
Preparing for certification of malaria elimination

Second edition



World Health
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Abbreviations

GMP	Global Malaria Programme
MPAG	Malaria Policy Advisory Group
NMP	national malaria programme
SOP	standard operating procedure
TAG-MEC	Technical Advisory Group on Malaria Elimination and Certification

Glossary

This glossary comprises all the key terms used in the present publication. The definitions are extracted from *WHO malaria terminology*, updated in December 2021 (1). As the terminology is reviewed continuously, readers should visit the WHO GMP website at <https://www.who.int/teams/global-malaria-programme> for updates.

case investigation	<p>Collection of information to allow classification of a malaria case by origin of infection, i.e. imported, indigenous, induced, introduced, relapsing or recrudescent</p> <p><i>Note: Case investigation may include administration of a standardized questionnaire to a person in whom a malaria infection is diagnosed and screening and testing of people living in the same household or surrounding areas.</i></p>
case, imported	<p>Malaria case or infection in which the infection was acquired outside the area in which it is diagnosed</p>
case, index	<p>A case of which the epidemiological characteristics trigger additional active case or infection detection. The term “index case” is also used to designate the case identified as the origin of infection of one or a number of introduced cases.</p>
case, indigenous	<p>A case contracted locally with no evidence of importation and no direct link to transmission from an imported case</p>
case, induced	<p>A case the origin of which can be traced to a blood transfusion or other form of parenteral inoculation of the parasite but not to transmission by a natural mosquito-borne inoculation</p> <p><i>Note: In controlled human malaria infections in malaria research, the parasite infection (challenge) may originate from inoculated sporozoites, blood or infected mosquitoes.</i></p>
case, introduced	<p>A case contracted locally, with strong epidemiological evidence linking it directly to a known imported case (first-generation local transmission)</p>

case, locally acquired	<p>A case acquired locally by mosquito-borne transmission</p> <p><i>Note: Locally acquired cases can be indigenous, introduced, relapsing or recrudescent; the term "autochthonous" is not commonly used.</i></p>
case, malaria	<p>Occurrence of malaria infection in a person in whom the presence of malaria parasites in the blood has been confirmed by a diagnostic test</p> <p><i>Note: A suspected malaria case cannot be considered a malaria case until parasitological confirmation. A malaria case can be classified as indigenous, induced, introduced, imported, relapsing or recrudescent (depending on the origin of infection); and as symptomatic or asymptomatic. In malaria control settings, a "case" is the occurrence of confirmed malaria infection with illness or disease. In settings where malaria is actively being eliminated or has been eliminated, a "case" is the occurrence of any confirmed malaria infection with or without symptoms.</i></p>
case, relapsing	<p>Malaria case attributed to activation of hypnozoites of <i>Plasmodium vivax</i> or <i>P. ovale</i> acquired previously</p> <p><i>Note: The latency of a relapsing case can be > 6-12 months. The occurrence of relapsing cases is not an indication of operational failure, but their existence should lead to evaluation of the possibility of ongoing transmission.</i></p>
chemoprophylaxis	<p>Administration of a medicine, at predefined intervals, to prevent either the development of an infection or progression of an infection to manifest disease</p>
focus, malaria	<p>A defined and circumscribed area situated in a currently or formerly malarious area that contains the epidemiological and ecological factors necessary for malaria transmission</p> <p><i>Note: Foci can be classified as active, residual non-active or cleared.</i></p>
importation, rate (or risk) of	<p>Rate (or risk) of influx of parasites via infected individuals or infected <i>Anopheles</i> spp. mosquitoes</p> <p><i>Note: "Infected individuals" include residents infected while visiting endemic areas as well as infected immigrants. This term replaces the term "vulnerability".</i></p>

infectivity	Ability of sporozoites of a specific strain of <i>Plasmodium</i> to be injected by <i>Anopheles</i> mosquitoes into susceptible humans and develop through the liver stage to infect red blood cells (“infectivity to humans”) and the ability of competent <i>Anopheles</i> mosquitoes to ingest human <i>Plasmodium</i> gametocytes which undergo development until the mosquito has infective sporozoites in its salivary glands (“infectivity to mosquitoes”).
malaria elimination	<p>Interruption of local transmission (reduction to zero incidence of indigenous cases) of a specified malaria parasite species in a defined geographical area as a result of deliberate activities. Continued measures to prevent re-establishment of transmission are required.</p> <p><i>Note: Certification of malaria elimination in a country requires that local transmission is interrupted for the four main human malaria parasites.</i></p>
malaria eradication	Permanent reduction to zero of the worldwide incidence of infection caused by all human malaria parasite species as a result of deliberate activities. Interventions are no longer required once eradication has been achieved.
malaria receptivity	<p>Degree to which an ecosystem in a given area at a given time allows for the transmission of <i>Plasmodium</i> spp. from a human through a vector mosquito to another human.</p> <p><i>Note: This concept reflects vectorial capacity, susceptibility of the human population to malaria infection, and the strength of the health system, including malaria interventions. Receptivity depends on vector susceptibility to particular species of <i>Plasmodium</i>, and is influenced by ecological and climatic factors.</i></p>
malaria reintroduction	<p>Malaria reintroduction is the occurrence of introduced cases (cases of first-generation local transmission that are epidemiologically linked to a confirmed imported case) in a country or area where the disease had previously been eliminated</p> <p><i>Note: Malaria reintroduction is different from re-establishment of malaria transmission (see definition).</i></p>
malaria-free	Describes an area in which there is no continuing local mosquito-borne malaria transmission and the risk for acquiring malaria is limited to infection from introduced cases

malariogenic potential	<p>Potential level of transmission in a given area arising from the combination of malaria receptivity, importation rate (or risk) of malaria parasites and infectivity.</p> <p><i>Note: The concept of malariogenic potential is most relevant for elimination and prevention of re-establishment when indigenous transmission is almost or entirely eliminated.</i></p>
population at risk	<p>Population living in a geographical area where locally acquired malaria cases have occurred in the past 3 years</p>
transmission, re-establishment of	<p>Renewed presence of a measurable incidence of locally acquired malaria infection due to repeated cycles of mosquito-borne infections in an area in which transmission had been interrupted</p> <p><i>Note: A minimum indication of possible re-establishment of transmission would be the occurrence of three or more indigenous malaria cases of the same species per year in the same focus, for 3 consecutive years.</i></p>
vigilance	<p>A function of public health services for preventing reintroduction of malaria. Vigilance consists of close monitoring for any occurrence of malaria in receptive areas and application of the necessary measures to prevent re-establishment of transmission</p>

Introduction

Certification of malaria elimination is granted by WHO to a country, further to a request from its government, after it has been proven beyond reasonable doubt that local malaria transmission by *Anopheles* mosquitoes¹ has been interrupted in the country, resulting in zero indigenous malaria cases for at least the past 3 consecutive years, and a programme for the prevention of re-establishment of transmission is in place. WHO was given the mandate to certify countries malaria-free by the World Health Assembly in resolution WHA13.55 in 1960, which “requests the Director-General to establish an official register, listing areas where malaria eradication has been achieved, after inspection and certification by a WHO evaluation team.”²

The *Global technical strategy for malaria 2016–2030*, endorsed by the World Health Assembly in 2015 and updated in 2021, includes targets for malaria elimination and prevention of re-establishment of transmission (2). WHO provides guidance on the dynamic strategies and activities that will help countries achieve elimination and prevent re-establishment of transmission in the *Framework for malaria elimination* (3). The Framework updated the criteria and process for WHO certification of malaria elimination initially established during the Global Malaria Eradication Programme between 1955 and 1969. In line with these updates, the Malaria Elimination Certification Panel (MECP), a standing committee entrusted with reviewing and evaluating countries’ reports of malaria elimination and recommending certification to WHO, was established in 2017. In 2021, the MECP was renamed as Technical Advisory Group on Malaria Elimination and Certification (TAG-MEC) (4).

The purpose of this document is to extend guidance to countries that are nearing malaria elimination on preparing for certification. It provides an overview of the certification procedure and details of activities required in national preparation for certification. It includes tools that countries can use to organize the documentation required for certification, to prepare a national elimination report and to assess their readiness for certification.

¹ Certification of malaria elimination by WHO requires the elimination of the four main human parasite species: *Plasmodium falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. Certification might be granted to countries where cases of other Plasmodium species are reported if the risk to humans is assessed negligible.

² In the 1960s, the term “eradication” was used to describe interruption of transmission within a defined geographical boundary. More recently, WHO defined “eradication” as the permanent reduction to zero of the worldwide incidence of malaria. “Elimination” is used to refer to interruption of malaria transmission in a defined geographical area (1).

For countries with subnational elimination goals, the manual provides guidance on verification of subnational malaria elimination, which is overseen by national authorities. The target readership of this manual is officials in ministries of health and other relevant departments, national malaria programme (NMP) managers and staff, national elimination advisory committees and partners who support countries in eliminating malaria and preventing re-establishment.

1. Overview of the certification procedure

Certification of malaria elimination is voluntary and is initiated at a country's request. The process provides an expert, objective and independent review and evaluation of a country's declaration of malaria elimination and its programme to prevent re-establishment of transmission. Preparation for certification begins before countries interrupt malaria transmission through development of national malaria elimination strategic plans, effective implementation of planned activities, monitoring of progress and evaluation of impact. Documenting the efforts for malaria elimination should begin during this time to prepare evidence for certification.

