Criteria and procedures

for the verification of elimination of transmission of *T. b. gambiense* to the human population in a given country

World Health Organization

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Contents

Process of document development

The development of this document was elaborated in discussion within the human African trypanosomiasis elimination Technical Advisory Group (HAT-e-TAG), led by the WHO Department of Control of Neglected Tropical Diseases (WHO/NTD), in collaboration with the WHO Regional Office for Africa.

Having established the goal of eliminating transmission of gambiense human African trypanosomiasis (g-HAT) to humans, the HAT-e-TAG considered which elements should be developed to assess this goal.

The HAT-e-TAG includes independent experts from academia and representatives of national control programmes of endemic countries, nominated by World Health Organization . The standard World Health Organization procedures for Declaration of Interest are followed.

At its various meetings (16–17 December 2020; 9–10 February 2022) and remote consultations, the HAT-e-TAG defined the framework for the elimination of transmission of g-HAT, defining key concepts, indicators and procedures, and produced a template to help countries to claim the verification of elimination of transmission of g-HAT.

Acknowledgements

Abbreviations and acronyms

AAT	animal African trypanosomiasis
g-HAT	human African trypanosomiasis due to *Trypanosoma brucei gambiense* (gambiense HAT)
HAT-e-TAG	Human African Trypanosomiasis elimination Technical Advisory Group
MoH	Ministry of Health (or equivalent)
T+	parasitologically confirmed
To	parasitologically unconfirmed
WHO	World Health Organization
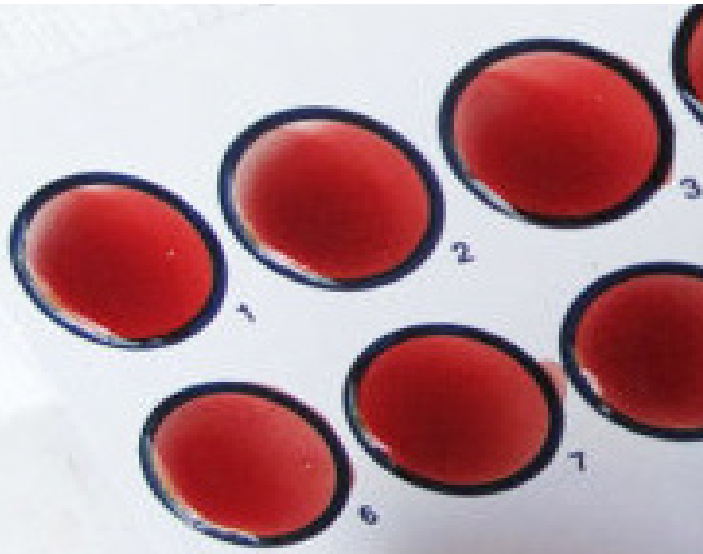
Human African trypanosomiasis (sleeping sickness) – A protozoan infection spread by the bites of tsetse flies that is almost 100% fatal without prompt diagnosis and treatment.

1   Introduction

The World Health Organization (WHO) published the *Generic framework for control, elimination and eradication of neglected tropical diseases in 2006 (1).* The "elimination of transmission" (also referred to as "interruption of transmission") was defined as "**the reduction to zero of the incidence of infection caused by a specific pathogen in a defined geographical area, with minimal risk of reintroduction, as a result of deliberate efforts; continued actions to prevent re-establishment of transmission may be required**". The process of documenting elimination of transmission is called **verification**.

The goal of eliminating gambiense human African trypanosomiasis (g-HAT) was agreed by the disease-endemic countries at a meeting convened by WHO in December 2012 *(2).* The meeting concluded with an agreement to target the elimination of human African trypanosomiasis (HAT) as a public health problem by 2020. This goal was duly included in the first (2012) WHO roadmap on neglected tropical diseases *(3)* as an intermediate step, with a subsequent goal to eliminate transmission of g-HAT by 2030. Therefore, the Technical Advisory Group for HAT elimination (HAT-e-TAG) concluded that **the elimination of transmission of g-HAT to the human population is defined as the reduction to zero of the incidence of human cases infected by *Trypanosoma brucei gambiense* in a given country for a period of at least 5 consecutive years, based on evidence from appropriate surveillance.**

Subsequently, a country could be considered as having eliminated transmission of g-HAT to the human population when zero cases of the disease are reported from all of the country's health districts over the 5 years preceding the claim (during which period disease-surveillance has been operational).

G-HAT is a vector-borne disease transmitted by several species and subspecies of tsetse fly (Diptera: Glossinidae). In addition, the existence of vertebrate hosts infected by *T. b. gambiense* other than humans has been demonstrated. It is noteworthy that the verification of *elimination of transmission* to humans is not a certification of eradication; the latter term describes a situation where the pathogen is no longer present in the natural environment and, consequently, there is no further innate risk of reintroduction and, therefore, no further actions are required.

Therefore, the verification of the elimination of g-HAT transmission to humans focuses on the human population but accepts that the parasite may still be present and circulate among non-human hosts. The presence (or absence) of *T. b. gambiense* in non-human hosts (including the tsetse vector) is not a mandatory indicator for the verification of elimination of transmission of *T. b. gambiense* to the human population. However, this information, if available, will contribute to the characterization of the risk of transmission or re-emergence of g-HAT, since the presence of a vectorial transmission cycle of *T. b. gambiense* in domestic or wild animals represents a risk for human transmission and a challenge for eradication, the following step.

This is one reason why eliminating transmission of *T. b. gambiense* to the human population is not a final step and why continued action to prevent the resurgence of the disease in the human population will be required.

2. Concepts to be considered during the verification process

2.1 Case definition

A case of g-HAT is defined as any human individual with an epidemiological link to _T. b. gambiense_ infection, in whom trypanosomes are detected by microscopy in any body fluid or tissue.

Therefore, the concept of "zero g-HAT cases" implies that no trypanosome assumed to be _T. b. gambiense_ could be observed by microscopic investigation in the body fluids or tissues of any examined person or, exceptionally, if observed, it could be demonstrated that:

- it was acquired in a different country;
- it was transmitted by routes other than vectorial, such as laboratory accident;
- it could be clearly established that the infection was acquired before the period covered by the dossier (i.e. 5 years); or
- the trypanosome observed by microscopy in the human fluid or tissue is not of the subspecies _T. b. gambiense_.

2.2 Time period for which absence of cases reported is required

As g-HAT cases are often detected months or even years after infection, a criterion of a minimum time period without cases is needed. Given that the diagnosis of a g-HAT case generally occurs 2–3 years following infection, a minimum of 5 consecutive years without reported cases is believed to offer a robust timeframe to assume that transmission to the human population has ceased.

2.3 Parasite species and subspecies

There is evidence of human infection by species or subspecies of _Trypanosoma_ other than _T. b. gambiense_. In the event of any microscopic, clinical or epidemiological doubt with regards to the species/subspecies of trypanosome observed, a molecular characterization of the parasite should ascertain whether _T. b. gambiense_ or another species/subspecies is the cause of infection. If characterization is not performed, and if the geographical region is within a zone of historical _T. b. gambiense_ transmission, _T. b. gambiense_ infection is assumed.

