,000 in Bolivia, Brazil, and Colombia.

The determinants of these situations form an amalgam of both environmental and social factors. The rates are found in communities at high risk because of poor housing and working conditions and limited access to health services. Despite the notable differences between ecosystems in the Amazon region and the island of Hispaniola, the factor shared in common is the high vulnerability of these populations, who struggle with difficult access to services, scant institutional development at the local level, extreme poverty, and residence in remote, scattered rural, or periurban areas.

In 2009 the countries' slide positivity rates varied markedly. Positive thick blood films ranged from 0.02% in El Salvador to 18.5% in Colombia. The countries with the lowest slide positivity rates were El Salvador (0.02%), Nicaragua (0.11%), and Paraguay (0.14%). In the Amazon region, where the percentages were much higher, Ecuador had the lowest rate, with 0.9 positive cases out of 100 slides examined. Low slide positivity rates can reflect control programs that engage in active case-finding and have a wide network of health agents to ensure that febrile patients are tested for malaria. However, in some situations extremely low positivity rates with thick blood film may also be the sign of a surveillance system that is not "working smart," overburdened with activities that are not effective in finding the cases that need to be treated early to interrupt the chain of transmission.

Changes Needed in the Programs

Table 1 outlines the changes that need to take place in the in the Malaria Control Programs in order to begin reorienting actions toward the elimination phase. It corresponds to the **first program reorientation**. In addition, for each suggested change, a set of operational requirements are proposed for the programs to meet in order to advance toward elimination.

This first program reorientation is achieved when autochthonous cases are being found only in clearly defined **foci** and when changes listed in Table 1 have taken place. In this regard, two fundamental goals need to be emphasized: characterization of the foci, and the capacity of the program to follow up each individual case. To achieve this operational status, the program has to develop **epidemiological intelligence**. The capacity to establish reliable surveillance and understand the transmission dynamic at the level of each focus is key to guiding high-impact interventions that will make it possible to consolidate the control achieved and progress toward elimination.

Table 1 Changes needed in Malaria Control Programs in order to reorient actions toward disease elimination

Changes that need to be in	Requirements
place during the first	Kequitements
program reorientation	
1. All cases are being	Adoption of highly effective treatment regimens for the reduction of
confirmed microscopically	gametocytes and prevention of recurrences(<i>P. vivax</i>)
and treated in accordance	Elimination of problems in the supply of antimalarial medicines
with national policy	Strategy to ensure correct prescribing and dispensing: prepackaged
with hadonal policy	treatment courses and/or supervised treatment
	Systematic case follow-up
	Expansion of the microscopy network
	Integration with high-coverage services and programs in scattered
	communities
	"Intelligent" active case-finding
	Database management system for individual case reporting
	Strategy for supervising the quality of care and the supply of
	antimalarial medicines and other basic consumables
2. There is a fully	Strategy for certifying competency and performing evaluations based on
functioning diagnosis quality	international standards
management system in place	Performance being monitored using an objective and efficient
	methodology
3. All cases are being	Development and implementation of case-finding protocols
reported, investigated	Database management system for individual case reporting
epidemiologically, and	Implementation of database analysis routines
registered at the central level	
4. The malarious areas are	Database management system for individual case reporting
clearly delimited and an	Identification and characterization of foci
inventory of transmission	Understanding of the transmission in each focus
foci has been completed	
5. Database management and	Database management system for individual case reporting
geographic information	Coding and characterization of localities
systems have been created	Strategy for monitoring entomological parameters: residual persistence
containing information on	(on walls and mosquito nets), biting rates, and insecticide resistance
cases, interventions, and	Development of relational database management model and
parasite and vector behavior	implementation of analysis routines
patterns 6 Managarial	Adaptation of control program's organizational structure with a view
6. Managerial, administrative,	toward disease elimination
technological, financial, and	
social needs have been	Estimation of staffing strength by technical capacity to coordinate activities at different administrative levels
identified within the public	
health context	Determination of needs for mass media and transportation
	Identification of current and potential areas of social conflict and
	difficult access, populations on the move and in border areas
	Identification of challenges for transitioning the control program to an
	elimination program in the national public health context
	Determination of needs for supplementary funding to transition program
	from control to elimination