Countries may request certification from WHO after reporting zero indigenous human malaria cases for 3 consecutive years (36 months). Countries prepare a national elimination report characterizing the history of malaria in the country, detailing the activities undertaken to achieve elimination, presenting evidence that the elimination goal has been achieved and describing the programme to prevent re-establishment. The TAG-MEC reviews the report and conducts an independent evaluation mission to verify the findings in the report by reviewing documents and records and conducting field visits and interviews with the ministry of health, the NMP and other relevant sectors. The TAG-MEC weighs the findings of the independent evaluation mission and recommends to WHO, through the Malaria Policy Advisory Group (MPAG), whether the country should be certified as having achieved malaria elimination at that time or certification should be postponed. The WHO Director-General makes a final decision on certification. When granted, countries are listed in the official WHO *Register of areas where malaria elimination has been achieved* (5).

2. Criteria for certification of malaria elimination

WHO certification of malaria elimination requires applicant countries to provide evidence that:

- local malaria transmission has been fully interrupted, resulting in zero indigenous human malaria cases for at least the past 3 consecutive years (36 months), and
- an adequate programme for preventing re-establishment of indigenous transmission is fully functional throughout the country.

To examine a country's claim of malaria elimination, the TAG-MEC reviews the activities and impact of the malaria programme in the years before elimination to determine whether the activities, as recorded, could have interrupted transmission in that country; and evaluates the coverage and quality of the surveillance system during the 3 years (36 months) of reporting zero indigenous malaria cases to determine whether the surveillance system could have detected any indigenous malaria cases should they have occurred.

To evaluate the adequacy of a country's programme to prevent re-establishment of malaria transmission, the TAG-MEC examines the strategies, the technical soundness and comprehensiveness of the activities in the plan, the quality and coverage of malaria surveillance and response, the quality and coverage of diagnosis and treatment, capacity for entomological surveillance and vector control and the sustainability of provision of financial and human resources.

The evidence that the TAG-MEC uses to evaluate a country's claim of malaria elimination and an adequate programme to prevent re-establishment includes:

- a national elimination report;

- documents including written policies, processes and procedures of the programme that provide overall guidance or instructions for implementation of activities;
- records or information captured during performance, reporting or evaluation of a malaria activity;
- observations and findings from the independent evaluation mission; and
- other documentation, such as WHO documents and peer-reviewed journal articles.

The TAG-MEC carefully reviews and evaluates the evidence presented by the country and the findings of the independent evaluation mission and determines whether the evidence supports both criteria for certification.

3. Steps in certification of malaria elimination

WHO officially initiates a certification procedure once an official request for certification is sent from the government (usually the minister of health) to the WHO Director-General. National preparation for certification must, however, begin well before elimination is achieved to ensure that the essential documentation and records are available and organized to substantiate the country's claim of elimination.

The steps in certification of malaria elimination are shown in **Fig. 1** and listed below.

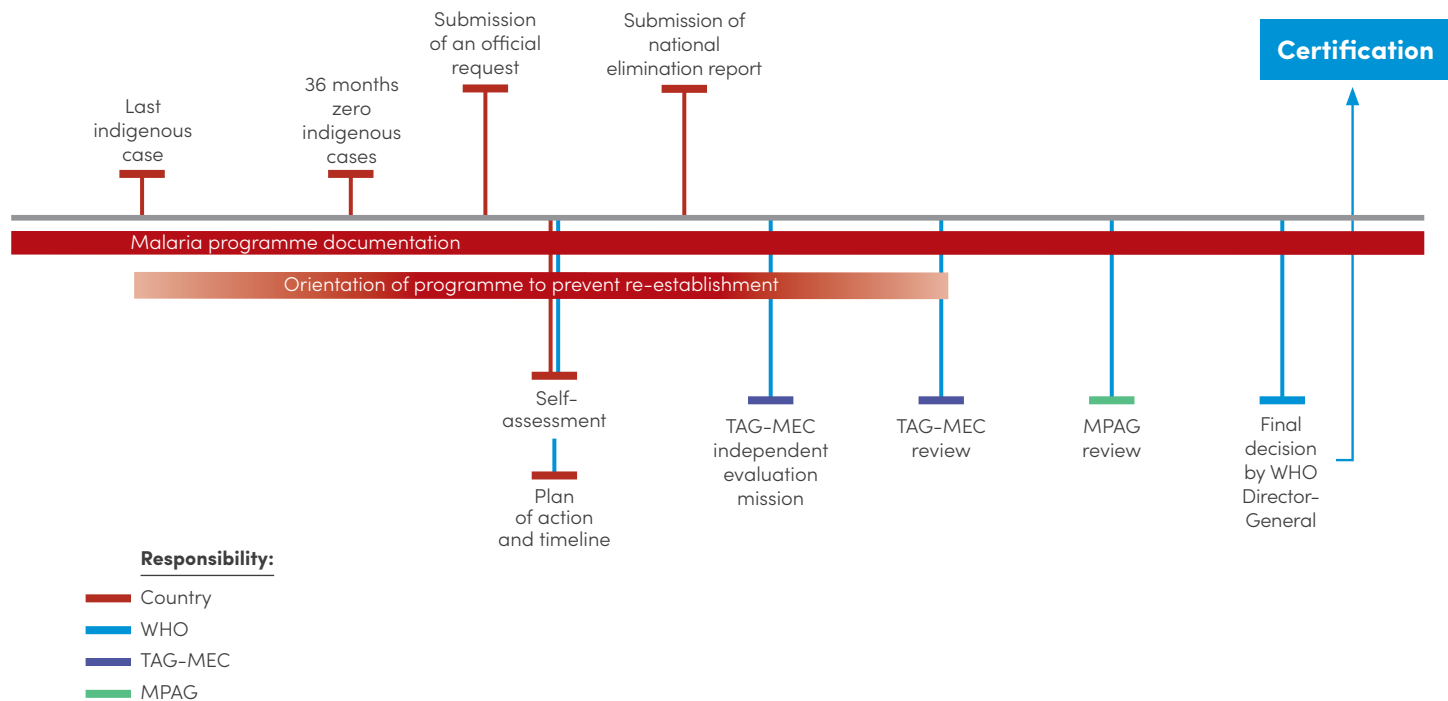
- 1. Documentation of an effective elimination programme:** In an effective elimination programme, records are generated routinely. Once a country embarks on elimination, the programme manager should ensure that all records of patients, samples and activities are retained according to legal requirements and for the time period requested by WHO (**Annex 1**).
- 2. Orientation of the elimination programme to prevent re-establishment:** Countries re-orient their elimination programmes to prevent re-establishment after elimination has been achieved in order to maintain their malaria-free status. The programme structure and surveillance might have to be changed to sustain malaria activities.
- 3. Official request:** After a country has reported zero indigenous malaria cases for at least the past 3 consecutive years (36 months) through a sensitive, robust surveillance system, the authorities submit an official request for certification to the WHO Director-General, through the WHO representative or the regional director if there is no WHO office in the country. WHO then officially initiates the certification procedure.

*An example of an official request for certification is provided in **Annex 2**. Completion of a national elimination report is not a precondition for submitting an official request for certification. The WHO Director-General will officially acknowledge receipt of the request.*

- 4. Readiness assessment:** Countries self-assess their readiness for certification with WHO assistance.
- 5. Plan of action and timeline:** In consultation with the WHO regional office and the WHO GMP, countries formulate a plan of action and timeline for certification.
*Examples of a plan of action and a timeline are provided in **Annex 3**.*
- 6. Submission of a national elimination report:** Countries finalize a national elimination report and submit it to the WHO GMP through their country and regional WHO offices.
*An outline of a national elimination report is found in **Annex 4**. The WHO GMP will officially acknowledge receipt of the report.*
- 7. Independent evaluation mission:** A subset of the TAG-MEC validates findings in the national elimination report by conducting an independent evaluation mission to the country.
The requirement for an independent evaluation mission might be waived for countries in which the last indigenous case was reported more than 15 years before submission of an official request for certification.
- 8. Consideration of evidence and recommendation:** The full TAG-MEC reviews the national elimination report and the report of the independent evaluation mission and reaches consensus on whether certification should be recommended or postponed.
- 9. Endorsement of the recommendation:** The WHO MPAG reviews the TAG-MEC recommendation to the WHO Director-General.
- 10. Certification:** The WHO Director-General makes a final decision and officially informs the government of the country in a letter to the minister of health.

After announcement of certification by WHO, a brief account of the country's achievement of elimination and certification is published in the *Weekly Epidemiological Record*. The country is subsequently listed in the official WHO *Register of areas where malaria elimination has been achieved* (5). The country continues work to prevent re-establishment of transmission and reports any malaria cases annually to WHO, until global malaria eradication is achieved.

FIGURE 1: Steps in certification of malaria elimination



4. National preparation for certification of malaria elimination

4.1 OVERSIGHT AND MANAGEMENT

Usually, the NMP oversees and manages national preparation for certification. If a country no longer has an NMP at the time it is eligible to request certification, a task force or working group can be set up to serve in its stead.