2.4 Management of "parasitologically unconfirmed suspects"

During control and surveillance activities, individuals could be suspected of being infected by *T. b. gambiense* because of positive results from serological or molecular tests, or, more rarely, by strong clinical suspicion, although without confirmation of the presence of the parasite by microscopy. These individuals, who are often referred to as "parasitologically unconfirmed suspects", do not meet the requirements for case definition. Furthermore, it should be considered that the positive predictive value of indirect diagnostic tests (serological and molecular) approaches zero when the prevalence of the disease is close to zero. This means that as elimination efforts reduce the number of true cases, indirect diagnostic tests yield high numbers of false-positives and a detailed study of "parasitologically unconfirmed" suspects will thus be needed.

Accordingly, samples should be collected from "parasitologically unconfirmed suspects" and sent to WHO collaborating centres or reference laboratories for additional tests to corroborate the suspicion of *T. b. gambiense* infection. If the reference laboratory tests are negative, the "parasitologically unconfirmed suspect" will be discarded as a case and subsequently will not compromise the verification of g-HAT elimination. However, if the results in the reference laboratory are also positive, the suspicion is reinforced and a follow-up should be performed. If sample referral of "parasitologically unconfirmed suspects" is not performed, parasitological follow-up must be performed where capacity is available, although follow-up with the card agglutination test for trypanosomiasis (CATT) or a rapid diagnostic test (RDT) can be accepted in the event of other options being unavailable. If such follow-up shows negative results, then the suspicion can be discarded and these individuals will not be taken into account in assessing the risk of disease transmission (*Algorithm 1*).

Algorithm 1. Algorithm to fulfil zero case definition
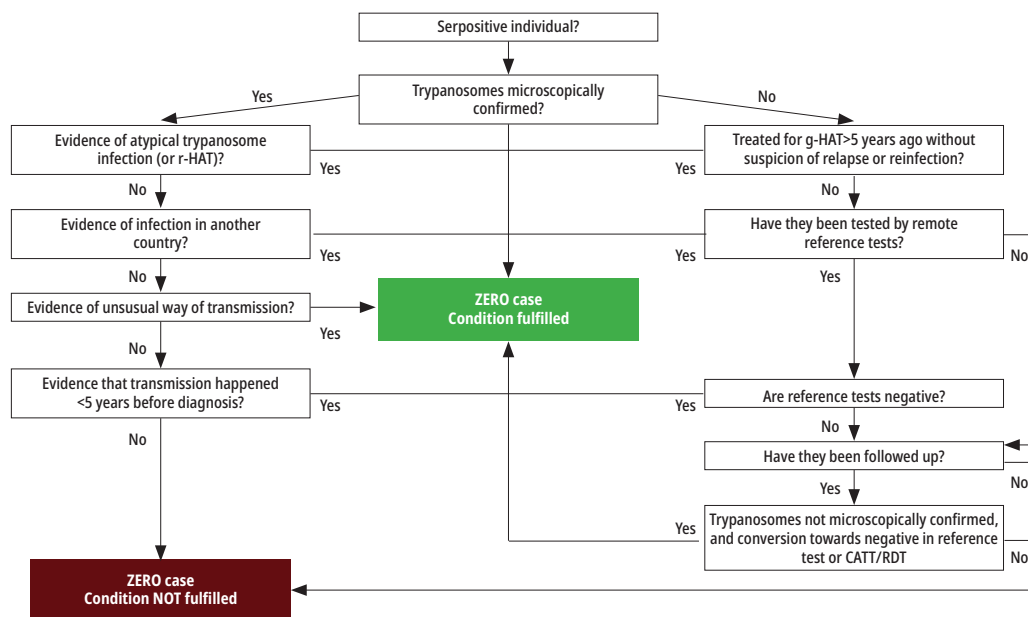
CATT: card agglutination test for trypanosomiasis; RDT: rapid diagnostic test; r-HAT: rhodesiense human African trypanosomiasis; g-HAT: gambiense human African trypanosomiasis.

For seropositive individuals who were diagnosed and treated more than 5 years ago, and who are without any symptoms of relapse or reinfection, the seropositivity could be related to the former infection and they should be considered individually.

If no follow-up is carried out in "parasitologically unconfirmed suspects", they should be considered to represent a real infection with a risk of disease transmission, and therefore the criteria for "zero cases" will not be met (*Algorithm 1*). In instances where "parasitologically unconfirmed suspects" have been lost to follow-up, the assigned verification team will assess the likelihood of their being true cases or not.

2.5 Management of "parasitologically unconfirmed suspects" who have received HAT treatment

Some control strategies consider the treatment of "parasitologically unconfirmed suspects", who may receive anti-g-HAT treatment aiming to decrease disease transmission. In these situations, the collection of specimens, before treatment, for further laboratory testing at a WHO collaborating centre or reference laboratory is mandatory to determine whether these "parasitologically unconfirmed suspects" should be classified as probable cases or not. If no specimens have been collected before treatment, specimens taken after treatment might still allow potential infection to be confirmed or refuted using antibody detection tests, although molecular tests will have ceased to be informative. However, the complete lack of reference laboratory tests for individuals who received anti-g-HAT treatment will render it impossible to establish the absence of cases and, consequently, it will not be possible to claim the elimination of transmission.

3. Surveillance approaches

Surveillance of the transmission of *T. b. gambiense* to humans can be performed by various approaches, which may be combined where appropriate.

3.1 Passive surveillance

3.1.1 Definition

Passive surveillance **is carried out in fixed health facilities** where the detection of g-HAT suspects and subsequent steps for diagnosis are part of the routine health care provided to the population.

3.1.2 Methods

In order to ensure a comprehensive coverage of the area, passive surveillance can be performed in all fixed health facilities within a transmission area, or else in sentinel sites strategically selected according to their rate of use by the population and the geographical area and distribution of the disease.

3.1.3 Target population

Passive surveillance can be targeted to the entire population attending a health facility, or to a sample of attendees, or only to clinically suspected individuals.

Passive surveillance requires skills and awareness of the disease among the health staff concerned. Maintenance of these skills is a key element to ensure that health staff sustain surveillance for g-HAT alongside other competing health concerns.

To be operational, a passive surveillance programme must ensure that the fixed health facilities involved (i) adequately cover the population considered at risk of g-HAT; (ii) are regularly monitored to assess and to support their performance; (iii) ensure that serological or strong clinical suspects detected in the facilities are investigated to confirm or discard a diagnosis of g-HAT; (iv) ensure that in "parasitologicallly unconfirmed cases", specimens are collected and sent to a reference laboratory; (v) verify that any "parasitologically unconfirmed suspect" is properly followed up; and (vi) ensure that the diagnosis of a g-HAT case triggers reactive screening of the relevant population.

3.2 Active surveillance

3.2.1 Definition

Active surveillance involves the activities performed by **dedicated teams that visit the transmission areas or the areas to be investigated aiming to test the target population**. This may be done as planned surveillance of recent transmission areas or as investigation of defined geographical areas suspected for other epidemiological reasons, including historical g-HAT transmission areas.