Implementation in the First Program Reorientation Context

When it comes to shifting the programs' emphasis from control to elimination of the disease, WHO proposes that the first program reorientation be initiated when the rate of positives slides (or rapid tests) falls below 5%. Some of the countries in the Americas have been reporting very low slide positivity rates in recent years, coupled with incidence rates well below 5 cases per 1,000 population. But these criteria should not be rigid. What is most important for the Region's malaria programs that are reporting such low transmission rates is to determine whether their foci are well defined and whether they have the capacity to follow up each case individually. If the program meets both these criteria, then it would be in position to progress toward disease elimination and start making the changes proposed here—as long as there is sufficient political will and financial support for assuming the responsibilities entailed. In any case, regardless of the name attached to this phase in the transition of control programs, the operational requirements proposed here constitute a road map for consolidating situations in which transmission of the disease has reached low levels.

The present Guide defines a list of a program's **aspects that should be evaluated** to assist managers in the reorientation proposed by WHO. The aim is for countries to be able to use this set of elements both as a checklist to evaluate the current status of their programs and as very concrete **milestones** in devising the strategic plans that will have to be prepared in moving toward the first program reorientation phase.

Whether in the context of prevention, control, or elimination, appropriate attention needs to be given to a number of interrelated perspectives, including gender, ethnicity, human rights, health promotion, primary health care, and social protection. Consideration and application of these perspectives can facilitate the identification and management of shortcomings that are hampering the programs' progress from one phase to the next, including those involved in transitioning from malaria control to malaria elimination. PAHO has developed tools and checklists in some of these areas to aid the programs in optimizing progress toward the attainment of several health targets. These tools can be adapted by the countries for orientation of their national programs, as appropriate.^{6,7,8,9,10} Also, it's important not to forget to enlist the participation of other stakeholders in the private and public sectors—including education, agriculture, environment, mining, forestry, fish farming, other national government offices, international agencies, and nongovernmental organizations—in improving the health of the people, and, especially, reducing and eliminating malaria wherever feasible in the Region of the Americas.

In the tables that follow, for each of the changes needed, an effort has been made to identify the operational requirements, justifications, and monitoring and evaluation criteria that these changes may entail for the programs in the countries.

⁶ Pan American Health Organization. 2009. 49th Directing Council. Elimination of neglected diseases and other poverty-related infections. Washington, DC. Document CD49/9. Available at: <u>http://new.paho.org/hq/dmdocuments/2009/CD49-09-e.pdf</u>

⁷ Human Rights Modules: <u>http://new.paho.org/hq/index.php?option=com_content&task=view&id=1132&Itemid=643</u>

⁸ Health Promotion: <u>http://www.bvsde.ops-oms.org/sde/ops-sde/ingles/bv-promosalud.shtml</u>

⁹ Primary Health Care: <u>http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=523&Itemid=712</u>

¹⁰ Social Protection in Health: <u>http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=1932&Itemid=2075&lang=en</u>