WHO recommends that countries establish an independent national malaria elimination advisory committee when they launch their elimination programme to provide an objective, external view of progress, address programmatic gaps and assist the country in achieving elimination and preparing for certification (3).³ If an independent national advisory committee was not formed before elimination, a national certification committee or its equivalent could be formed to assist in preparation.

Box 1 provides the example of the terms of reference of a national certification committee in Uzbekistan.

BOX 1.

Terms of reference for a national certification committee

1. Support coordination of all national entities engaged in certification of malaria elimination, and determine a plan of action with a specific timeline for completing national preparation.
2. Assist the national programme in gathering the documents and records required for certification and in preparing a national elimination report.
3. Support preparation for certification at subnational level.
4. Support assessment of the adequacy of the programme to prevent re-establishment of transmission.
5. Support assessment of readiness to receive the independent evaluation mission.

³ Generic terms of reference for an independent national malaria elimination advisory committee are provided in the *Framework for malaria elimination*.

The members of the national certification committee, like those of the independent national malaria elimination advisory committee, might include academics or retired government malaria experts, including epidemiologists, entomologists, health system specialists and representatives of other ministries and departments that contributed to malaria elimination or participate in prevention of re-establishment.

4.2 DOCUMENTATION OF AN EFFECTIVE ELIMINATION PROGRAMME

Documents and records are generated routinely in an effective national malaria programme. They capture lessons learnt along the way towards elimination and provide information to support a country's claims of malaria elimination and a functioning programme to prevent re-establishment of transmission. In the years prior to malaria elimination, and during the malaria-free period leading up to certification, NMPs should assess whether the activities and results are documented appropriately and ensure that documents and records are retained and organized to prepare evidence for certification.

The **documents** required consist of the essential guidelines for all the operations and activities of a programme. They provide written information on policies, processes and procedures and are updated when new evidence becomes available or there are changes in the health system. They help ensure accuracy and consistency in implementation of a programme and should be accessible to all relevant staff. The documents reflect a programme's organization and the quality of its management. For certification, the documents that countries should keep and present to the TAG-MEC are:

- national strategic and operational plans;
- strategies or plans of action for preventing re-establishment of malaria;
- legislation or regulations related to malaria and vector control;
- guidelines, manuals or standard operating procedures (SOPs) for surveillance, including forms for case notification, case investigation and focus investigation and response;
- manuals and SOPs for diagnostic quality assurance;
- malaria treatment guidelines, including guidelines on chemoprophylaxis for travelers;

- guidelines, manuals and SOPs for entomological surveillance and vector control; and
- memoranda of understanding for cross-border collaboration, if applicable.

The necessary **records** consist of information, written by hand or on a computer, recorded during the performance, reporting or evaluation of a malaria activity. They are used for many purposes, including continuous monitoring of implementation, evaluation of problems and management. Records should be complete, legible and carefully maintained. They should not be revised or modified without appropriate procedures such as dating, signing and explaining the reason for each change. The completeness and quality of the data (especially surveillance data) in records is essential to ensure the strength of the evidence to support the claim of elimination. Therefore NMPs must regularly validate the data with appropriate procedures (6).

The records that countries should retain and make available for review by the independent evaluation mission of the TAG-MEC can be grouped into three categories.

ROUTINE MALARIA CONTROL ACTIVITIES	TRAINING, MONITORING AND EVALUATION	OTHER RECORDS
<ul style="list-style-type: none"> • patient registers at health facilities • sample logs in laboratories • case notification forms • case investigation forms • malaria case database • focus register including maps • focus investigation forms • reports on activities and results of vector control and entomological surveillance • reports on activities and results of quality assurance for diagnosis 	<ul style="list-style-type: none"> • training for various cadres of health staff • supervision and monitoring, feedback to units receiving supervision • annual malaria programme reports and/or surveillance reports • malaria programme reviews or programme audits • self-assessment of readiness for certification • all results of subnational verification 	<ul style="list-style-type: none"> • reports of outbreaks and responses • meeting reports of the independent national malaria elimination advisory committee, multi-sectoral collaboration committee and cross-border meetings • reports on health education and raising awareness of health professionals, populations at risk of malaria and travelers to endemic areas • other records that the NMP considers may be useful for certification

The minimum requirements for documents and records for certification at different levels of the system and the periods they should cover are summarized in **Annex 1**. Some countries organize the documents and records required at the national level into folders to ensure ready retrieval during the independent evaluation mission (**Fig. 2**). At subnational level, documents and records might not necessarily be organized in folders but should be accessible at subnational health offices, health facilities and laboratories.

FIGURE. 2:
Organization of documents and records in folders in Uzbekistan



4.3 NATIONAL ELIMINATION REPORT

The national elimination report is a comprehensive summary of the country's work to eliminate malaria and is the main document used by the TAG-MEC to consider whether certification of malaria elimination should be granted to an applicant country. It is a narrative report that provides data and information to demonstrate that the country has met the two criteria for certification. The ministry of health is responsible for the credibility of the data and the information presented and submits the report to WHO on behalf of the government. Guidance on preparation of a national elimination report is provided in a template developed by GMP.⁴ **Annex 4** gives an outline of a national elimination report. While it is strongly recommended that countries prepare their reports according to the format and instructions provided in the template, some variation is expected, given differences among countries. The national elimination report should be provided to WHO preferably in English, although reports written in other official languages of the United Nations are also accepted.⁵ WHO will officially acknowledge receipt of the report.

⁴ A Word template with detailed instructions on preparing a national elimination report is available at the following link: <https://www.who.int/publications/m/item/national-malaria-elimination-report>

⁵ The six official languages of the United Nations are Arabic, Chinese, English, French, Russian and Spanish.

4.4 PREVENTION OF RE-ESTABLISHMENT OF TRANSMISSION

After malaria has been eliminated, countries should reorient their programmes to sustain the minimum activities necessary to prevent re-establishment. As malaria is no longer a primary public health problem when elimination is achieved, countries may integrate some of the functions of a previously dedicated or vertical malaria programme into other parts of the public health system. Measures should be taken, however, to ensure that malaria services, particularly curative, preventive and epidemiological services, remain operational during and after integration to prevent resurgence.

Certification requires a costed, government-approved plan for prevention of re-establishment of transmission and demonstration that key elements of the programme are functional.

4.4.1 National plan

A national plan for prevention of re-establishment of transmission should include the objectives to be achieved, the activities to be conducted, the timeline for implementation of activities and the roles and responsibilities of each participating sector (including non-health sectors). The plan should be endorsed by the government, and the resources necessary at central and subnational levels should be included in budgets to ensure implementation.

The risk that malaria transmission will be re-established in a country is heterogeneous, as it depends on the degree of receptivity of the ecosystem for malaria transmission and the risk of importation of malaria parasites. Receptivity and the risk of importation together determine the malariogenic potential of an area, which in turn should determine the intensity of surveillance, response activities and vector control that are necessary to prevent re-establishment. Countries should stratify their subnational units by malariogenic potential and consider the appropriate mix of interventions to be targeted to the different strata. In non-receptive areas, the goal of surveillance and case management is to detect and treat cases early to prevent serious clinical consequences of the disease, including death; thus, high-quality passive surveillance coupled with good case management is the appropriate mix of interventions. In receptive areas, the right mix of interventions will depend on the malariogenic potential, but, at a minimum, should include high-quality passive surveillance, good case management and case investigations (6). Countries should describe the strategies they will use, including vector control, to mitigate the risk of transmission in areas with high malariogenic potential.

As an imported case of malaria could be identified anywhere and at any time, malaria case management and surveillance for the disease must be functional throughout the country. Nevertheless, as malaria is eliminated and cases become rare, health care providers will naturally become less familiar with the disease. Thus, the plan for prevention of re-establishment should include activities to maintain vigilance for malaria in general health services to avoid delayed diagnosis and treatment.

4.4.2 Key elements of a programme for preventing re-establishment of transmission

As malariogenic potential differs (e.g. risk of importation of malaria cases, species of malaria vectors, the physical environment, levels of social and economic development, the strength of the health system), the activities necessary to prevent re-establishment of malaria transmission will also differ, as will the cost of maintaining malaria-free status. Nevertheless, appropriate financing and human resource must be sustained in every country so that the system maintains the capacity to detect and respond to malaria cases, should they occur, in a timely, effective manner to prevent severe clinical consequence and onward transmission.

Countries that interrupted indigenous transmission should consider a number of key elements to ensure the adequacy of a programme to prevent re-establishment.

- **National structure:** A national structure (e.g. a unit or a focal point) should be in place to oversee and coordinate effective implementation of the activities defined in the plan to prevent re-establishment, even if the NMP no longer exists.
- **Surveillance and response:** An effective surveillance and response system should be in place to ensure that all suspected malaria cases are tested, treated, notified, investigated and responded to promptly and that malaria outbreaks are detected early and contained effectively (6). The country must have a strategy to maintain the quality and coverage of surveillance and response.
- **Malaria diagnosis network:** The network of laboratories (or testing centres) in the country should be able to provide quality-assured parasitological confirmation of malaria infections (7) and confirm the clearance of infection. A programme for periodic assessment of the competence of laboratory staff must be in place and functional.
- **Case management:** Good-quality malaria diagnosis and treatment services (8) should be available throughout the country and to everyone, irrespective of nationality. General health services must maintain vigilance for prompt detection and treatment of any malaria cases that might occur.