The diagnosis of a g-HAT case should trigger a response through **reactive screening** targeting the relevant population that shares the risk with the individual case detected.

3.2.2 Methods

Active surveillance can involve different methods, including traditional mobile teams or mini mobile teams. The teams aim to screen as much of the population as possible present within a previously defined area (which could involve bringing individuals to a central location or testing individuals by moving from "door-to-door") or occasionally, a selected sample of the population. In some circumstances, a multidisciplinary team investigating various diseases may be considered.

3.2.3 Target population

The target population for active surveillance can be (i) subject to mass-screening, i.e. the maximum number of people gathered at a designated location for screening or the maximum number of inhabitants dwelling in each household; or (ii) a sample of the population to be investigated through a population survey. The survey sample should be appropriately defined and planned in terms of geographical extension, selection of villages and sample size, to ensure that the results obtained are representative of the entire population of the study area.

The choice of the method, or a combination thereof, and the definition of the target population should therefore be based on the epidemiological situation. The feasibility of either approach may be linked to the availability of technical tools and financial resources. In any event, the reasons for the choice of approach should be documented.

In addition to the skills of the health staff concerned, active surveillance requires that the population to be screened is made aware of the necessity of the programme, thus maximizing participation in the survey.

To be effective, active screening must ensure that the teams involved (i) sufficiently cover the targeted villages and the population; (ii) are themselves regularly monitored to assess and to support their performance; (iii) investigate detected serological suspects to confirm or discard a diagnosis of g-HAT; (iv) collect specimens from "parasitologically unconfirmed suspects" to be sent to a reference laboratory; (v) follow-up any "parasitologically unconfirmed suspect" properly; and (vi) ensure that any diagnosis of a g-HAT case leads to reactive screening.

🌍4. Indicators and criteria

Two indicators of the elimination of transmission of g-HAT at the global level were defined in the second WHO road map for neglected tropical diseases 2021–2030 *(4)* and the companion indicator compendium *(5)*, including the related targets, namely: (i) the number of countries verified for interruption of transmission (target for 2030: 15 countries); and (ii) the number of g-HAT cases reported annually (target for 2030: 0 cases).

The country-level indicators are divided into two categories: mandatory and complementary. Mandatory indicators (see sections 4.1 and 4.2) are those related to g-HAT transmission that are required to prove that zero cases were detected and that surveillance was effective (see sections 2 and 3). Complementary indicators are those focusing on vector control and the investigation of the non-human reservoirs (see section 4.3).

4.1   Indicator of elimination of transmission of g-HAT

The country indicator of elimination of transmission is the number of g-HAT cases as defined in section 2, and the elimination criterion is defined as: **zero g-HAT human cases detected in all of the country's health districts for a minimum of 5 consecutive years**. This implies the absence of parasitologically-confirmed human cases, meaning that trypanosomes (assumed or confirmed as *T. b. gambiense*) were not observed under a microscope in any body fluid or tissue of any individual investigated by the surveillance system implemented during the period considered.

4.2   Indicators of surveillance

Indicators of effective surveillance are needed to determine whether or not the indicator of elimination of transmission is credible. The aim of these indicators is to demonstrate that surveillance capacity and implementation have been adequate for case detection and appropriate reporting. The indicators focus on passive and active surveillance respectively.

4.2.1 Indicators of passive surveillance

The indicators of the intensity and quality of passive surveillance include:

(i)   The number and geographical location of fixed health facilities with capacity for g-HAT surveillance and/or diagnosis in relation to recent areas of transmission or historical foci.

(ii)   The number of people examined and tested for g-HAT (per facility, per year, and per type of test used).

(iii) The number of serological suspects detected (per facility and per year), and the number of those further investigated locally (target 100%), indicating the diagnostic methods used and the number of parasitologically positive and negative individuals.

(iv) The number of "parasitologically unconfirmed suspects" detected locally (per facility and per year), and the number of corresponding specimens of these "parasitologically unconfirmed suspects" dispatched to a reference laboratory for further investigations (target 100%).

(v) The number of results received from the reference laboratory over the number of specimens sent per facility and per year (target 100%), indicating the number of positive and negative results.

(vi) The number of "parasitologically unconfirmed suspects" followed over the number of "parasitologically unconfirmed suspects" to be followed, per site and per year (target 100%).

(vii) The number of reactive screenings performed per site and per year in relation to g-HAT cases detected, including a record of the time elapsed between the detection of the confirmed case and the implementation of reactive screening.

(viii) The number of staff trained and supervised per site and per year.

(ix) Records of supervision covering the quality of the performance and the measures implemented if deficiencies were observed in each health facility involved.

4.2.2 Indicators of active surveillance

The indicators of active surveillance include:

(i) The number of villages screened over the number of villages targeted for screening, explaining the relevance and reasons for the selection, and including the geographical location of the villages screened in relation to recent areas of transmission or historical foci.

(ii) The tested population over the estimated target population, per village (if possible), per year.

(iii) The number of "parasitologically unconfirmed suspects" detected, the number of those further investigated (target 100%), per village (if possible), per year, indicating the diagnostic methods used and the number of parasitologically confirmed and non-confirmed.

(iv) The number of samples of "parasitologically unconfirmed suspects" forwarded to the reference laboratory over the number of "parasitologically unconfirmed suspects" detected (target 100%), per village (if possible), per year.

(v) The number of results received from a reference laboratory over the number of specimens sent (target 100%), indicating the number of positive and negative results, per village (if possible), per year.

(vi) The number of "parasitologically unconfirmed suspects" testing positive by a reference laboratory receiving follow-up over the total number of "parasitologically unconfirmed suspects" testing positive (target 100%). Results of the follow-up should be included in the dossier to assess how many suspects were excluded during the follow-up, per village (if possible), per year.

(vii) The number of staff trained and supervised per mobile team and per year. Records of supervision covering the quality of the performance and the measures implemented if deficiencies were observed in each team.

4.3 Indicators of tsetse presence, vector control and investigation of non-human reservoirs

The data on the possible presence (or absence) of tsetse in a region along with the presence or absence of *T. b. gambiense* in domestic animals, wild animals or in tsetse **is not considered mandatory** for the verification process. However, these data should be included in the validation dossier, if they are available, because they contribute to the characterization of the risk of g-HAT re-emergence in a given area and the challenges to future eradication.

The indicators related to tsetse presence and vector control assessment are:

(i) The presence or absence of tsetse and their geographical distribution.

(ii) The spatial and temporal coverage of vector control activities in relation to the area of potential g-HAT transmission.

(iii) The intensity of vector control activities if applicable (e.g. number of traps or targets deployed, number of animals sprayed or dipped).

(iv) The reduction in tsetse densities as a result of vector control.

(v) The number of animals treated for animal African trypanosomiasis (AAT) in an area of g-HAT transmission.