Requirement	Detail/justification	Program elements to be monitored and evaluated
1.1 Adoption of highly effective treatment regimens for the reduction of gametocytes and prevention of recurrences(<i>P. vivax</i>)	 Interruption of transmission will depend to a great extent on the use of highly effective treatment regimens. In <i>P. falciparum</i> malaria, artemisinin-based combination therapies (ACT) are recommended for obtaining rapid reduction of the asexual parasite burden and reduction of parasitemia. When ACT is used as the first-line treatment for <i>P. falciparum</i>, the scheme should also include primaquine for greater effect in eliminating gametocytes. In <i>P. vivax</i> malaria, relapses are one of the main factors in the perpetuation of transmission. The scheme recommended for <i>P. vivax</i>, which is most effective in eliminating hypnozoites, is primaquine for 14 days combined with chloroquine 25 mg/kg bodyweight divided over 3 days for blood schizonticidal and gametocidal effect. 	 The schemes recommended by WHO/PAHO¹¹ have been adopted as first-line treatments for <i>P. falciparum</i> and <i>P. vivax</i> malaria. Primaquine (0.75 mg/kg bodyweight, single dose) has been included in the scheme for uncomplicated <i>P. falciparum</i> malaria. The use of incomplete treatments, treatments in subcurative doses, and mass treatments has been abolished. The regimen for <i>P. vivax</i> malaria includes three days of chloroquine and 14 days of primaquine in a daily dose of at least 0.25 mg/kg bodyweight. Alternative regimens with primaquine are 0.5 mg/kg bodyweight for 7 days or 0.75 mg/kg bodyweight weekly for 8 weeks. Primaquine should not be given to persons with G6PD deficiency, pregnant women, or infants under 6 months old.
1.2 Elimination of problems in the supply of antimalarial medicines	 The shortage of antimalarial drugs is one of the main challenges in malaria control programs. Efforts to guarantee timely and reliable parasitological diagnosis are wasted without a regular supply of antimalarial drugs. The complex challenges inherent in ensuring the supply of antimalarial drugs in remote and widely scattered areas is are underestimated in many programs. The supply processes need to be reviewed at all points in the cycle of a given drug. 	 Tools and methodologies have been adopted for the calculation of needs. A system has been created to monitor and manage supplies. Shortages of antimalarial supplies at health facilities and diagnostic and treatment posts have been corrected. Programming and logistic shortcomings have been corrected. Drug procurement mechanisms have been established for imported or introduced cases of resistant <i>P. falciparum</i> in areas where such strains do not normally circulate.
1.3 Strategy to ensure correct prescribing and dispensing	 Compliance is key to the effectiveness of the therapy and an important factor in malaria treatment. Adherence problems are a major limiting factor in the 14-day primaquine treatment for <i>P. vivax</i> malaria. One way to control this problem is to promote the use of antimalarial formulations with regimens that are easy to understand and require fewer tablets and doses. Programs should therefore endeavor to obtain antimalarials in adequate formulations. Prepackaged drugs or co-blisters are alternatives. 	 The program is procuring pre prepackaged drugs, fixed formulations, or co-blisters. A strategy has been designed and implemented to ensure direct supervision of treatment for <i>P. falciparum</i> malaria. Health professionals or health agents who prescribe and dispense antimalarials in both the public and private sectors have received training in an institutional strategy for good treatment practices that promote adherence. There are standardized, up-to-date national treatment guidelines There are standardized, up-to-date procedures for prescribing and dispensing, as well as practices in place that promote adherence.

Change 1. All cases are being confirmed microscopically and treated in accordance with national policy

¹¹ WHO. 2010. Guidelines for the treatment of malaria. Geneva. 2d ed. ISBN 978 92 4 154792 5 <u>http://www.who.int/malaria/publications/atoz/9789241547925/en/index.html</u>