- **Vector control and entomological surveillance:** In areas with high malariogenic potential, entomological surveillance and vector control must be maintained in order to reduce the likelihood of onward transmission from imported parasites (6). Capacity to conduct vector control as part of a response to interrupt local transmission during outbreaks must be maintained in all receptive areas. Countries should have a strategy to sustain necessary entomological surveillance.
- **Multisectoral collaboration:** Coordination and collaboration with non-health sectors are important to ensure optimal coverage and use of interventions in high-risk populations and to ensure the impact and efficiency of those interventions.
- **Inter-country information sharing and border collaboration:** Effective coordination and communication between bordering countries can help mitigate the risk of re-establishment, particularly in areas bordering countries with ongoing transmission, where the malariogenic potential is frequently high.
- **Raising awareness and providing preventive strategies for travellers:** Early detection of malaria cases can be improved by raising the awareness of health practitioners and travellers to and from malaria-endemic countries. Countries should provide advice to travellers to endemic countries on malaria risk, avoiding mosquito bites and chemoprophylaxis (9). Chemoprophylaxis may significantly reduce the risk of infection and severe disease and should therefore be made available to travellers to endemic countries.

A checklist of elements for assessing the adequacy of national programmes for preventing re-establishment of transmission of malaria is given in **Annex 5**.

4.5 SELF-ASSESSMENT OF READINESS FOR CERTIFICATION

The purpose of self-assessment is to ensure the availability of the evidence that the two criteria for certification have been met. The assessment of readiness for certification is organized by the ministry of health and could be implemented by the NMP, the independent national malaria elimination advisory committee or a certification committee. Coordination and engagement with other departments and sectors that participate in malaria elimination and prevention of re-establishment is necessary in self-assessment. WHO conducts field visits jointly with the ministry of health to provide technical support to prepare for certification and an external point of view on the readiness for certification. The results of the joint mission of WHO and the ministry of health will inform a plan of action and timeline for certification.

Methods for self-assessment of readiness for certification include desk reviews and field visits. As the coverage and quality of the surveillance and response system and its probable sustainability after elimination are essential for determining whether the country has met the two certification criteria, the performance of the surveillance and response system should be a priority in the self-assessment. Results of the self-assessment and any other evaluations are important records and should be retained for certification (6).

Three components should be assessed for readiness for certification.

- **Documents and records.** The completeness of documents and records should be assessed according to the requirements for certification (**Annex 1**). At national level, countries are expected to compile the necessary documents and records systematically, so that they can be retrieved readily. Countries should ensure that documents such as guideline and SOPs are up to date, available and accessible to staff who need them. For example, SOPs for quality-assured diagnosis should be available in laboratories while treatment guidelines should be available in health facilities. Original records should be stored in the health facilities and laboratories that generated the data, with copies available at higher levels. The completeness and quality of data must be reviewed as part of the self-assessment. For example, countries should determine whether the data from the national malaria database is consistent with that on the original records in health facilities and laboratories, whether all case notification and investigation forms were filled in completely, and whether the evidence in the case investigation form is adequate to support the case classification.
- **National elimination report.** The report should be based on the template provided in **Annex 4**. The ministry of health might consider inviting senior malaria experts or the independent national elimination advisory committee to review and verify the report to ensure its quality.
- **Programme to prevent re-establishment of transmission.** As part of self-assessment of the programme to prevent re-establishment of transmission, countries should evaluate whether the curative, preventive and epidemiological services are fully functional throughout the country (3). "Fully functional" means not only that policies, strategies, written guidelines and SOPs are in place to provide guidance for the implementation of activities but also that staff are well trained and competent to provide the required services. The assessment of whether the national health system will be able to prevent re-establishment of malaria transmission should include a review of the sustainability of financial and

human resources, the quality and coverage of malaria surveillance and response, diagnostic capacity and its sustainability and the capacity for entomological surveillance and vector control. **Annex 5** provides a list of the elements required to assess the adequacy of a programme to prevent re-establishment of transmission.

4.6 INDEPENDENT EVALUATION MISSION

WHO requests a group of malaria experts from the TAG-MEC to validate the findings of the national elimination report during an independent evaluation mission to the country.

4.6.1 Timing

The timing of the independent evaluation mission depends on the country's progress in preparing all the required documentation and records, its preparedness to prevent re-establishment of transmission, the results of the joint assessment mission by WHO and the ministry of health, the timing of submission of the national elimination report, the availability of the members of the TAG-MEC and the availability of the country to receive the mission. WHO and the ministry of health will agree on the dates for the mission.

4.6.2 Support expected from the country

The NMP is expected to provide support in drafting and finalizing the itinerary and agenda of the TAG-MEC independent evaluation mission, in coordination with the WHO secretariat. The support could include information on the availability of transport, distances between areas and clearances required for the mission. At least one national representative, usually the national programme manager, should accompany the team on the independent evaluation mission and coordinate with subnational health authorities. The cost of the participation of nationals in the mission is expected to be borne by the government.

4.6.3 Composition of an independent evaluation mission

The team members for an independent evaluation mission are a selected subset of the TAG-MEC and may include ad hoc members. The members determine the activities of the mission, including the locations for field visits, in consultation with WHO, and are responsible for the conclusion of the mission. In addition to national representatives of the ministry of health, WHO staff may join the mission as observers and provide coordination and support.

4.6.4 Activities of an independent evaluation mission

The independent evaluation mission verifies the data provided in the national elimination report by examining documents, records and interviews. The team also assesses the quality of surveillance, the level of vigilance and the quality of other malaria services during field visits.

Team members usually arrive in the capital, where they visit the ministry of health and the office of the NMP to orient themselves to the health system and the malaria programme. Visits are also made to financial and other departments to assess the human and financial resources invested in malaria and the likelihood of their sustainability. The team reviews supporting documents and records made available at national level, including the database of malaria cases and foci. Depending on the number of cases and foci in the country in the previous few years, the team might review all or a sample of case and focus investigation forms to determine whether the investigations were properly conducted and whether the case classifications were justified.

The sites for field visits are selected by the members of the mission. Considerations for areas to be visited include: the locations where the last indigenous cases occurred; areas with high malariogenic potential; localities with recent or past outbreaks; areas with multiple potential malaria vectors; and locations with high-risk populations, such as temporary workers, border communities, undocumented migrants, refugees and indigenous populations. The team may decide to visit areas in which there has been no malaria transmission for a number of years, if they consider it necessary.

The team will visit public and private health facilities, laboratories, pharmacies and epidemiological services at different levels of the system, international points of entry and other government departments and sectors that contributed to malaria elimination or participate in prevention of re-establishment. The purpose of visits to health facilities and laboratories is to determine the coverage and the quality of malaria services and to assess their sustainability. During these visits, the team will review documents and records and cross-check the data from various administrative levels against information presented in the national elimination report. The team will meet health staff to understand better how the malaria programme was implemented, factors that contributed to the achievement of elimination and the strategies that will be used to sustain malaria-free status. The team interviews public and private health practitioners in peripheral areas to determine the level of vigilance for malaria in the general health services and thus the likelihood that malaria cases will be detected, confirmed cases will be promptly and appropriately treated and interventions will be rapidly deployed to prevent or interrupt transmission. The team may visit facilities that are likely to underreport

cases to the surveillance system, including private pharmacies, private medical practitioners, drug vendors and military and other health services to determine the completeness of case reporting.

When security concerns prohibit the independent evaluation mission from visiting certain areas of a country that they have proposed for field visits, their activities can be modified to include off-site interviews with local staff, virtual meetings and desk reviews of data from the affected areas. In exceptional circumstances, when security concerns or travel restrictions, including the impact of the COVID-19 pandemic, prevent an independent evaluation mission from taking place as described, its postponement will be considered. If the exceptional situation is unlikely to be resolved in the foreseeable future, however, additional modifications that will not impair the integrity of the process may be adopted. In addition to virtual meetings, such modifications could include deployment of national or international experts to conduct the field assessments as external evaluators under the guidance of the TAG-MEC. Only members of the TAG-MEC will decide on and recommend certification, including under such exceptional circumstances. Significant modifications to the independent evaluation mission proposed by WHO secretariat will be reviewed and approved in advance by the TAG-MEC and the MPAG.

The team will brief the ministry of health on their findings after the field visits have been completed. The conclusions and recommendations presented by the team represent the views of the team members who conducted the independent evaluation mission and not those of the full TAG-MEC or of WHO. **Annex 6** provides a generic agenda for an independent evaluation mission.

4.7 GRANTING AND MAINTAINING CERTIFICATION

The TAG-MEC will meet to discuss the national elimination report and the findings of the independent evaluation mission and will reach consensus on whether certification should be recommended or postponed. The main activities of the TAG-MEC during the certification procedure will be summarized in a short report and reviewed by the MPAG, the role of which is to ensure that the procedure has been conducted according to the SOPs. The WHO Director-General will review the recommendation of the TAG-MEC and take a final decision on certification. The government will be informed of the decision in a letter to the minister of health.