The indicators assessing the presence of *T. b. gambiense* in tsetse and non-human vertebrates are:

(i) The number of tsetse flies tested for possible *T. b. gambiense* infection and the proportion of tsetse-positives, recording the geographical location and methods used in any study.

(ii) The number of animals tested for *T. b. gambiense* infection (by animal species) and the proportion of positives, recording the geographical origin and the sampling and detection methods used in any study.

(iii) The geographical and temporal coverage of these data over the potential area of *T. b. gambiense* transmission.

5. Procedures for the verification of the elimination of transmission of *T. b. gambiense* to the human population

In general, the validation of g-HAT elimination as a public health problem followed by a period of post-validation surveillance should precede the claim of elimination of transmission of *T. b. gambiense* to the human population. However, if a country that has not claimed elimination as a public health problem meets the requirements for elimination of transmission to the human population, it can be considered directly as a candidate to claim such elimination status.

5.1 Dossier to claim the elimination of transmission of *T. b. gambiense* to the human population

The process of verification of elimination of transmission of g-HAT in a country is based on the submission to WHO of a dossier prepared by the Ministry of Health (MoH) or equivalent and its partners, presenting the evidence to demonstrate the absence of g-HAT cases infected in the country for at least 5 years before the claim.

A template has been designed to assist national HAT programmes in preparing this dossier. The information presented following this template will allow evaluators to appraise the achievements of the national programme, the specific context, and the epidemiological data.

The dossier is divided into two parts and presented in *annexes 1* and *2* respectively.

- **Part 1**: Presents **the data required for validation of the elimination of g-HAT as a public health problem**. This includes the following elements:

    1. Description of the country and the characteristics and capacities of the health system.
    2. Historical data of g-HAT and delimitation of endemic areas.
    3. HAT control activities and surveillance.
    4. Epidemiological data for g-HAT.
    5. Vector control.
    6. African animal trypanosomiasis.

To comply with this part, the countries that were already validated for elimination of g-HAT as public health problem can present the dossier submitted for validation jointly with the report of the validation assessment team. Countries that were not yet validated must complete part 1.

-     **Part 2**: Focuses on **the data required for the verification of the elimination of transmission**.

In the countries already validated for elimination as a public health problem, part 2 concerns the activities implemented after validation, and for at least 5 years.

Countries that claim directly for verification of elimination of transmission, without having gone through the prior validation stage of elimination as a public health problem, must present the reasons behind claiming the elimination of transmission.

Part 2 comprises the following elements:

1.   **Introduction.**

     In countries where elimination as a public health problem has been validated, the history of the process of eliminating HAT as a public health problem should be described, including dates of the landmarks such as the submission, details of the expert reviews and its recommendations, and the acknowledgment of validation. It should also include the political and social reactions to validation and their impact on the health personnel concerned, and the changes in the policy and organization of HAT control since validation as well as notable changes in the country's health system. Any major ecological or demographic changes relative to endemic areas should be indicated.

     The introduction must outline the g-HAT post-validation strategy and its implementation as well as the monitoring activities including the strengths and weaknesses of the strategy.

     Countries claiming elimination of transmission, without going through the prior validation stage of elimination as a public health problem, must present the reasons for such a claim.

2.   **Human population. HAT surveillance activities implemented.**

     For countries having eliminated g-HAT as a public health problem, they must present the activities implemented after validation of elimination as a public health problem, and for a period of at least 5 years.

     Countries directly requesting verification must present data generated over the preceding 5 years to complete the dossier. This can be included in chapters 3 and 4 of Part 1.

3. **Vector control and animal reservoir surveillance activities implemented in the years preceding a request for verification.**

    Where a country has eliminated g-HAT as a public health problem, this section should focus on the activities implemented after validation of elimination as a public health problem, and for at least 5 years.

    Countries applying directly for verification must present the data generated in the preceding 5 years to complete the dossier. This can be included in chapters 5 and 6 of Part 1.

4. **Post-verification surveillance plan.**

    The status of interruption of transmission of g-HAT should be monitored by surveillance activities and possible response to prevent emergence, re-emergence or reintroduction of the disease in the country.

    The post-verification surveillance plan must be described, indicating stakeholders, locations and planned methods to monitor for any possible re-emergence of the disease and appropriate response. Data must be reported annually.

    The exceptional appearance of trypanosome-infected humans is possible. When this occurs, provisions must be made to retain or discard the case according to the "zero g-HAT" case definition (section 2.1; *Algorithm 1*).

    The presence of *T. b. gambiense* in tsetse and/or non-human vertebrates in the absence of endogenous cases of g-HAT does not, *per se*, compromise the status of countries that have achieved interruption of transmission.

A group of WHO-designated experts will form a verification team to evaluate the dossier and the strength of the evidence presented therein. The verification process involves several steps and procedures, engaging several levels: the country, the verification team and WHO.

5.2 Procedures at country level

The country is responsible for preparing the dossier to claim the elimination of transmission of *T. b. gambiense* to the human population. The dossier should be written at country level by the MoH officials and, in particular, by staff in charge of g-HAT control and surveillance. Other national actors from different domains could be invited as per the MoH decision. The country may also request technical support from WHO to develop the dossier.

The dossier must present, in a comprehensive manner, the information necessary to establish that the transmission of *T. b. gambiense* to the human population has been eliminated in the country. The dossier must be officially submitted by the MoH to the WHO Country Office (*Algorithm 2*).

Annexes 1 and *2* provide the templates developed by the HAT-e-TAG to assist in creating the two parts of the dossier for verification.

The country is responsible for responding to the requests for clarification issued by the verification team, if any, and to facilitate and organize a visit by the verification team, if needed.

5.3 Procedures at the verification team level

The dossier is examined by a verification team (reviewing authority) appointed by the WHO Regional Office. The verification team will be composed of four independent experts, namely two members from the HAT-e-TAG and two from the WHO Regional Programme Review Group for Case Management of Neglected Tropical Diseases (CM-NTD RPRG).

The secretariat of the verification team will be composed of two WHO members: one from the WHO Regional Office (the HAT focal point) and one from WHO headquarters (the HAT technical officer).

Upon examination of the dossier the verification team advises the WHO Regional Office to either: (i) verify the claim of elimination of transmission of g-HAT; or (ii) request additional evidence to be provided in a revised version of the dossier. If appropriate, the usefulness of the verification team visiting the country may be considered to complete the evaluation of the dossier.

In the event that clarifications or additional evidence is requested and provided, the verification team will review the country feedback to assess the responses and, if needed, request additional clarifications (Algorithm 2).

5.4   Procedures at WHO level

The WHO Country Office is the recipient of the submitted dossier, and it will forward the dossier to the technical unit in the WHO Regional Office for Africa. The Regional Office appoints the verification team and receives their advice, which is forwarded to the country via the Country Office, if clarifications and further details are requested. For the country to provide further clarification or more details, the same procedure as per the first submission is used.

Once the WHO Director-General receives the result of a positive verification assessment, a letter acknowledging this achievement and declaring the elimination of transmission of gHAT in the country is sent to the country via the Country Office with a recommendation to set up post-verification surveillance. The Global Health Observatory is thereby updated and the new status is published in the *WHO Weekly Epidemiological Record*.