Requirement	Detail/justification	Program elements to be monitored and evaluated
		 Both the public and the private sectors, as well as all who prescribe antimalarials to patients, are providing information to the system within 24 hours. There is a referral system in place for the diagnosis and management of severe cases.
1.4 Systematic case follow-up	 Multidrug resistance to the antimalarials in <i>P. falciparum</i> malaria is widespread in the Amazon region and could affect the rest of the endemic area in the Region. Monitoring for resistance is an essential component of the program. When case numbers are low, it is recommended that 100% of <i>P. falciparum</i> cases, and <i>P. vivax</i> cases as well, be monitored clinically and parasitologically on a regular basis. 	 A systematic strategy has been adopted for monitoring cases caused by <i>P. falciparum</i> and <i>P. vivax</i>. A database and instruments for this type of surveillance have been designed. A protocol has been adopted for the extraction, transportation, and storage of blood samples on filter paper for monitoring molecular resistance markers and genotyping <i>Plasmodium</i> strains. There is adequate infrastructure, as well as materials and equipment, for transporting and storing blood samples for parasite genotyping and determination of molecular markers.
1.5 Expansion of the microscopy network	 The microscopy network should be built up to the point that it can guarantee timely access to parasitological diagnosis for 100% of cases. Developing such a network is feasible as long as few foci are being targeted (a prior condition for achieving first-level program reorientation). This is an exercise in analyzing the availability of resources vis-àvis the origin and accessibility of the cases. The goal may be to initiate treatment of all cases, based on parasitological diagnosis, within the first 3 days after the onset of symptoms. With <i>P. falciparum</i>, gametocytes can start to appear after 3 days, so this is a key epidemiological turning point in interrupting the chain of transmission. The concept of "network" implies the existence of a support structure, including a reference laboratory and sufficient levels of oversight to ensure quality management. The location of diagnostic posts should be based on an analysis that takes into account the transmission dynamic of each focus. 	 Schotyping and determination of morecular markets. 100% of the localities with malaria foci have access to a post with parasitological diagnosis and treatment that can be reached within a few hours by available transportation. The information system is monitoring the length of time for access to diagnosis. At least 80% of cases are being diagnosed and treated within 72 hours after onset of symptoms. All microscopy posts are connected to a network of reference laboratories that apply quality management. The information system is generating regular reliable data on the variables of case origin and residence which are guiding adjustments in the diagnostic network. Whenever rapid diagnostic tests are used for case management, thick and thin blood smears are being taken for analysis and cross-reference. In localities where the disease burden is very low, all positive slides are being kept for future reference and submission to the network's quality management program. There is a quality control system in place governing microscopy.
1.6 "Intetelligent"active case-finding	 Early case detection depends on active surveillance and thick blood film testing of febrile patients who have symptoms compatible with malaria. However, the haphazard nature of this practice can lead to unnecessary waste of services. Active case-finding should be based on an understanding of the transmission dynamic in the particular focus and an information 	 In each focus an active case-finding system has been designed and implemented with the following characteristics: Analysis of focus data on a weekly basis Standardization of case definitions Adoption of case monitoring protocols (with specific guidelines for <i>P. falciparum</i> and <i>P. vivax</i>) Timely examination of slides

Requirement	Detail/justification	Program elements to be monitored and evaluated
Requirement	Detail/justification system that permits timely monitoring of the disease's pattern at the local level. - The point of active case-finding is to interrupt the chain of transmission as soon as possible by initiating treatment during the first days of the infection. - Treatment should be given only to patients with a parasitological diagnosis. Presumptive mass treatment based on clinical diagnosis is a scattershot approach that produces the following effects: - Large numbers of people without malaria receive the treatment unnecessarily. - It interferes with application of the complete regimens	 Program elements to be monitored and evaluated Early initiation of treatment in cases with parasitological diagnosis New active case-finding triggered on the basis of a protocol for case follow-up.
	 It interferes with application of the complete regimens recommended by WHO/PAHO (primaquine for 14 days in cases of <i>P. vivax</i>). Cases of malaria can end up being treated as suspected cases, which means that they do not receive complete treatment; they are not supervised; and there is no follow-up. In the meantime, many people with fever who do not have malaria fail to receive appropriate treatment for the cause of their condition. It delays active contact-tracing and case-finding related to confirmed cases. 	
	 It discourages timely parasitological diagnosis and in some cases delays diagnosis. There is no longer any point to the effort of analyzing the information and gaining an understanding of the transmission dynamic in each focus. The use of large-scale suboptimal doses encourages the spread of resistant strains. Slides collected during active case-finding should be examined on a timely basis so that early treatment can be initiated. 	