After certification, countries continue to implement the programme to prevent re-establishment of malaria transmission and are expected to report at least annually on confirmed malaria cases detected, by species, case classification and origin of cases for the *World Malaria Report*.

Countries should immediately report any indigenous cases or outbreaks to WHO so that the Organization can advise on further action to prevent re-establishment. A minimum indication of possible re-establishment of transmission is the occurrence of three or more indigenous malaria cases of the same species per year in the same focus for 3 consecutive years. As certification represents recognition of a considerable operational achievement by a country, a careful investigation and consultation with the TAG-MEC will be conducted before a country's malaria-free certification status is revoked.

5. Verification of subnational malaria elimination

Verification of subnational malaria elimination may be an option in large countries and those with subnational elimination goals. It can promote ownership of malaria elimination in subnational areas and strengthen the commitment of local government to prevent re-establishment. Subnational verification can help strengthen surveillance and response systems and prepare the country for national certification, although it is not a prerequisite for national certification. WHO provides technical assistance to countries for subnational verification by advising them on the procedure to be used. WHO does not, however, provide external validation of elimination at subnational level, which is overseen by the country itself.

5.1 OVERSIGHT AND MANAGEMENT

A national authority, usually the ministry of health, is responsible for deciding on the method and granting malaria-free status to areas of the country that have met national criteria for subnational elimination. The independent national malaria elimination advisory committee (if there is one) or a national certification committee could be entrusted by the ministry of health to oversee subnational verification. As an example, the terms of reference of such a committee in subnational verification in China are listed in **Box 2**.

Depending on the number of subnational areas (states, regions or provinces) that request verification, countries might send experts who are not members of the national certification committee to join the evaluation team in field visits. These might be academic or retired government malaria experts, health system specialists or entomologists. Personnel from subnational health authorities and programmes in the areas requesting verification should not participate in assessment of their own states, regions or provinces but could be deployed to other subnational areas.

BOX 2.

Terms of reference for a national certification committee overseeing verification of subnational elimination

1. Establish the method and procedures for subnational verification, and pilot-test them in at least one subnational area.
2. Review the subnational elimination report and supporting documents and records submitted by the government of the subnational area.
3. Form an evaluation team to conduct field visits to verify the data and information presented in the subnational elimination report and to determine that there has been no indigenous cases in at least the past 3 consecutive years (36 months) and that activities are in place to prevent re-establishment of transmission.
4. Recommend to the ministry of health that the subnational area can be declared malaria-free.

5.2 CRITERIA FOR VERIFICATION OF SUBNATIONAL MALARIA ELIMINATION

The criteria used in verifying subnational elimination should be similar to those for national certification.

The evidence used to evaluate a claim of malaria elimination in a subnational area and to verify that effective activities are under way to prevent re-establishment is similar to that used for national certification. It comprises:

- a subnational elimination report;
- documents and records;
- observations and findings from a subnational verification mission and
- additional documentation, such as peer-reviewed journal articles.

5.3 STEPS IN VERIFICATION OF SUBNATIONAL ELIMINATION

The steps in subnational verification are likely to vary from country to country according to the structure of their health system and the

organization of malaria activities. Engagement with subnational government authorities is recommended, not only because it indicates recognition of their leadership and their contribution to malaria elimination but also because it will strengthen and sustain political commitment to prevent re-establishment in the area. National and local authorities have different roles in subnational verification: national authorities verify the malaria free-status of subnational areas, in effect validating the achievements of local authorities.

The steps in subnational verification might include the following.

1. The national authority designs a method for subnational verification, using the WHO national certification process as a reference.
2. The health department of the state, region or province submits a request to the national authority for subnational verification on behalf of the local government authority.
3. The subnational health department submits a subnational elimination report and compiles the supporting documents and records required.
4. Upon receiving the request, the national authority organizes a subnational verification mission. An evaluation team formed by malariologists and experts in other areas, such as public health and entomology, reviews the subnational elimination report and other documents and records and conducts field visits to verify the information. Countries might invite international malaria experts to participate in subnational verification.
5. The evaluation team reports their findings and recommendation about whether the area should be declared malaria-free.
6. The national authority makes a final decision to grant malaria-free status to the state, region or province.

5.3.1 Subnational elimination report, supporting documents and records

The subnational elimination report describes the characteristics of malaria transmission in the subnational area, summarizes activities undertaken to achieve malaria elimination, presents evidence that elimination has been achieved and describes the activities under way to prevent re-establishment. It should follow the format of the national elimination report so that the data and information can be readily integrated into the final national elimination report when the country applies for WHO certification.

Countries should decide which documents and records are to be used for subnational verification, with reference to the minimum documentation required by WHO for national certification (**Annex 1**).

5.3.2 Subnational verification mission

The subnational verification mission is an important part of subnational verification. Its objectives are to verify the data presented in the subnational elimination report and the supporting documents and records and to assess the adequacy of activities to prevent re-establishment of transmission in the area. As surveillance is important to both objectives, the mission should prioritize verification of core functions and the quality of the surveillance system (6), the vigilance of the general health services and whether the last foci were cleared of transmission (zero indigenous cases in the past 3 consecutive years).

The principles for selecting locations for field visits are the same as for national certification, as described above. Countries might refer to the list of elements required for prevention of re-establishment (**Annex 5**) and the generic agenda for an independent evaluation mission (**Annex 6**) to determine the activities and agendas of field visits. **Annex 7** provides an example of subnational verification in China.

5.4 ANNOUNCEMENT OF VERIFICATION OF MALARIA-FREE STATUS IN SUBNATIONAL AREAS

On the basis of the recommendation of the entity overseeing subnational verification, the ministry of health decides whether malaria elimination has been achieved in the region, state or province. The ministry of health is encouraged to publish and announce verification of malaria-free status in subnational areas as a means of recognizing the significance of this public health achievement and encouraging other subnational areas to pursue subnational elimination.

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Annexes

ANNEX 1. DOCUMENTATION REQUIRED FOR CERTIFICATION OF MALARIA ELIMINATION

Countries are expected to compile the national-level documents and records required systematically so that they can be retrieved readily. At subnational level, documents such as SOPs and guidelines should be accessible to staff who use them. Records should be kept in subnational health offices, health facilities and laboratories where the original data were generated.

The time chart below illustrates the period that each required document or record should cover. "Elimination" is the month in which a country reports its last indigenous case. "-10" (or "-1") represents 10 years (or 1 year) before the last indigenous case, when transmission was ongoing. "1" (or "2") represents the first (or the second) year after the last indigenous case. "Present" is the point in time when the country receives the independent evaluation mission, which can occur only after a country has reported zero indigenous cases for at least 3 years (36 months). "Present" represents any year after a country becomes eligible for certification. The reference period to be covered by each required document or record is highlighted in orange in each row of the table.

Ongoing transmission										Elimination		Eligible for certification			
-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6
REQUIRED DOCUMENTS AND RATIONALE										AVAILABILITY OF DOCUMENTS AND RECORDS					
										National level		Subnational level		Health facility and laboratory	
Plans, reports and legislation															
1. National malaria elimination strategic plan and operational or implementation plans To understand how the country got to zero indigenous cases and provide an overview of the elimination strategy										✓					
-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6
Reference time period: -5 to elimination															
2. Plan of action for the prevention of re-establishment of malaria transmission To assess the likelihood that malaria-free status can be maintained in the country										✓					
Reference time period: present															

REQUIRED DOCUMENTS AND RATIONALE	AVAILABILITY OF DOCUMENTS AND RECORDS															
	National level				Subnational level				Health facility and laboratory							
3. Annual malaria programme reports^a To provide an overview of malaria activities undertaken and evidence that an annual review system is in place to monitor programme progress and optimize response																
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6
Reference time period: -5 years to present																
4. Recent published and unpublished reports of studies on malaria epidemiology and malaria vectors^b To provide evidence for current strategies to prevent re-establishment																
Reference time period: Any reports that the programme believes may support the current strategies to prevent re-establishment																
5. Legislation or regulations related to malaria and vector control To demonstrate that malaria is a mandatory notifiable disease																
Reference time period: All current legislation																
Surveillance																
6. Guidelines and SOPs for malaria surveillance To assess that the design of the surveillance system is appropriate for prevention of re-establishment																
Reference time period: Current guidelines ^c																
7. Annual malaria surveillance reports^d To show changes in malaria transmission over time																
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6
Reference time period: -5 years to present																
8. Malaria case database To provide information on cases for assessment of the surveillance system and to understand the epidemiology of malaria over time. ^e																
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6
Reference time period: -10 years to present																

REQUIRED DOCUMENTS AND RATIONALE	AVAILABILITY OF DOCUMENTS AND RECORDS																			
	National level					Subnational level					Health facility and laboratory									
9. Malaria case investigation and notification forms The original case investigation and notification forms must be provided to permit evaluation of the completeness of data collection and accuracy of case classification																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: –5 years to present ^f																				
10. Focus register, including focus investigation forms and maps Including reports on focus management and response to demonstrate effectiveness of activities to interrupt transmission in the last foci ^g																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: –5 years to 3																				
Diagnosis																				
11. SOPs and bench aids for malaria diagnosis To demonstrate that laboratories have correct guidance, aligned with that of WHO																				
Reference time period: Current document																				
12. Reports (or records) of quality control and assurance activities for diagnosis To demonstrate that the quality of malaria diagnosis is assured in the country and the capacity is likely to be sustained																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: 0 to present																				
13. Sample (laboratory) register To validate case notifications against source material and to assess the quality of surveillance data																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: –5 years to present																				