Algorithm 2. Pathway for the verification of the elimination of transmission of *T. b. gambiense* to the human population
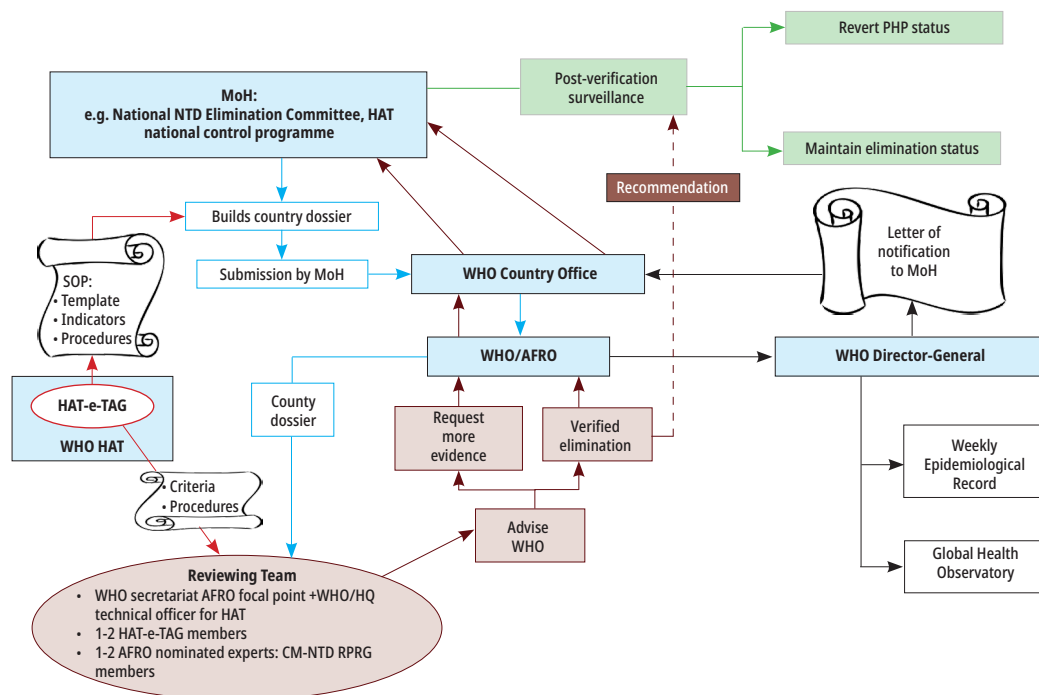
HAT: Human African trypanosomiasis, AFRO: WHO Regional Office for Africa; CM-NTD RPRG: WHO Regional Programme Review Group for Case Management of Neglected Tropical Diseases; HAT-e-TAG: human African trypanosomiasis elimination Technical Advisory Group; MoH: Ministry of Health; NTD: neglected tropical disease; PHP: public health problem; SOP: standard operating procedure; WHO: World Health Organization.

6. Post-verification surveillance

Health policy-makers in the country should be reminded during this process that eliminating the transmission of *T. b. gambiense* to the human population does not necessarily exclude the presence of cryptic residual human and non-human animal (domestic or wild) reservoirs. In addition, reintroduction of transmission from other endemic countries is also possible, and therefore re-emergence of the disease is possible as long as tsetse flies are present. The elimination of transmission of *T. b. gambiense* to the human population is, therefore, a potentially reversible status and authorities must consider this in making their decisions.

Consequently, following the verification of elimination of transmission of *T. b. gambiense* to the human population, the country should continue to conduct post-verification surveillance for the disease and ensure that the surveillance data are made available to WHO annually, as well as immediately reporting the detection of any new case. This surveillance should be targeted to areas where the transmission of g-HAT has occurred in the past, complemented with information obtained from overarching structures (referral hospitals, research institutions, etc.). A description of the post-verification surveillance strategy and the commitment to its implementation must be included in the dossier.

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ANNEXES

Annex 1. Template dossier to claim the elimination of transmission to the human population of gambiense human African trypanosomiasis: part 1

Preamble

Generally, the starting point for the verification of the elimination of transmission of gambiense human African trypanosomiasis (g-HAT) is the validation of the elimination of g-HAT as a public health problem, through the submission to the World Health Organization (WHO) of a dossier for this purpose, and its subsequent approval. However, it is possible that a country, in particular circumstances, may be directly eligible to request verification of elimination of transmission of g-HAT without going through the prior validation of elimination as a public health problem. Specific reasons may include:

- proven absence of g-HAT cases in the country for several years but without the validation process being developed; and
- proven absence of tsetse vectors of g-HAT naturally or intentionally-caused (urbanization, deforestation, vector control, etc.).

Part 1 of the verification dossier includes the essential data requested for the validation of elimination of g-HAT as a public health problem. To comply with this part, the countries that are already validated for elimination of HAT as a public health problem can present the dossier submitted for validation jointly with the report of the validation assessment team.

Countries that are not yet validated but have evidence to proceed directly to verification of the elimination of transmission of g-HAT must complete Part 1 in detail. In this case, they must complete both Part 1 and Part 2.

The following must be included in Part 1:

1. Description of the country and the characteristics and capacities of the health system.
2. Historical data of g-HAT and delimitation of endemic areas.
3. HAT control activities and surveillance.
4. Epidemiological data for g-HAT.
5. Description of vector control activities.
6. Status of African animal trypanosomiasis.

1. Description of the country and capabilities of the health system

1.1 Country general background

Summarize (1–3 pages) the geographical, demographic and economic characteristics of the country, with reference to relevant documentation. If possible, provide indicators and/or maps. Include the following information:

1.1.1 Total area, hydro-geographical features, protected areas (type, number).

1.1.2 Economy of the country: GDP (gross domestic product), health expenditure.

1.1.3 Total population and density, life expectancy.

1.1.4 Administrative division, listing the administrative units in the country and the divisions of the health system (total number of regions, districts, etc.).

1.1.5 Population movements influencing areas affected by HAT: refugees/displaced persons/ nomadism/transhumance/seasonal workers.

1.2. The country's health system

In narrative form, provide a brief overview of the health system, including:

1.2.1 Basic description, structures and their capabilities.

1.2.2 Health information system, data management, disease surveillance data analysis.

1.2.3 Health personnel: type and number, ratio per inhabitant, average number per type of health facility.

1.2.4 Health system utilization. Attendance rate.

2. HISTORICAL DATA AND DELINEATION OF ENDEMIC AREAS

2.1 History of HAT (essential)

Provide a narrative of the history of HAT in the country, including:

2.1.1. The historical geographical distribution of HAT outbreaks and control activities.

2.1.2. The total number of HAT cases reported per year, as well as the number of persons examined per year, if possible since the beginning of registration, and at least since the 1960s.

2.2. Description/delineation of current HAT-endemic areas (essential)

Indicate how the country has defined the current endemic areas, and what criteria have been used. Include:

2.2.1 The ecological context (forests, forest gallery, mangroves, rivers, savannahs) and the socioeconomic context (risky activities) related to HAT transmission.