1.7 Database management system for individual case reporting	 The main purpose of a malaria information system should be to orient the early detection and treatment of cases. The key to planning actions for early diagnosis is understanding the transmission dynamic in each focus. The way to obtain this epidemiological intelligence is to have a case reporting system that is linked to automated databases with analysis routines that generate reports broken down to provide the information needed as often as the situation requires. Systematic analysis of the variables of each case is what it makes it possible to understand the transmission dynamic, define the boundaries of the foci, improve the availability of diagnosis and treatment, and prioritize vector control measures. These essential variables are: <i>Plasmodium</i> species, place (focus) of transmission, place of diagnosis, date of onset of symptoms, date of diagnosis, time of access to diagnosis, patient's age and sex, history of recent treatment, and presence of gametocytes in the cases taken as a whole are analyzed systematically, which is what the databases are for. It is not enough for this individual information to be processed by the local team; the intermediate and central levels also need to be able to understand the local transmission dynamic. Access to information at any level of disaggregation is possible because data from individual case records are entered in the automatic databases. These databases need to be able to go beyond the level of consolidated reports and include individual case records. 	 The malaria information system is based on reporting each individual case, including the following data elements: age, sex, date of onset of symptoms, date of diagnosis, place of diagnosis, probable place of infection, place of residence, species of <i>Plasmodium</i>, pregnancy status, last previous treatment for malaria. Capture software is being used to process information using data from individual case reports. Routines have been designed and implemented for entering data in the system, controlling quality, and performing analyses. Links have been established between data from the laboratories and information on the treatments being given to patients to prevent duplicated information and monitor for worsened symptoms and relapses. Investigations are being conducted in areas identified on the basis of epidemiological as well as administrative criteria.
1.8 Strategy for	greatly limits the possibilities for analysis, no longer makes sense.The efforts described above to procure and distribute treatments in	- A strategy has been developed for overseeing malaria diagnostic and
supervising the quality of care and the supply of antimalarial medicines and other basic consumables	 The enorts described above to produce and distribute treatments in appropriate formulations, institutionalize prescribing and dispensing practices, expand the diagnostic network, and improve information management will only be successful if protocols and established procedures are strictly adhere to at the local level. While shortages of antimalarial drugs may be corrected at the central and first administrative (ADM1) levels, distribution problems are likely to continue on the ground. Periodic supervision of treatment posts makes it possible to identify shortages on a timely basis and improve the quality of care. 	 A strategy has been developed for overseeing matura diagnostic and treatment posts that includes the following: A simplified oversight program that emphasizes shortages of antimalarials, compliance with standards for prescribing and dispensing, and quality of notification procedures Training of supervisors Development of a database and applications to automate the processing of information Implementation of analysis and decision-making routines

Change 1(cont.). All cases are being confirmed microscopically and treated in accordance with national policy

- Although there is oversight in many countries, it is not systematic, there are no procedures in place, and the information system is not standardized. Without an institutionalized methodology, procedures in the field are left to the discretion of the health agents, which means that essential aspects of the program (such as the supply of antimalarials) are not properly supervised and that the program's	
 antimization is being handled haphazardly. There are two reasons for having a systematized oversight strategy: (i) to be able to rapidly correct critical deficiencies (shortage of antimalarials or diagnostic supplies), and (ii) to generate a database of parameters for monitoring temporary management issues. To be effective, practical, and functional, the oversight and its supporting procedures should focus on the most critical aspects that affect care (shortage of antimalarials, failure to follow prescribing 	
 and dispensing standards, quality of reporting). The procedures should be very simple.	