REQUIRED DOCUMENTS AND RATIONALE	AVAILABILITY OF DOCUMENTS AND RECORDS													
	National level					Subnational level					Health facility and laboratory			
Case management														
14. National malaria treatment guidelines^h To determine whether guidelines are aligned with current WHO recommendations	✓					✓					✓			
Reference time period: Current guidelines (any past guidelines can be included)														
15. Patient log or register To determine the completeness and quality of malaria treatment and to assess the consistency of surveillance data											✓			
-10 -9 -8 -7 -6 -5 -4 -3 -2 -1 1 2 3 4 5 6														
Reference time period: –5 years to present														
Vector control														
16. Guidelines or SOPs for entomological surveillance and vector control To determine whether guidelines are appropriate and aligned with WHO recommendations	✓					✓								
Reference time period: Current guidelines (any past guidelines can be included)														
17. Annual reports of entomological and vector control activities To understand how the country arrived at zero indigenous cases and whether activities are appropriate to prevent re-establishment	✓					✓								
-10 -9 -8 -7 -6 -5 -4 -3 -2 -1 1 2 3 4 5 6														
Reference time period: –5 years to present														
Enabling environment to support elimination and prevention of re-establishment of transmission														
18. Reports of multi-sectoral collaboration To demonstrate that multi-sectoral collaboration was in place during the elimination phase and will support the country's plan to prevent re-establishment	✓					✓								
-10 -9 -8 -7 -6 -5 -4 -3 -2 -1 1 2 3 4 5 6														
Reference time period: –5 years to present ⁱ														

REQUIRED DOCUMENTS AND RATIONALE	AVAILABILITY OF DOCUMENTS AND RECORDS																			
	National level				Subnational level				Health facility and laboratory											
19. Reports of cross-border coordination activities^j To document cross-border collaboration to support elimination and prevention of re-establishment																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: –5 years to present																				
20. Documentation of health education and community awareness-raising^k To demonstrate that health education and community engagement were used to achieve elimination and will support the country's plan to prevent re-establishment																				
	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6				
Reference time period: –5 years to present																				

- ^a The annual programme report can be combined with the annual surveillance report. Training activities may be included in the annual programme report or presented separately.
- ^b Results of operational research should be included.
- ^c If guidelines and SOPs for malaria surveillance have changed after countries report zero indigenous cases, the previous guidelines and SOPs of the surveillance system during the elimination phase should be included.
- ^d This may be combined with the annual malaria programme report. Records of surveillance assessments should be included, if available.
- ^e The malaria case database should be electronic, and access should be provided to WHO pre-certification and independent evaluation mission teams. Subnational authorities should have access to or copies of the database that include the cases diagnosed or infected in their jurisdiction.
- ^f The investigation forms for all cases identified during the previous 3 years (36 months) of zero indigenous cases, at least, must be made available.
- ^g The focus register is a database of all focus investigations and the activities for management and response. Countries that did not use a focus approach should provide equivalent reports on how transmission was interrupted during the 5 years before the country reached zero indigenous cases.
- ^h If the national treatment guidelines are not aligned with WHO recommendations, countries should provide justification for any differences.
- ⁱ Reports on multi-sectoral collaboration before reaching zero indigenous cases should be included to demonstrate the established collaboration mechanism, if available. Meeting reports, agreements such as memoranda of understanding, action plans and implementation reports should be included, if available.
- ^j Includes meeting reports, signed agreements, action plans and implementation reports. Reports on cross-border collaboration before reaching zero indigenous cases should be included, if available.
- ^k Reports on relevant health education programmes or other relevant activities.

ANNEX 2. AN EXAMPLE OF AN OFFICIAL LETTER TO REQUEST CERTIFICATION OF MALARIA ELIMINATION*

To: *[Name of Director-General]*
Director-General
World Health Organization
Geneva, Switzerland

The letter should be sent to the current WHO Director-General

Dear *[name of Director-General]*

I am writing to inform you that the Ministry of Health of *[country name]* has registered a satisfactory result in eliminating malaria. The last indigenous case of malaria occurred more than 36 months ago, on *[date]*. Our country is implementing a plan to prevent re-establishment of malaria transmission to maintain our malaria-free status.

To describe the purpose of the letter. Provide the date of the last indigenous case of malaria.

This success has been the result of many decades of effort and great sacrifice on the part of our health care workers. Our country is pleased to contribute to the global vision of a world free of malaria.

Briefly describe how malaria elimination is achieved

I would like to request WHO to initiate the process of certification of malaria elimination in *[country name]*. We will be pleased to provide all the necessary support for completing the process of certification of malaria elimination.

Request WHO to initiate the certification process

[Signature]

Minister of Health

Minister of Health should sign off the letter, on behalf of the Government

* The letter should be sent to the WHO Director-General through the WHO representative or the regional director if there is no WHO office in the country.

ANNEX 3. PLAN OF ACTION AND TIMELINE FOR CERTIFICATION

The duration of the certification procedure after submission of an official request varies significantly by country for several reasons, including the time necessary for countries to finalize, translate and submit their national elimination reports, their readiness to receive an independent evaluation mission, the availability of TAG-MEC members and the time required to prepare for an independent evaluation mission. Once WHO receives a final version of the national elimination report, certification may take a minimum of 4 months.

	ACTIVITY	RESPONSIBLE PARTY	REMARKS
1	Submit an official request	Ministry of health	Countries should approach WHO as early as possible when at least 3 consecutive years (36 months) have passed without an indigenous case and a decision has been taken to apply for certification.
2	Submit the national elimination report to WHO	Ministry of health	The national elimination report should be provided to WHO preferably in English. Reports written in other official languages of the United Nations are also accepted.
3	Review of the national elimination report	TAG-MEC	The TAG-MEC requires a minimum of 4 weeks to complete its review.
4	Independent evaluation mission	Subset of TAG-MEC	In general, missions last 2 weeks, but the duration may depend on the size of the country and the complexity of the malaria situation.
5	Mission evaluation report	Subset of TAG-MEC	The TAG-MEC requires a minimum of 4 weeks to complete its evaluation report after conclusion of the independent evaluation mission.
6	Review and discussion of the mission evaluation report and recommendation on certification	TAG-MEC, GMP	Meetings of the TAG-MEC are generally scheduled once a year.
7	MPAG reviews and concurs with the recommendation of the TAG-MEC	MPAG, GMP	Within 2 weeks of TAG-MEC recommendation
8	Decision made by the WHO Director-General	WHO Director-General	Within 3 weeks of concurrence by the MPAG

ANNEX 4. OUTLINE OF A NATIONAL ELIMINATION REPORT

A Word template with detailed instructions on preparing a national elimination report is available at the following link: <https://www.who.int/publications/m/item/national-malaria-elimination-report>.

Executive summary

1. General information

- 1.1 Geography
- 1.2 Ecological regions
- 1.3 Climate
- 1.4 Population and its movements
- 1.5 Economy
- 1.6 Health profile
- 1.7 Description of health system and organization of health services

2. Malaria in the country

- 2.1 History
- 2.2 Epidemiology
- 2.3 High-risk populations and hard-to-reach areas
- 2.4 Last indigenous malaria cases and foci in the country
- 2.5 Entomological aspects of malaria transmission

3. Organizational structure of national malaria programme

- 3.1 Programme
- 3.2 National malaria elimination advisory committee
- 3.3 Malaria partner organizations

4. Strategies and activities undertaken to eliminate malaria

- 4.1 Legislation and regulations relevant to malaria elimination
- 4.2 Stratification and targeted strategies
- 4.3 Surveillance and response systems
- 4.4 Monitoring and evaluation of the surveillance system
- 4.5 Malaria diagnosis
- 4.6 Case management
- 4.7 Vector control and entomological surveillance
- 4.8 High-risk populations and hard-to-reach areas
- 4.9 Operational research

- 4.10 Public health education and community engagement
- 4.11 Inter- or multi-sectoral collaboration
- 4.12 Cross-border coordination and collaboration

5. Prevention of re-establishment of malaria transmission

- 5.1 Overview
- 5.2 Stratification by receptivity and risk of importation
- 5.3 Surveillance and response system
- 5.4 Malaria diagnosis
- 5.5 Case management
- 5.6 Vector control and entomological surveillance
- 5.7 Travellers' health
- 5.8 Public health education
- 5.9 Inter- and multi-sectoral collaboration
- 5.10 Cross-border coordination and collaboration
- 5.11 Monitoring and evaluation of the plan to prevent re-establishment of transmission