2.2.2 Enumeration, description and mapping of HAT-endemic areas.

2.2.3 Include the list and map of health districts (called health zones in some countries) endemic for HAT.

2.2.. Existence of HAT grey areas, where there is no reliable information but where transmission is possible (depending on history and ecology).

2.2.5 Description of internationally-detected domestic cases.

2.2.6 Major ecological and demographic changes in HAT-related endemic areas since the confirmation of the most recent cases of HAT in the country.

3. HAT control and surveillance activities.

3.1 Structure and capabilities to control HAT (essential)

Describe the abilities to control HAT including:

3.1.1 Existence of a national policy document outlining HAT programme strategy and activities.

3.1.2 Existence of a structure dedicated to the HAT control or elimination (programme) and its institutional anchoring.

3.1.3 Existence of partners (national and international) and research structures dedicated to HAT.

3.1.4 Organization of HAT control including vector control.

3.1.5 Financial and material resources available at central and peripheral levels.

3.1.6 Human resources and their competence in HAT (training, experience).

3.1.7 Capacity-building policies and activities: skills refreshment, training, etc.

3.1.8 Entomology skills: trained staff, capacity-building.

3.1.9 Technical capabilities: diagnosis, treatment, vector control, supply chain (diagnostics and medicines), reference laboratory.

3.1.10 Quality assurance system.

3.1.11 HAT surveillance information system: transmission circuit, data processing, analytical capabilities and decision-making process.

3.2. Active surveillance strategy (essential)

Describe the active surveillance strategies implemented in the country since 2000. If there have been none, give the date of the last active screening. Include studies and surveys other than classic active screening, including those conducted in areas of unknown HAT status. Provide the diagnostic algorithm (specify the tests used), the definitions of HAT cases

(suspected and confirmed, stage 1 and stage 2), and any changes in the definitions since 2000.

Describe the protocol applied to HAT seropositive individuals (treatment, specimen for trypanolysis or molecular tests, active follow-up, etc.).

Include the training carried out for staff in charge of active surveillance. The number of staff trained per team and per year and the monitoring and evaluation activities carried out for staff in charge of active surveillance should be specified.

3.3 Passive surveillance strategy (essential)

3.3.1 Narrative of passive surveillance activities since 2000.

3.3.2 Passive diagnostic algorithm applied in the country (specify the tests used). Include selection criteria for patient examination.

3.3.3 Case and stage definitions, and protocol for HAT seropositive individuals, if different from active surveillance.

3.3.4 List of diagnostic sites, including their type (serological screening, parasitological confirmation), start and end date of screening, with a map of the sites. In case of sentinel surveillance, give the criteria used for the selection of sentinel sites. If available, provide the latest data on utilization rate.

3.3.5 The training, monitoring and evaluation activities carried out by site. The number of staff trained and supervised per site and per year.

3.3.6 The records of supervision covering the quality of the performance. The measures put in place if deficiencies have been observed and what is their impact.

3.4 Response to suspected/confirmed cases of HAT (essential)

3.4.1 Describe investigations of suspected or confirmed cases to determine whether there is (or was) local transmission (status of other household members, travel to endemic areas, presence of tsetse, animals, trypanosome species/strains, etc.) and outcomes. Specify the conclusions about the probable site of infection (geolocation) and the likelihood of local transmission.

3.4.2 Describe the measures put in place (active surveillance, passive surveillance, vector control, treatment of domestic animals, etc.).

3.5 Description of the last cases of HAT in the country (essential)

3.5.1 Describe the last (most recent) cases of HAT in the country including the last parasitologically confirmed case, if applicable, and the distribution by district or focus.

3.5.2 Provide the results of investigations around the last parasitologically confirmed cases of HAT (T+).

3.5.3. Provide the results of investigations around parasitologically unconfirmed cases of HAT (To).

3.5.4. Provide the results of further in-depth testing of parasitologically confirmed and unconfirmed cases of HAT, including trypanolysis and molecular biology tests. Specify, if applicable, the name and address of the WHO Collaborating Centre or the National Reference Laboratory that performed the tests.

4. Epidemiological data for HAT

4.1 Current data, at national level (essential)

Provide the following data at the national level, starting from the year 2000:

4.1.1. Number of cases per year, region and/or focus and health district. Always distinguish parasitologically confirmed (T+) and parasitology unconfirmed (To) cases.[1]

4.1.2. Ratio of active/passive surveillance cases per year.

4.1.3. Ratio of Stage 1/Stage 2 cases per year.

4.1.4. Proportion of cases confirmed by parasitology (T+), per year.

4.1.5. Population examined (passive/active) per year.

4.1.6. Proportion of cases treated.

4.1.7. Distribution of cases by village and year (table and map).

4.1.8. Include the number of villages visited in active screening in relation to the number of villages targeted for active screening, explaining the relevance and reasons for the selection, and including the geographical location of the villages screened in relation to recent areas of transmission or historical foci.

4.1.9. Include a table of active screening with the number of people tested over the estimated target population (rate of participation), per village (if possible), per year with the number of HAT cases (stage 1 and stage 2, parasitologically confirmed (T+) versus unconfirmed (To)) and the number of serological suspects detected, and those examined for parasitological diagnosis, indicating the diagnostic methods used.

4.1.10. In the case of "parasitologically unconfirmed suspects" detected in active screening indicate:

- the number of specimens sent to a reference laboratory for further investigation compared to "parasitologically unconfirmed suspects" detected, per village (if possible), per year. If applicable (in case of treatment of "parasitologically unconfirmed suspects"), specify if specimen collection was performed before or after treatment.

- the number of results received from the reference laboratory in relation to the number of specimens sent. Indicate how many specimens were reported as

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[1] T+: trypanosomes seen at microcopy; To: microscopy negative for trypanosomes.

negative and how many as positive and the methods used for examining the specimens in the reference laboratory.

- the number of serological suspects reported as positive by the reference laboratory who were followed up against the total number of serological suspects reported positive. If applicable, specify if HAT treatment was administered. Specify the methods used for follow-up and the results.

4.1.11. The number of reactive screenings that have been conducted compared to those planned based on the number of g-HAT cases detected. Detailed information about these reactive screenings should be reported, indicating the time elapsed between the detection of the confirmed case and the initiation of reactive screening.

4.1.12. Include a table of passive surveillance data per site and per year, with the number screened and test used, the number of seropositive cases, the number of HAT cases by stage and the numbers that were parasitologically confirmed (T+) and unconfirmed (To).

4.1.13. Provide a list of health facilities involved in HAT surveillance, with:

4.1.13.1. The origin of people who are examined for HAT by health structures (georeferencing), if available.

4.1.13.2. Data about follow-up of "parasitologically unconfirmed suspects" detected in passive screening, indicating:

- the number detected by site and year and how many of them were examined at the site level to establish parasitological diagnosis, methods used and results.

