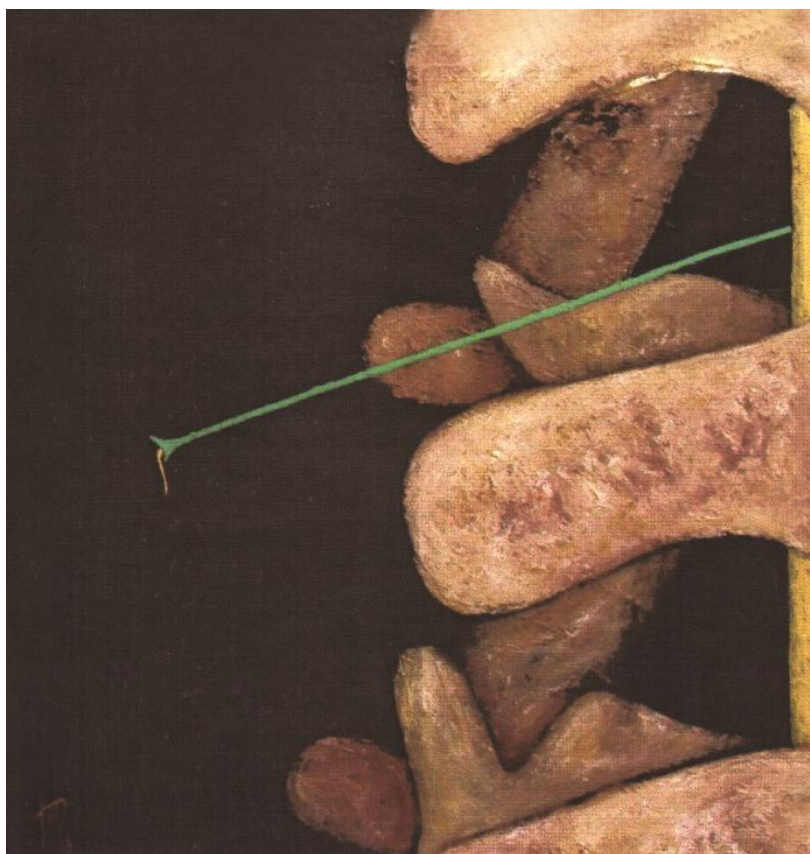


Report of the first WHO stakeholders meeting on gambiense human African trypanosomiasis elimination

Geneva, 25–27 March 2014



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WHO/HTM/NTD/IDM/2014.4

Cover page :Illustration from the original donated painting “La ponction” from Nestor Favre

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1. Introduction

Following a dramatic resurgence of human African trypanosomiasis (HAT) in the 1980–1990s, joint efforts carried out since 2000 by the World Health Organization (WHO) and partners helped reverse the epidemic and led to a decline in the number of new cases reported annually.¹ These efforts led also to scientific and technical advances in several domains, including epidemiology, diagnostic and therapeutic tools, and vector control.

In 2007, in Geneva, representatives of HAT endemic countries endorsed the goal of elimination of the disease as a public health problem.² In 2011, the WHO Strategic and Technical Advisory Group (STAG) for neglected tropical diseases (NTDs) judged elimination to be technically feasible and HAT was included in the WHO Roadmap on NTDs with a target for elimination as a public health problem by 2020.³

In January 2012, in London, a number of partners from the public and private sectors launched the largest coordinated effort against NTDs and issued the *London Declaration on Neglected Tropical Diseases*⁴, a renewed, coordinated approach for accelerating the eradication, elimination or control of 10 NTDs by 2020. The partners pledged to work together to improve the lives of the 1.4 billion people affected by NTDs worldwide by enhancing the supply of existing medicines, stimulating collaborative research for new treatments and increasing funding for control and elimination activities. They targeted HAT for elimination alongside five other diseases, and endorsed the WHO Roadmap.