6. Budget for malaria

7. Annexes

Annex 1. Results of surveillance assessment by administrative divisions

ANNEX 5. CHECKLIST OF ELEMENTS FOR PREVENTION OF RE-ESTABLISHMENT OF MALARIA TRANSMISSION

CRITICAL ELEMENT	MILESTONES
<p>1.</p> <p>National plan for prevention of re-establishment of transmission</p> <p>The plan should define the objectives to be achieved, the activities to be conducted, the entities responsible for conducting the activities, the resources necessary at central and subnational levels and the timeline for implementation. The plan should be reviewed regularly to adapt to changes in malariogenic potential.</p>	<p>1.1</p> <p>The plan is appropriate, costed and endorsed by the government.</p>
	<p>1.2</p> <p>The plan defines the roles and responsibilities of different sectors (including non-health sectors) involved.</p>
	<p>1.3</p> <p>An updated map of the country stratified by receptivity and risk of importation, at a minimum, is included in the plan to prevent re-establishment. Key interventions at different strata are described.</p>
	<p>1.4</p> <p>A sufficient budget is allocated for implementation of activities, and finances have been mobilized to support the plan.</p>
<p>2.</p> <p>National programme structure</p> <p>All programmes require a central structure for oversight of implementation of national strategies, to provide technical leadership, set policies and guidelines, coordinate national training, and evaluate overall progress.</p>	<p>2.1</p> <p>A central unit is responsible for preventing re-establishment of malaria transmission.^a If the functions of the central structure are shared among several entities or institutions, their roles and responsibilities are clearly defined and coordination among different entities is effective.</p>
	<p>2.2</p> <p>The national structure is effective in overseeing implementation of activities, coordinating national training, monitoring disease trends, reporting malaria cases and coordinating outbreak response.</p>
<p>3.</p> <p>Diagnosis</p> <p>The network of laboratories (or testing centres) is functional and can provide quality-assured parasitological confirmation of malaria infection to all populations. A microscopy quality assurance system is in place and functional.</p>	<p>3.1</p> <p>A national focal point or coordinator has been appointed to oversee the quality assurance programme.</p>
	<p>3.2</p> <p>An official national reference laboratory has been designated.^b</p>
	<p>3.3</p> <p>The roles and responsibilities of institutions engaged in quality assurance at national and subnational levels are defined.</p>

CRITICAL ELEMENT	MILESTONES
<p>3.</p> <p>Diagnosis (cont.)</p>	<p>3.4</p> <p>A group of highly competent microscopists has been identified as the core group for the national quality assurance programme. It is preferable that all are certified through an external competence assessment.^c</p>
	<p>3.5</p> <p>All microscopists receive regular training, re-training and competence assessments.^d</p>
	<p>3.6</p> <p>An internal quality assurance system, particularly for Giemsa staining and cross-checking of blood slides, is in place.</p>
	<p>3.7</p> <p>At least one of the following approaches is used for external quality assessment: regular on-site supportive supervision, proficiency testing (or direct evaluation) or blinded cross-checking of slides by laboratories at different levels.^e</p>
	<p>3.8</p> <p>Laboratories or diagnostic (testing) centres are well staffed and equipped with adequate diagnostic capacity and good record-keeping.^f</p>
	<p>3.9</p> <p>Written SOPs and bench aids are available in all laboratories.</p>
	<p>3.10</p> <p>Microscopists and laboratory technicians follow SOPs, as evidenced by good-quality stained blood slides and accurate readings.</p>
	<p>3.11</p> <p>Laboratory consumables and reagents are supplied continuously, with no stock-outs.</p>
	<p>3.12</p> <p>Rapid diagnostic tests, if used in the country, are WHO-prequalified and appropriately target the malaria species most common in the country or likely to be imported.</p>
	<p>3.13</p> <p>Written SOPs and bench aids for use of rapid diagnostic tests for malaria are available and used according to the manufacturer's guidance.</p>
	<p>3.14</p> <p>Rapid diagnostic tests are available at health facilities.^g</p>

CRITICAL ELEMENT	MILESTONES
<p>3.</p> <p>Diagnosis (cont.)</p>	<p>3.15</p> <p>When applicable, health facility staff are trained and proficient in using and interpreting rapid diagnostic tests.^h</p> <p>3.16</p> <p>Outreach training and supportive supervision are provided to support use of rapid diagnostic tests in peripheral health facilities.</p>
<p>4.</p> <p>Case management</p> <p>A system that provides good-quality curative services is functional throughout the country.</p>	<p>4.1</p> <p>Written national treatment guidelines are available in all health facilities that provide malaria treatment and are aligned with WHO guidance, including for severe malaria.</p> <p>4.2</p> <p>A programme to raise awareness among general health care providers is in place to maintain vigilance. General health care providers are vigilant in suspecting malaria in patients with fever and a history of travel to or from a malaria-endemic area, and they are aware of the availability of diagnosis and treatment in the country.</p> <p>4.3</p> <p>Training in malaria diagnosis and case management, including updated malaria information, is provided to health practitioners who provide malaria diagnosis and treatment.</p> <p>4.4</p> <p>A functional referral system is in place to refer patients with severe malaria to hospitals.</p> <p>4.5</p> <p>Sufficient treatment courses are available when and where needed; stock-outs of antimalarial drugs are prevented.</p>
<p>5.</p> <p>Surveillance and response system</p> <p>A system of early detection, treatment, mandatory notification, case and focus investigation is in place throughout the country. The capacity and the quality of case investigation, malaria outbreak investigation and response are maintained; all malaria cases are investigated, and the collected information is kept in the national case database.</p>	<p>5.1</p> <p>Written surveillance guidelines (SOPs, manuals, guidelines) for passive, proactive and reactive case detection, case reporting and case investigations are available, aligned with WHO recommendations and implemented.</p> <p>5.2</p> <p>Regular task-based training in surveillance is provided to provincial, district or health facility staff responsible for case notification, investigation and classification.ⁱ</p> <p>5.3</p> <p>Private clinics and providers that see patients with fever are trained in appropriate surveillance procedures.</p> <p>5.4</p> <p>By law, malaria is a notifiable disease, and a protocol for case notification exists, including for the private sector.</p>

CRITICAL ELEMENT	MILESTONES
<p>5.</p> <p>Surveillance and response system (cont.)</p>	<p>5.5</p> <p>A suspected case is clearly defined in guidelines and SOPs.</p>
	<p>5.6</p> <p>All suspected cases are tested for malaria by microscopy or with rapid diagnostic tests and results are reported.^l</p>
	<p>5.7</p> <p>The minimum data for each case are recorded electronically.^k</p>
	<p>5.8</p> <p>Case-based data are reported to provincial, district and national levels according to protocol.</p>
	<p>5.9</p> <p>Private, military, police, faith-based and nongovernmental organization clinics also report case-based data to the ministry of health.</p>
	<p>5.10</p> <p>The strategy and guidelines for the proactive case detection strategy (objectives, high-risk populations, geographical units, timing) are available, appropriate and implemented.</p>
	<p>5.11</p> <p>Case investigation forms elicit minimal essential data (patient demographics, residence, illness history, diagnostic test results, treatment, travel history) for case classification, are available and are fully completed for each case.</p>
	<p>5.12</p> <p>All cases are classified correctly according to WHO guidelines and are reviewed by technical bodies.^l</p>
	<p>5.13</p> <p>Protocols to investigate and respond to malaria outbreaks are included in the country's outbreak response system.</p>
	<p>5.14</p> <p>Contingency plans for rapid deployment of supplies (diagnostic tests, antimalarial treatments and vector control) are in place in case of outbreaks.</p>
	<p>5.15</p> <p>Country reports all malaria cases annually to WHO.</p>

CRITICAL ELEMENT	MILESTONES
<p>6.</p> <p>Entomological surveillance and vector control</p> <p>Entomological surveillance and vector control should be continued, with emphasis on areas of high malariogenic potential (i.e. receptive areas with a risk of importation).</p> <p>Capacity to respond to possible resurgences with appropriate vector control should be maintained.</p>	<p>6.1</p> <p>Written SOPs for entomological surveillance are available, aligned with WHO guidance for preventing re-establishment and implemented.</p> <hr/> <p>6.2</p> <p>Sentinel sites for entomological surveillance have been established according to national guidelines.</p> <hr/> <p>6.3</p> <p>Basic behavioural characteristics (indoor vs outdoor biting preferences, indoor vs outdoor resting preferences, blood meal preferences) are known for primary and secondary vectors.</p> <hr/> <p>6.4</p> <p>Written vector control guidelines and SOPs are available, aligned with WHO recommendations and implemented.</p> <hr/> <p>6.5</p> <p>Vector control is used at optimal coverage in areas with significant malariogenic potential.</p> <hr/> <p>6.6</p> <p>The coverage, quality and effectiveness of vector control are routinely monitored in areas with significant malariogenic potential.</p> <hr/> <p>6.7</p> <p>Vector control staff who conduct indoor residual spraying, distribute long-lasting insecticide treated nets or conduct larviciding have received training within the past 3 years.</p> <hr/> <p>6.8</p> <p>Equipment and insecticide are available, and their quality is assured.</p>
<p>7.</p> <p>Multi-sectoral collaboration</p> <p>Coordination and collaboration with non-health sectors ensures optimal coverage and use of interventions by high-risk populations, and the implementation of interventions achieve impact and efficiency.^m</p>	<p>7.1</p> <p>A mechanism for coordination or information-sharing among sectors is established and functional.</p> <hr/> <p>7.2</p> <p>For large countries, a mechanism for coordination among sectors is established and functional at subnational level.</p>

CRITICAL ELEMENT	MILESTONES
<p>8.</p> <p>Inter-country information-sharing and border collaboration</p> <p>Effective coordination and communication among neighbouring countries can mitigate the risk of re-establishment.</p>	<p>8.1</p> <p>A mechanism for sharing information on malaria outbreaks or cases has been established with neighbouring malaria-endemic countries and is being used to exchange information.</p> <p>8.2</p> <p>For malaria foci that traverse the border with a neighbouring country, measures are in place to ensure that transmission is eliminated throughout the focus and the risk of re-establishment of transmission is mitigated.</p>
<p>9.</p> <p>Raising awareness and provision of prevention strategies</p> <p>Early detection can be improved, and re-establishment of malaria transmission can be avoided if the population at risk of malaria is aware of the risk and is provided with information, measures and strategies to prevent infection and obtain diagnosis and treatment.</p>	<p>9.1</p> <p>At points of entry, travellers are provided with information on malaria, including guidance on where and when to seek care.</p> <p>9.2</p> <p>A programme to raise awareness among people travelling to malaria-endemic countries on preventing malaria (chemoprophylaxis and prevention of mosquito bites) is in place.</p> <p>9.3</p> <p>Drugs for chemoprophylaxis are available in the country.</p>

Source: This checklist of elements for prevention of re-establishment is taken from the Malaria Elimination Audit Tool currently under development. This tool can be requested from malaria-elimination@who.int.