- the number of specimens of serological or clinical suspects by site and year who could not be confirmed locally that were shipped to a reference laboratory for further investigation against the total number of detected serological or clinical suspects. If applicable (in case of treatment of "parasitologically unconfirmed suspects"), specify if specimen collection was performed before or after treatment.

- the number of results per site and per year received from the reference laboratory in relation to the number of specimens sent. Indicate how many specimens were reported as negative and how many as positive and the methods used for examining the specimens in the reference laboratory.

- the number of "parasitologically unconfirmed suspects" reported as positive for reference tests by the reference laboratory who were followed up against the total number reported as positive. If applicable, specify if HAT treatment was administered. Specify the methods used for follow-up and the results.

4.1.14. List the numbers of cases reported in the past 5 years who were considered not to meet the case definition, providing the rationale (infected in another country, negative seroconversion on follow-up, evidence of infection > 5 years earlier, etc.).

4.2   HAT in neighbouring countries

4.2.1   Cross-border foci and countries involved (with map).

    4.2.1.1   List of cases diagnosed in the country but considered infected in neighbouring countries (specifying the origin), for at least the past 5 years.

    4.2.1.2   Number of national cases diagnosed in neighbouring (cross-border) or non-endemic (exported) countries, by specific origin, by year.

    4.2.1.3   Reactive investigations in response to imported and exported cases, and results.

4..2.2   Narrative on cross-border collaboration on testing and control.

5   Description of vector control activities.

5.1   Tsetse presence or absence and vector control strategy

Provide a narrative of data on tsetse presence or absence and on the vector control approach deployed since 2000.

5.1.1   Areas where surveys on vectors and/or vector control have been implemented, start and end dates, strategies, tools and methods used, spatial coverage in relation to the historical area of disease transmission.

5.2   Results of vector control related to g-HAT

5.2.1   Tsetse distribution maps, if possible, by species.

5.2.2   Tsetse density data and monitoring over time.

5.2.3   Proportion of flies infected with trypanosomes infectious to humans (if applicable). (Note that the presence of *T. b. gambiense* in tsetse is a potential risk of transmission that should not compromise the status of elimination in the country until the epidemiological evolution of g-HAT in humans is proven.

5.3.   Special cases

In case of tsetse-absence in general, and specifically the absence of anthropophilic species that are vectors of g-HAT in the ecological context of a country for a period of more than 5 years, a dossier for verification of the elimination of transmission may be directly submitted without the requirement for HAT surveillance data.

6.   Status of African animal trypanosomiasis (AAT)

Please note that stakeholders in the animal sector must contribute to the dossier.

6.1   Structure and capabilities to control AAT

6.1.1   Provide a narrative of livestock systems.

6.1.2   Describe the AAT control programmes and their links with the health sector. Include vector control against AAT and animal treatment activities.

6.2   Animal trypanosomiasis data

6.2.1   AAT distribution maps.

6.2.2   National Park maps and livestock density (by species).

6.2.3   AAT control activities (stakeholders, methods, coverage).

6.3   Description of existing data on the presence of *T. b. gambiense* in animals

If there are data about the presence of *T. b. gambiense* in non-human potential hosts in domestic and wild animals in the country, they must be presented.

6.3.1.   Specify the number of animals examined for *T. b. gambiense* infection by animal species, the number of positives and the methods used for sampling and detection.

6.3.2.   What is the geographical coverage of this knowledge in relation to the historical area of transmission of g-HAT?

Annex 2. Template dossier to claim the verification of the elimination of transmission to the human population of gambiense human African trypanosomiasis: part 2

Preamble

Part 2 of the dossier focusses on the data needed for the verification of the elimination of transmission.

In countries already validated for elimination as a public health problem, the starting point for the verification of the elimination of transmission of gambiense human African trypanosomiasis (g-HAT) is the dossier that has been submitted by the country for validation of elimination as a public health problem, along with the report of the assessment carried out by the validation team appointed by the World Health Organization (WHO). The activities implemented after validation of the elimination of g-HAT as a public health problem, covering at least the past 5 years, must be presented in this Part 2. In this case, only Part 2 needs to be presented, as Part 1 corresponds to the dossier already submitted for validation jointly with the report of the validation assessment team.

In countries that claim the elimination of transmission directly, without going through the prior validation stage of elimination as a public health problem, it is necessary to complete Part 1 and only the Introduction (point 1) and point 4 of Part 2.

Two main elements have to be clearly demonstrated in Part 2 of the dossier:

– the absence of parasitologically-confirmed g-HAT cases in the past 5 years; and
– the existence of a functional epidemiological surveillance system capable of detecting the occurrence of a case of g-HAT.

Part 2 comprises:

1. Introduction
2. Human health surveillance activities implemented after validation (only countries validated)
3. Vector control and animal reservoir surveillance activities implemented after validation of elimination of g-HAT as a public health problem.
4. Post-verification surveillance plan.

1.   Introduction

In countries where elimination as a public health problem has been validated, describe:

1.1   Elimination as a public health problem

1.1.1   The history of the process of eliminating g-HAT as a public health problem including dates of such milestones as the submission, the expert reviews and the acknowledgment of validation.

1.1.2   The political and social reactions to validation and their impact on the health personnel concerned.

1.1.3   A summary of the recommendations of the expert group assessing the validation dossiers, and the changes in the policy and organization of g-HAT control since validation as well as notable changes in the country's health system.

1.1.4   Major ecological or demographic changes relative to endemic areas.

1.2   The post-validation period

1.2.1   Describe the post-validation surveillance system: the implementation process, the monitoring activities performed, and the strengths and weaknesses of the strategy.

1.2.2   List the elements that led the country to submit the dossier to request verification of the elimination of transmission.

In countries claiming elimination of transmission, without going through the prior validation stage of elimination as a public health problem, describe:

The reasons and rationale that led to the country presenting the dossier for verification of the elimination of transmission without previous validation of elimination as a public health problem.

2.   Human population surveillance activities implemented.

Countries having eliminated g-HAT as a public health problem must present here the activities implemented after validation of elimination as a public health problem, for at least the past 5 years.

Countries applying directly for verification must present these data in chapters 3 and 4 of Part 1.

2.1   Passive surveillance

Passive surveillance takes place in health facilities where screening and diagnosis of people with serological and/or clinical suspicion of g-HAT have been added to other routine activities.

Include the case definition used in the country as well as the protocol for HAT-seropositive individuals, showing the passive diagnostic algorithm applied (specify the tests used) and the selection criteria used for examination of patients.

Indicate with tables, maps and the corresponding narrative text:

2.1.1 The list and geographical location of fixed health facilities with capacity for g-HAT surveillance and/or diagnosis in relation to known areas of g-HAT transmission or historical foci, with the start and end date of screening.

2.1.2 The number of people examined and tested for g-HAT (per facility, per year, and per type of test used).

2.1.3 The number of "parasitologically unconfirmed suspects" detected by site and year. Indicate how many of them were examined at the site level to establish parasitological diagnosis, methods used and results (number of parasitologically positive, negative and non-examined).