In December 2012, in Geneva, national sleeping sickness control programmes (NSSCPs), experts from WHO collaborating centres and the STAG-NTDs formulated the strategies, tools, monitoring indicators and milestones for the process of eliminating gambiense HAT (g-HAT). They considered elimination of g-HAT as public health problem as an intermediate objective that should be followed by the elimination of the disease, defined as absence of transmission resulting in zero cases reported in all foci, and proposed 2030 as the deadline for this new outcome of elimination.⁵

In 2013, a WHO Expert Committee report was published, which provides a comprehensive update on new diagnostic tools, new therapeutic regimens and on the distribution of the disease with high-quality mapping. New information on the roles of human and animal reservoirs and the tsetse fly vectors is included as well. The report also contains recommendations on approaches for the elimination of g-HAT.⁶

Considering the current situation of the disease, WHO convened a meeting of the main stakeholders working to fight g-HAT to analyse the current situation, the challenges to elimination and the needs for research in order to reinforce commitment to elimination and strengthen the mechanisms of collaboration through a structured network of stakeholders (see Agenda in Annex 1). The meeting focused on g-HAT caused by the parasite *Trypanosoma brucei gambiense*, prevalent in West and

¹ Simarro PP et al. The Human African Trypanosomiasis Control and Surveillance Programme of the World Health Organization 2000–2009: the way forward. *PLoS Negl Trop Dis*. 2011;5:e1007.

² Report of a WHO informal consultation on sustainable control of human African Trypanosomiasis. Geneva, 1–3 May 2007. Geneva: World Health Organization; 2007 (WHO/CDS/NTD/IDM/2007.6; also available at http://whqlibdoc.who.int/hq/2007/WHO_CDS_NTD_IDM_2007.6_eng.pdf; accessed 28 February 2013).

³ Accelerating work to overcome the global impact of neglected tropical diseases: a roadmap for implementation. Geneva: World Health Organization; 2012 (WHO/HTM/NTD/2012.1; also available at http://www.who.int/neglected_diseases/NTD_RoadMap_2012_Fullversion.pdf; accessed 28 February 2013).

⁴ The London Declaration on Neglected Tropical Diseases (available at http://www.unitingtocombatntds.org/downloads/press/london_declaration_on_ntds.pdf).

⁵ Report of a WHO meeting on elimination of African trypanosomiasis (*Trypanosoma brucei gambiense*). Geneva, 3–5 December 2012. Geneva: World Health Organization; 2013 (WHO/HTM/NTD/IDM/2013.4) (http://apps.who.int/iris/bitstream/10665/79689/1/WHO_HTM_NTD_IDM_2013.4_eng.pdf).

⁶ Control and surveillance of human African trypanosomiasis: report of a WHO Expert Committee. Geneva: World Health Organization; 2013 (WHO Technical Report Series, No. 984).

Central Africa, which accounts for around 98% of all reported cases of HAT.

As rhodesiense HAT (r-HAT) is a zoonosis with both domestic and wild hosts, its elimination as total interruption of transmission is not considered technically feasible at this time. Elimination of r-HAT requires a tailored and multisectoral approach not necessarily the same as that developed for g-HAT. A meeting is planned in October 2014 to formulate objectives for control of r-HAT, identify gaps in operational research, select partners and stakeholders, and set up a coordination network.

2. Objectives

The objectives of the meeting were:

1. To step up the commitment of national authorities and technical and financial partners to WHO's elimination objective for g-HAT.
2. To share achievements, challenges and views on the elimination goal among countries and implementing partners.
3. To assess the status of critical technical aspects to be solved in research and development of drugs and diagnostic tools, epidemiology, vector control and animal reservoirs.
4. To define the mechanisms for strengthening and organizing collaboration and coordination among stakeholders.

3. Opening remarks

Dr Hiroki Nakatani, Assistant-Director General, HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, opened the meeting, remarking on the special opportunity and momentum for the elimination and eradication of NTDs as partners from the public and private sectors aligned with unprecedented strength.

Dr Dirk Engels, Director, WHO Department of Control of Neglected Tropical Diseases, stressed the fact that even with imperfect tools, advance in HAT control and elimination is possible via a coordinated and systematic approach.

Dr Jean Jannin, Coordinator, Innovative and Intensified Disease Management unit, NTD Department, recalled the partnership-building efforts of the past two decades that had paved the way for the current success in curbing the disease, and the strong commitment of donors, scientists, manufacturers of drugs and diagnostic tools, and nongovernmental organizations (NGOs) in supporting NSSCPs to eliminate g-HAT. The deliberations of the meeting would be key to solidifying this commitment into a structured coordination mechanism to work towards the 2020 elimination goal.