Requirement	Detail-justification	Program elements to be monitored and evaluated
2.1 Strategy for certifying competency and performing evaluations based on international standards	 Systematic errors in the diagnosis of malaria are unacceptable in a control program transitioning to elimination. Errors in identification of the pathogen are bound to create major problems in situations where the number of <i>P. falciparum</i> cases is very low. This has already happened in several countries of the Americas. To assure diagnostic quality, in the first place the competency of the microscopists needs to be guaranteed. There are international standards for the profile of microscopists, including the content, duration, and other characteristics of their training. WHO/PAHO has also defined very objective criteria for the periodic evaluation and certification of competencies. Traditionally, quality control systems in the malaria programs have focused on monitoring performance based on slide reviews. This component should exist, but it should be combined with a strategy for the certification of competencies. WHO/PAHO has developed technical documents to guide the programs in implementing these aspects of quality management. 	 The program has implemented a strategy for evaluating and certifying competencies in microscopy based on the technical recommendations of WHO/PAHO, and as a result: The country has a team of senior microscopists certified by international standards. All microscopists at other levels in the network are certified and evaluated periodically based on standardized criteria. There are standards for the placement and training of new microscopists that the WHO recommended criteria¹².
2.2 Performance being monitored using an objective and efficient methodology	 In control programs that are advancing toward elimination, the negative predictive value (NPV) of microscopy is very important. NPV is affected by frequency of the event and sensitivity. In order for the surveillance system to achieve the highest levels of sensitivity that can be expected with thick blood film, as well as to guarantee the competency of microscopists, it is important to carefully monitor the large number of slides being reported as negative. Performance monitoring refers to the slide review that malaria programs have classically conducted in the past. It is the second essential component of a diagnosis quality management system. The performance monitoring methodology used by most malaria programs has several shortcomings: (i) the second reading is not actually "blind"; (ii) priority is not given to slides with low levels of parasitemia; (iii) it generates a high workload for reviewers and reference laboratories; (iv) feedback is given late or not at all; (v) it 	 The microscopy network has made the necessary adjustments in the slide review methodology based on WHO/PAHO recommendations, with emphasis on: Blinded cross-checking Selection of (negative) slides at random Timely feedback

Change 2. There is a fully functioning diagnosis quality management system in place

¹² PAHO/WHO. 2009, 2010. [Guidelines for quality control of microscopy in malaria programs]. <u>http://new.paho.org/hq/index.php?option=com_content&task=view&id=2453&Itemid=2153</u> <u>http://www.wpro.who.int/NR/rdonlyres/D854E190-F1B2-41E4-93B4-EB3D1A0163E4/0/MalariaMicroscopyManualVer1EDITED0609.pdf</u>

Requirement	Detail-justification	Program elements to be monitored and evaluated
	also creates a burden for laboratory workers.	
	- WHO/PAHO has developed technical documents that guide malaria	
	programs toward slide review methodologies that are more efficient	
	and objective.	

Requirement	Detail-justification	Program elements to be monitored and evaluated
3.1 Development and implementation of case- finding protocols	 Shifting from control to elimination implies much more careful monitoring of each malaria case than is done normally as part of the control strategy. In the program's new situation, each case must be studied individually to generate a search for possible new cases. For this reason, case-finding protocols need to be developed that correspond to the program's new situation. Bearing in mind the specific elimination objectives for <i>P</i>. <i>falciparum</i> (or any case of malaria), the case-finding protocols should be species-specific. 	 Malaria species-specific case-finding protocols have been designed and implemented. The case-finding protocol makes it possible to identify the place where the infection occurred.
3.2 Database	- See Item 1. 7.	- See Item 1.7.
management system for	- Coordination of information from different sources is an essential	
individual case reporting	feature of relational databases.	
3.3 Implementation of	- Database information management of individual case reports is	- An application has been developed that tabulates and generates
database analysis	fundamental for an information system that is monitoring malaria	automated reports including appropriate graphic representations
routines	patterns at the level of detail required for elimination. However,	(maps, tables, and figures).
	experience has shown that at the program's operational levels there	- The information generated in periodic reports is tabulated at a level
	is usually very little capacity for database processing and	of disaggregation that helps make it possible to see the transmission
	information extraction. Thus, initiatives to set up databases should	dynamic within the foci.
	include the design of automated reports with all the breakdowns	- Steps have been taken to ensure that local teams and epidemiology
	needed.	groups at the ADM1 and central levels hold weekly sessions to
	- In addition to developing the needed computer applications, local	analyze malaria patterns in the foci and make decisions.
	teams and epidemiology groups at the ADM1 level need to establish	- Information is being analyzed and used for decision-making in
	weekly routines for information analysis and decision-making.	response to warning signs.
	- Timely information is important for picking up warning signs.	