2.1.4 The number of specimens of serological or clinical suspects by site and year that could not be confirmed locally and were referred to a reference laboratory for further investigation against the total number of detected serological or clinical suspects. If applicable (in case of treatment of "parasitologically unconfirmed suspects"), specify if specimen collection was performed before or after treatment.

2.1.5 The number of results per site and per year received from the reference laboratory in relation to the number of specimens sent. Indicate how many specimens were reported as negative and how many as positive and the methods used for examining the specimens in the reference laboratory.

2.1.6 The number of "parasitological unconfirmed suspects" reported as positive for reference tests by the reference laboratory who were followed up against the total number reported as positive. If applicable, specify if HAT treatment was administered. Specify methods of follow-up and results.

2.1.7 The number of reactive screenings that have been conducted compared to those planned based on the g-HAT cases formerly detected. Indicate the time between detection of the confirmed case and reactive screening.

2.1.8 The supervision, training and evaluation activities carried out by site. The number of staff trained and supervised per site and per year.

2.1.9 The records of supervision covering the quality of the performance. The measures put in place if deficiencies have been observed and what is their impact.

2.2 Active surveillance

Active surveillance refers to activities carried out by mobile teams travelling to areas of transmission or to areas planned for investigation or reactive screening in order to examine the human populations concerned.

Active surveillance may be implemented by conventional mobile teams or by mobile mini teams. Both approaches aim to examine the maximum number of people within an identified population. Another approach may involve "population surveys", usually carried out on a sample defined by geographical and population factors.

The active surveillance strategies implemented should be described. If there have been none, the date of the last active screening should be given. Include studies and surveys other than classic active screening, including those conducted in areas of unknown HAT status. The diagnostic algorithm used in the active screening (specify the tests used) should be provided, as well as the protocol applied to HAT seropositive individuals (treatment, specimen for trypanolysis or molecular tests, active follow-up, etc.).

Data to be provided (tables, maps and the corresponding narrative text):

2.2.1   The number of villages visited in relation to the number of villages targeted for screening, explaining the relevance and reasons for the selection, and including the geographical location of the villages screened in relation to recent areas of transmission or historical foci.

2.2.2   The number of people tested over the estimated target population, per village (if possible), per year.

2.2.3   The number of serological suspects detected, and those examined for parasitological diagnosis, per village (if possible), per year, indicating the diagnostic methods used and the numbers parasitologically confirmed and unconfirmed.

2.2.4   The number of specimens of "parasitologically unconfirmed suspects" sent to a reference laboratory for further investigation compared with the numbers of "parasitologically unconfirmed suspects" detected, per village (if possible), per year. If applicable (in case of treatment of "parasitologically unconfirmed suspects"), specify if specimen collection was performed before or after treatment.

2.2.5   The number of results received from the reference laboratory in relation to the number of specimens sent. Indicate the results obtained and the methods used for examining the specimens in the reference laboratory.

2.2.6   The number of serological suspects reported as positive by the reference laboratory who were followed up against the total number of serological suspects reported positive. If applicable, specify if HAT treatment was administered. Specify the methods used for follow-up and the results.

2.2.7   The number of reactive screenings that have been conducted compared to those planned based on the number of g-HAT cases detected. Detailed information about these reactive screenings should be reported, indicating the time elapsed between the detection of the confirmed case and the initiation of reactive screening.

2.2.8   Training carried out for staff in charge of active surveillance. The number of staff trained per team and per year.

2.2.9   Supervision activities carried out for staff in charge of active surveillance. Records of supervision covering the quality of the performance. The number of staff supervised per site and per year. The results and measures put in place if deficiencies have been observed, and details of their impact.

2.3   Exceptions: cases not meeting the case definition

When none of the diagnosed cases meet the case definition, countries can consider that the zero-case condition is fulfilled.

2.3.1   List the cases in the past 5 years who were considered not to meet the case definition despite microscopic detection of trypanosomes, providing the rationale for each one (infected in another country, infected by laboratory accident, evidence of infection > 5 years earlier, trypanosome observed has been conclusively characterized as not of the subspecies *T. b. gambiense*).

2.3.2.   Provide other data or reasons for potentially fulfilling the zero-case condition such as negative seroconversion during follow-up. Provide an explanation on individuals lost to follow-up and any arguments to consider that the zero-case condition is fulfilled.

3.   Vector control and non-human reservoir surveillance activities implemented in the past 5 years.

Countries having eliminated g-HAT as a public health problem should include the activities implemented after validation of elimination as a public health problem for at least the past 5 years.

Countries applying directly for verification must present these data in chapters 5 and 6 of Part 1.

Data on the presence or absence of *T. b. gambiense* infection in domestic or wild animal reservoirs and in tsetse flies are not considered essential for verifying the elimination of transmission of g-HAT to human populations. Verifying the elimination of transmission to the human population may not exclude the fact that the parasite could still be present in non-human reservoirs and thus represents a risk of re-emergence of the disease. Therefore, if data on the presence of *T. b. gambiense* in the vector or in non-human reservoirs exist, they should be included in this dossier as they can help not only to assess the risk of re-emergence of the disease but also to assist in planning the post-verification phase.

3.1   Vector control

Vector control activities or any vector survey data conducted after validation of elimination as a public health problem.

Data to be provided.

3.1.1   The areas in which surveys on vectors and/or vector control have been implemented, start and end dates, strategies and methods used, and spatial coverage in relation to the historical area of disease transmission.

3.1.2   The number of tsetse flies that were examined for possible *T. b. gambiense* infection, the results and the methods used for sampling and detection.

3.2 Human infective trypanosomes in non-human animals

There is evidence of non-human potential hosts of *T. b. gambiense* in domestic and wild animals. If there are data on this subject in the country claiming elimination of g-HAT transmission, they must be presented in this dossier in the following form:

3.2.1   The number of animals examined for *T. b. gambiense* infection by animal species, and the results and methods used for sampling and detection.

3.2.2   The geographical coverage of this knowledge in relation to the historical area of transmission of g-HAT.

4.   Post-verification surveillance plan

The present dossier refers to the verification of elimination of transmission of *T. b. gambiense* to human populations. The dossier is based on a robust demonstration, following monitoring of the absence of parasite circulation in human populations inhabiting known areas of disease transmission, for a defined period of time. This does not preclude the possibility of the existence of a transmission cycle in domestic or wild animals. For this reason, elimination is considered an intermediate step towards eradication. Therefore, once verification of elimination has been established, a post-elimination action plan should be in place to monitor for possible re-emergence of the disease in the country.

The objective is to maintain the acquired status of zero endogenous cases in the human population. The appearance of sporadic cases is possible, and provision must be made to allow scrutiny of such cases individually and epidemiologically. The presence of *T. b. gambiense* in tsetse and/or non-human animals in the absence of endogenous cases of g-HAT does not compromise the status of elimination, but it may inform the surveillance methods used and the priority areas identified.

The post-verification surveillance plan should be described, indicating stakeholders, locations and planned methods for monitoring any possible re-emergence of transmission of the disease and possible response. Data must be reported annually.

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