A minute of silence was held to mark the passing of Dr Constantin Miaka Mia Bilengue, a prominent leader for many years in the fight against HAT in the Democratic Republic of the Congo.

Professor Peter Holmes, who is currently chairing the STAG-NTD, was elected as the Chair.

4. Open floor for stakeholders

The meeting was attended by high-level representatives of most of the stakeholders involved in the fight against g-HAT in different ways (see List of participants in Annex 2). The meeting included an open session during which stakeholders delivered the following key messages:

- Sanofi will continue accompanying the process until elimination.

- Bayer announced that in addition to the renewable drug donation, a 3-year pilot project (2013–2015) has been added to support active case-finding activities.
- The Bill & Melinda Gates Foundation reaffirmed its intention to maintain the support to developing control tools (diagnostics, treatment and vector control) that is channeled mainly through research and development partners.
- The Institute of Tropical Medicine (ITM) will assume for 3 years the former role of the Belgian Development Agency of support to the NSSCP in the Democratic Republic of the Congo. Although support to the medical sector was not included in the bilateral agreement with Belgium and the Democratic Republic of the Congo, HAT was considered an exception because of the long history of support and the elimination goal. It was considered that a “diagnostics donation programme” is needed to address the chronic limitations in the availability of diagnostic tools.
- The African Union/PATTEC (Pan African Tsetse and Trypanosomiasis Eradication Campaign) stressed the crucial need for support to national programmes.
- The Food and Agriculture Organization of the United Nations (FAO) and the International Atomic Energy Agency (IAEA) confirmed their continued commitment to and alignment with WHO on the elimination of HAT; both organizations are involved in HAT control in the framework of the Programme Against African Trypanosomiasis (PAAT)
- The portfolio of the Drugs for Neglected Diseases initiative (DNDi) is in line with and framed on the elimination of HAT. Synergy among stakeholders conducting control, surveillance and research activities is needed.
- The Foundation for Innovative New Diagnostics (FIND) reaffirmed its commitment to the collaboration with WHO that began in 2006 and supports the call by the ITM for a “diagnostics coalition” to ensure access to diagnostic tests for all.
- Médecins Sans Frontières (MSF) renewed its commitment to fighting HAT as pledged in 2013 but warned of the difficulties in practice of reconciling HAT with competing priorities within MSF.
- The Liverpool School of Tropical Medicine issued a call for increased financial support for vector control activities in support of the WHO HAT elimination target.
- IRD has secured the HAT research team for the period 2015–2019.
- Focal points from NSSCPs reiterated the need for better communication among countries and strong coordination by WHO in leading the elimination of HAT.

The stakeholders agreed to issue a declaration from the meeting to appeal for strengthened international support to g-HAT elimination.

5. Country and NGO reports

Country reports

Representatives of Angola, Cameroon, the Central African Republic, Chad, Côte d’Ivoire, the Democratic Republic of the Congo, Guinea, South Sudan and Uganda presented the disease situation in their countries. The main topics are presented in Annex 3, country by country, including the geographical distribution of the disease, capacities for g-HAT control and surveillance, and scores on progress towards g-HAT elimination. The following issues were addressed:

The epidemic curves for the decade 2004–2013 had an overall downward trend in all countries (see

Annex 3). The peaks of some years in the Central African Republic, Chad and Guinea were explained by more intensive screening being carried out. Conversely, some of the deep valleys were explained by interruption of activities due to lack of funding or civil unrest.

Among the strengths most often pointed out by countries was the success in decreasing the number of cases and the availability of medicines.

The weak points cited were more numerous and differed by country, but converged among several countries on:

- lack of ownership by national authorities
- lack of integration in the health system
- poor health system with discouraged staff
- gradual retirement of skilled staff and lack of appropriate staff
- weak knowledge of HAT among health staff
- low level of community awareness
- difficult access to affected populations
- social instability and population displacements
- insufficient funding, with demobilization of key actors supporting HAT control because of decreasing disease prevalence
- low investment in vector control.