Change 3. All cases are being reported, investigated epidemiologically, and registered at	the central level
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Requirement	Detail-justification	Program elements to be monitored and evaluated
4.1 Database	- See Item 1. 7.	- See Item 1.7.
management system for	- Coordination of information from different sources is an essential	
individual case reporting	feature of relational databases.	
4.2 Identification and characterization of foci	 The essential characteristic of elimination programs is the capacity to monitor the malaria situation at the level of each focus. The cornerstones are case-finding and rigor in reporting and controlling information quality. Careful recording of details about the place of residence and/or place where the infection probably occurred, coupled with case-finding, will provide orientation for delimiting the focus. Characterization of the foci relies on geographic reconnaissance, population censes, and characterization of the entomology. Most important, however, is understanding the transmission dynamic. 	 The country's malaria foci are being duly identified and characterized. The program has developed the capacity to monitor the disease's behavior pattern in each malaria focus. The health services and the malaria program have been organized at administrative levels ADM1 (states, provinces, or departments) and ADM2 (cantons, districts or municipalities) with emphasis on monitoring the malaria foci.
4.3 Understanding of the transmission dynamic in each focus	 Understanding how transmission occurs within the foci is key to controlling the disease. It is necessary to understand what is causing this confluence of infected individuals and vectors, and the tie-in between the vectors and the humans who are susceptible. Based on this knowledge, the next step is to plan measures and enlist services to interrupt the chain of transmission. The explanation of why transmission is being perpetuated lies in the routine of human activities and the ecology of each focus, and this is what the programs need to understand. The complexity of malaria transmission reflects the heterogeneity of contact between people and mosquitoes. There has to be a particular configuration that results in a small proportion of people being the subject of a large proportion of parasite inoculations. It will depend on such factors as the proximity of homes to breeding sites, some dwellings being more unprotected that others, occupations, peoples' habits that result in varying degrees of exposure, and susceptibility of individuals for genetic or immunological reasons.¹³ Despite this heterogeneity, control measures applied in an endemic area where transmission is high are usually effective. On the other 	 The transmission dynamic has been identified in each focus and a specific control strategy has been developed. The central level has a team of professionals in place who periodically analyze the situation in each focus and make any needed adjustments in the control strategy.

Change 4. The malarious areas are clearly delimited and an inventory of transmission foci has been completed

¹³ Mendis K, et al. 2009. From malaria control to eradication: the WHO perspective. Tropical Medicine & International Health. 25(7):802-809.

Requirement	Detail-justification	Program elements to be monitored and evaluated
	hand, when transmission is very low, actions need to be highly	
	targeted.	
	- In a program progressing toward elimination, emphasis is on	
	measures that will have a high impact on each focus.	

Requirement	Detail-justification	Program elements to be monitored and evaluated
5.1 Database	- See item 1. 7.	- See item 1.7.
management system for individual case reporting	- Coordination of information from different sources is an essential feature of relational databases.	
5.2 Coding and characterization of localities	 The information on each focus of malaria transmission should be duly recorded and coded to facilitate tabulation by the databases. Attention should be concentrated on areas that have a convergence of the people, parasites, vectors, and environmental conditions that allow for transmission of the disease. A focus can include all or parts of more than one locality. 	 Each focus of malaria transmission is being registered and coded, and the information system includes the management of duly coded places of residence and origin. In urban areas, neighborhoods have been registered as transmission foci and duly coded. All levels—local, intermediate, and central—are required to understand the transmission dynamic.
5.3 Strategy for monitoring entomological parameters: residual persistence (on walls and mosquito nets), biting rates, and insecticide resistance	 Decision-making should be guided by entomological characterization of the focus. The characterization should include the level of detail needed to allow monitoring of temporal and spatial variations in the parameters that are essential to orienting control. The methodology should be sufficiently rigorous to obtain the information needed to guide decision-making, but at the same time it should be operationally viable. Above all, the methodology should be well documented and kept up to date to permit analysis of variations in the parameters. The priority parameters for monitoring should be the hourly biting rate, residual persistence on walls and impregnated mosquito nets, and susceptibility of the mosquitoes to insecticides. 	 The entomological characterization of each focus has been updated using a standard methodology. A methodology has been adopted for monitoring entomological parameters in a standardized manner. An entomology team has been trained to rigorously follow a field methodology. There is a plan to conduct an entomological evaluation in the next year that is consistent with the disease burden. Routines and applications have been implemented for capturing information and entering it in the database. The entomological studies of the foci are intended to discover why transmission persists in the foci whereas control measures have been successful elsewhere. Consideration is given to studies of vector behavior as it relates to human beings and other animals.
5.4 Development of relational database management model and implementation of analysis routines	- The databases containing individual case reports should be part of a relational database structure in which the data are linked to information from other sources that is essential to analyzing the situation in the foci (characterization of the localities, microscopy network, supervision of posts, vector control)	 An information system has been created that has the following characteristics: It is based on automation of the information contained in databases of reported cases. It has a relational database structure that integrates case reporting with information tables containing data on the localities, the diagnostic network, and vector control Automated analysis routines with automatic generation of periodic reports at a level of disaggregation that shows the localities of origin and diagnostic posts.