- ^a The term “national malaria programme” is not used in this section because, after malaria is eliminated, the responsibility for prevention of re-establishment of malaria transmission may fall to several units, and a national programme may no longer exist as such.
- ^b A copy of the document authorizing the national reference laboratory to oversee quality assurance in the country should be made available.
- ^c The roster of microscopists who make up the core group should be available. Preferably, they will have valid certificates from an external quality assurance scheme.
- ^d All records of external competence assessments for malaria microscopy, training curricula and material should be available and reviewed.
- ^e Records of supervisory visits should be available in laboratories at all levels. Microscopists should receive written feedback from their proficiency panels and reports of slide cross-checking.
- ^f The sample register (log) is up to date and accurate; written feedback received from superior-level laboratories is available.
- ^g The availability of rapid diagnostic tests at different levels of the health system and the appropriate use of rapid diagnostic tests should be in accordance with the national strategic plan.
- ^h Health facility staff should be observed while performing a rapid diagnostic test to ensure accurate knowledge of procedures and interpretation.

- ^l To prevent re-establishment, many countries integrate their response to malaria cases into their outbreak response systems.
- ^j Countries should endeavour to report all suspected cases as well as the results of testing. Some countries may report these data in aggregate (i.e. number of suspected malaria cases tested and number found positive). Preferably, minimal data on demographics and risk factors should be reported for all suspected cases of malaria. Optimally, minimum data on risk factors should be recorded for all patients (e.g. travel history, symptom history) to permit analysis of the proportion of suspected cases identified and tested.
- ^k Information on the minimum data to be recorded for each case is provided in *Malaria surveillance, monitoring and evaluation: a reference manual*. Geneva: World Health Organization; 2018.
- ^l Technical bodies could consist of an independent national elimination advisory committee, a national certification committee or other technical committee that has expertise in epidemiological investigation. Technical bodies can provide objective, unbiased views of the data that support case classification and thus improve accuracy.
- ^m Non-health sectors and departments, such as for agriculture and water management, labour, tourism, immigration, education, security and the army, are involved in preventing malaria transmission and should be coordinated to increase impact.

ANNEX 6. GENERIC AGENDA FOR AN INDEPENDENT EVALUATION MISSION

The agenda is based on the assumption that the team is divided into two groups, although this will depend on the mission.

DATE	GROUP 1	GROUP 2
WEEK 1		
Monday	Morning: <ul style="list-style-type: none"> • Briefing in the WHO country office • Meeting with the minister of health and other national health officials^a • Meeting with a representative of finance ministry or equivalent • Meeting with the national malaria team and national certification committee^b Afternoon: <ul style="list-style-type: none"> • Visit to the national reference laboratory and meeting with staff • Review of supporting documents and records, including the national malaria case database 	
Tuesday	<ul style="list-style-type: none"> • Visits to other institutions involved in the programme for elimination and prevention of re-establishment (e.g. entomological institute, tropical disease treatment hospital) • Continue meeting with NMP • Continue reviewing supporting documents and records, especially surveillance data 	
Wednesday	<ul style="list-style-type: none"> • Travel to region A • Visit health office in region A 	<ul style="list-style-type: none"> • Travel to region B • Visit health office in region B
Thursday	<ul style="list-style-type: none"> • Visit malaria sector, entomological service and vector control unit and meet with staff • Travel to district A of region A • Visits to public and private health facilities (or community health centres) in district A of region A 	<ul style="list-style-type: none"> • Visit malaria sector, entomological service and vector control unit and meet with staff • Travel to district A of region B • Visits to public and private health facilities (or community health centres) in district A of region B
Friday	<ul style="list-style-type: none"> • Travel to district B of region A • Visits to public and private health facilities (or community health centres) in district B of region A 	<ul style="list-style-type: none"> • Travel to district B of region B • Visits to public and private health facilities (or community health centres) in district B of region B
Saturday	Visits to other sectors: border health posts, travel clinics, immigration offices	
Sunday	Break	

DATE	GROUP 1	GROUP 2
WEEK 2		
Monday	Travel back to capital city	Travel back to capital city
	Visit other sectors involved in malaria elimination and prevention of re-establishment (e.g. military hospitals, labour department, tourism office, water management department)	
Tuesday	<ul style="list-style-type: none"> • Continue visits to other sectors involved in malaria elimination and prevention of re-establishment • Team meeting to discuss findings from field visits 	
Wednesday	<ul style="list-style-type: none"> • Consolidate findings from field visits, and prepare a presentation 	
Thursday	<ul style="list-style-type: none"> • Call additional meetings with staff from NMP if necessary 	
Friday	Briefing to the ministry of health Briefing to the national malaria team	
Saturday	Departure	

^a Countries could consider preparing a presentation on their health system to facilitate the discussion.

^b The NMP could consider preparing a presentation on its history.

ANNEX 7. METHODS FOR VERIFICATION OF MALARIA-FREE STATUS IN A COUNTY - EXAMPLE OF CHINA

In China, the methods used for subnational verification differ slightly in counties, prefectures and provinces. While the methods used for subnational verification in a province are similar to those for national certification, the methods used to verify malaria-free status in a county or a prefecture are simplified, illustrated in the table below.

COMPONENT	ELEMENTS	STANDARD	METHODS	SITE
1. Self-assessment report		Subnational elimination report is complete.	Desk review	
2. Implementation of elimination strategy and quality of implementation	Testing of blood samples from patients with fever	Sample logs are available in laboratories. Sample logs are complete and up to date. Number of blood samples tested for malaria is appropriate and comparable to that defined in the work plans. ^a	Visit laboratories in health facilities, and review sample logs.	Laboratories
	Quality-assured diagnosis	Slides are cross-checked monthly, and the results of cross-checking of slides are available. Diagnosis is quality assured.	Review the record and feedback received on cross-checking of slides. Randomly select 30 negative slides, examine the quality of the blood smears and staining, and verify the results.	Laboratories
	Case notification	All detected cases are reported.	Review sample logs and patient logs. Cross-check the number of positive cases detected in the laboratory and the number of complete case notifications, and match the data with those in the national malaria database.	Public health office in health facilities ^b

	Case treatment	All cases were treated with a complete course; <i>P. vivax</i> cases completed anti-relapse treatment.	Review patient logs and treatment records.	Health facilities
	Case investigation	Case investigation forms are filled in completely. Adequate evidence is provided and supports the case classification.	Review all case investigation forms, and verify case classification.	County Centre of Disease Control and Prevention ^c
	Focus investigation and response	Every focus has a report on focus investigation and response. Response and management of focus are in line with national guidelines.	Review focus investigation reports.	County Centre of Disease Control and Prevention
3. Vigilance in general health services and capacity to provide quality-assured diagnosis		Vigilance for malaria in general health services is maintained.	Clinicians and health practitioners are selected to answer the questionnaire.	County Centre of Disease Control and Prevention
		Laboratory technicians are competent in identifying <i>Plasmodium</i> parasites.	Laboratory technicians are selected from different health facilities to assess competence.	County Centre of Disease Control and Prevention
4. Programme management	Support implementation of elimination strategies	Annual work plans and annual reports on implementation are available.	Check the availability of the plans.	County Centre of Disease Control and Prevention
		Local government provides budget for elimination.	Review the financing records.	
	Malaria programme structure and human resources	A unit responsible for malaria (or parasitic diseases) exists, and malaria service positions are occupied.	Visit the county Centre of Disease Control and Prevention, and check its organogram.	
	Training	Training is provided to various cadres of staff.	Review training records.	

- ^a According to national guidelines, all suspected cases should be tested for malaria. In addition, in areas where the risk of re-establishment of transmission is considered high, the NMP sets a standard on the number of blood samples expected to be tested for malaria. This standard is used for monitoring and supervision.
- ^b In China, each hospital has a public health officer who is responsible for case notification of all infectious diseases through the health information system.
- ^c County Centre of Diseases Control and Prevention is responsible for case and focus investigations and response.

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