NGO reports

MSF is practically the only NGO currently active in the field. It focuses on remote and politically unstable areas such as the northern Orientale Province (Democratic Republic of the Congo) and Batangafo (north-west Central African Republic), where 1371 and 65 cases were detected and treated in 2013, respectively. An MSF international mobile team carries out short-term interventions in foci without appropriate surveillance where disease transmission is suspected (“blind spots”) in several countries, having screened 94.359 people with 49 cases detected and treated for the period 2011–2013.

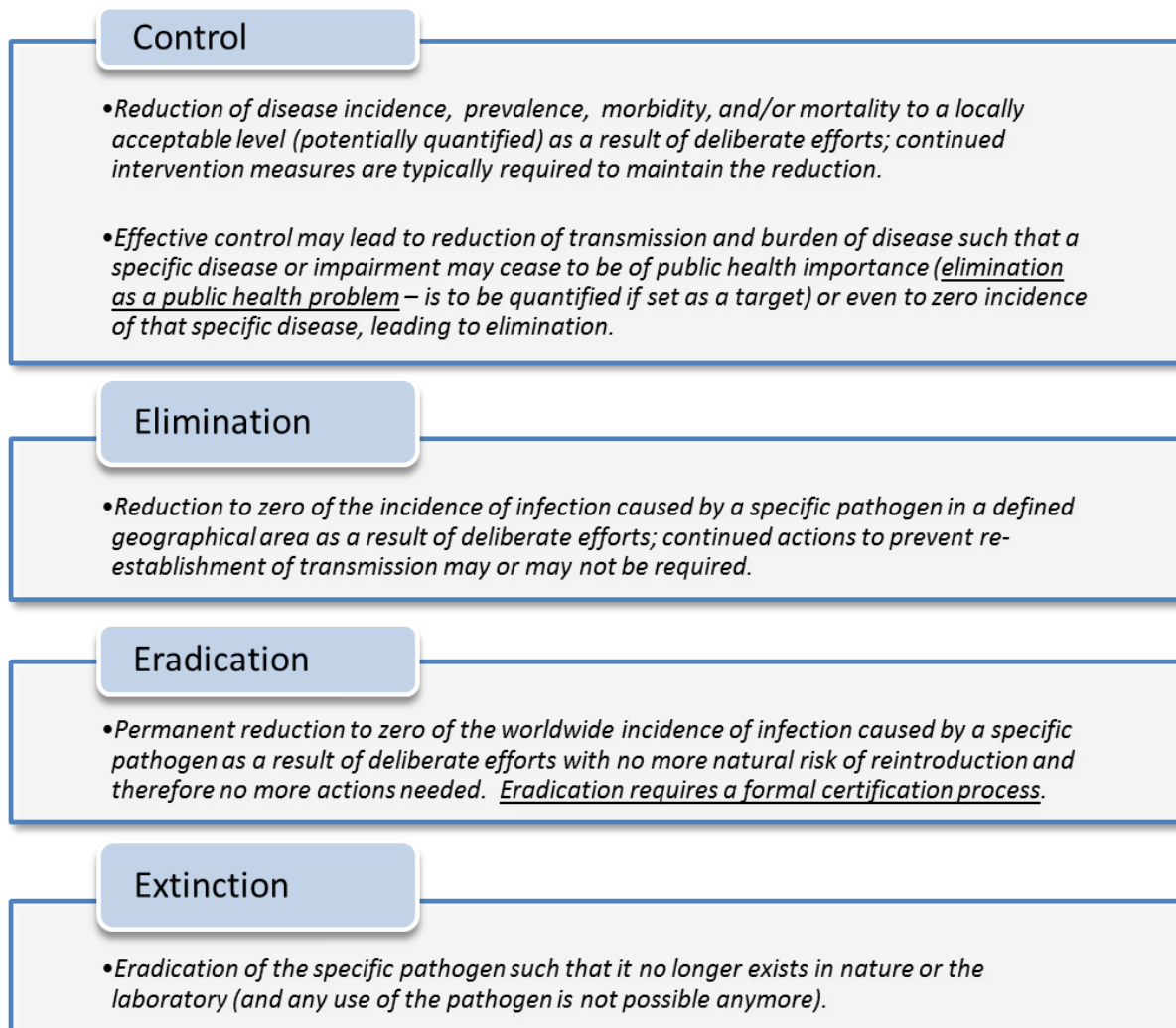
MSF programmes act as research sites for ongoing studies on new diagnostic tools (pilot implementation of individual serological tests) and new treatments (fexinidazole), while continuing to advocate sustained funding for research and disease control. MSF-Logistics provides services for the conditioning, storage and shipment of antitrypanosomal drugs, including nifurtimox–eflornithine combination therapy (NECT) kits, always under the instructions of WHO.