Change 5. Database management and geographic information systems have been created containing information on cases, interventions, and parasite and vector behavior

Requirement	Detail-justification	Criteria to be monitored and evaluated
6.1 Adaptation of control program's organizational structure with a view toward disease elimination	- The transformation of a control program to an elimination program requires stable technical direction and political stability at all levels.	 The program has an organization chart showing the different administrative levels, including connections with leaders, committees, and volunteers at the grass roots level. The responsible and operational personnel at each level are technically well trained and functionally well prepared.
6.2 Estimation of staffing strength by technical capacity to coordinate activities at different administrative levels	- Stratification, targeting of foci, strengthening of epidemiological research, individual monitoring of each focus, and other elimination program approaches may result in a larger contingent of trained personnel than for control programs.	 The personnel who have been recruited are well trained for the work they are assigned to and are performing tasks that are needed.
6.2 Determination of needs for mass media and transportation	- To have a daily flow of information about the situation, including data on epidemiological tracking, program administration, and movement in the supply system, requires adequate means of communication and functional transportation.	 Communication networks appropriate for the different geographical and social circumstances are established and functioning. A program is in place for maintaining the communication networks and supplies are available. Appropriate transportation is available for each geographic area, with a maintenance plan and supplies to ensure its operation.
6.3 Identification of current and potential areas of social conflict and difficult access, populations on the move and in border areas	 Internal and external social conflicts can hamper the disease elimination process. Mobile populations such as miners, lumberjacks, and farm workers, as well as people traveling between endemic countries, pose a significant challenge for intensified control and elimination activities. 	 Transmission foci located in areas of social conflict are registered, and efforts are being made to ensure program access and carry out activities geared toward elimination. Appropriate transportation is available in each geographic area, with a maintenance plan and supplies to ensure its operation.
6.4 Identification of challenges for transitioning the control program to an elimination program in the national public health context	- Different modalities and degrees of decentralization of health services, as well as different integration, structural, and management processes in the countries' malaria programs, make it indispensable to identify and overcome the challenges based on consensus between the different areas of responsibility and administrative levels.	- There is consensus between all areas of responsibility at the different administrative levels regarding direction, technical coordination, responsibilities, and the different activities geared toward the elimination of malaria.
6.5 Determination of needs for supplementary funding to transition program from control to elimination	 During the transition of control programs, as the number of cases gets closer to zero, activities to combat the disease need to be continued or stepped up, as does monitoring after the goal is reached. This may require additional budgetary resources. National political and financial commitments are needed to ensure the sustainability of efforts throughout the process. History has shown disastrous consequences in countries that have not kept up their programs and expertise after achieving elimination.¹⁴ 	 The financial needs for the elimination process are estimated annually and being met with funding from different national administrative levels and/or external financing. Once elimination has been achieved, financing for surveillance to prevent the reintroduction of transmission is being estimated on an annual basis and the funding is mainly covered by national administrative agencies.

Change 6. Managerial, administrative, technological, financial, and social needs have been identified within the public health context

¹⁴ Feachem RGA & Malaria Elimination Group. 2009. Shrinking the malaria map: a guide on malaria elimination for policy makers. San Francisco: Global Health Group, UCSF Global Science.