6. Gambiense HAT elimination

6.1. Concepts and terminology

Clarifications of concepts and terminology for control, elimination, eradication and extinction are detailed in *Figure 1*.

Figure 1. Concepts and terminology according to WHO STAG-NTDs



6.2. Rationale for gambiense HAT elimination

The International Task Force for Disease Eradication issued in 1988 a list of basic principles to guide the assessment and feasibility of infections for eradication and elimination. These principles considered the following aspects:

1. Epidemiological vulnerability (e.g. absence of non-human reservoirs, ease of spread, naturally induced immunity, ease of diagnosis, duration of relapse potential)
2. Availability of effective, practical interventions
3. Demonstrated feasibility of elimination
4. Political will and popular support
5. Resources and estimated cost

Within this framework, the rationale for g-HAT elimination is as follows:

1. Epidemiological vulnerability

Humans are the main reservoir of the parasite, although additional data are needed to elucidate the role played by some animals as reservoirs.

The distribution of the disease is limited to well-described foci; currently, 95% of cases occur in five countries.

2. Effective interventions are available

Active case detection and treatment and vector control have proven effective in achieving high levels of control.

New tools for diagnosis, treatment and vector control are in the pipeline (individual serological tests for screening, new oral drugs, new adapted devices for vector control).

All medicines are donated by the manufacturers, and access by patients to free treatment is ensured.

The Atlas of HAT, prepared jointly by WHO and FAO with collaboration from NSSCPs, provides detailed information about the disease distribution up to the village level.

3. Demonstrated feasibility of elimination

As proof of principle, g-HAT has been eliminated in several foci, for example in the focus of Luba (Equatorial Guinea). After intensive control activities initiated in 1985, the number of cases reduced drastically. The last case was reported in 1995 despite regular active and passive surveillance.

4. Political will

Multiple meetings, declarations and resolutions show that there is marked interest among political decision-makers to support HAT control and elimination.

In 2000, during the summit in Lomé of the African Union Organization, the Heads of State and Governments of African countries declared their willingness to free Africa from the scourge of tsetse and trypanosomiasis and promoted the Pan Africa Tsetse and Trypanosomiasis Eradication Campaign (PATTEC).

In 2003, the 56th World Health Assembly adopted resolution WHA56.7, calling on Member States to intensify HAT control efforts to “implement a programme for the elimination of human African trypanosomiasis as a public health problem”.

In 2005, elimination of HAT was endorsed during the 55th WHO Regional Committee for Africa in Maputo by AFR/RC/55/R3 and included in the conclusions of the International Scientific Council for Trypanosomiasis Research and Control (ISCTRC) in Addis Ababa, Ethiopia.

In 2007, endemic countries endorsed the elimination goal during a WHO meeting on elimination of g-HAT held in Geneva.

In 2011, the STAG-NTD assessed and deemed elimination of HAT to be feasible.

In 2012, elimination of HAT “as a public health problem” was included in the WHO Roadmap on NTDs.

In 2013, the 66th World Health Assembly adopted resolution WHA66.12 on NTDs to ensure continued country ownership to expand and implement interventions to reach the targets agreed in the Global Plan to Combat Neglected Tropical Diseases and set out in the Roadmap, where elimination of HAT is included.

5. Resources

In January 2012, representatives from partners supporting the control of different NTDs issued the London Declaration on Neglected Tropical Diseases. The Declaration supports the Roadmap's 2020 targets for NTDs and commits to sustain, expand and extend programmes to ensure the necessary supply of drugs and other interventions, including to achieve the targets for HAT elimination.

6.3. Strategy for gambiense HAT elimination

The goal set by the Roadmap is “to eliminate g-HAT as a public health problem” by 2020. Elimination as a public health problem is defined as less than 1 new case per 10 000 inhabitants in at least 90% of foci, with fewer than 2000 cases reported annually at continental level. The 2020 goal is an intermediate step. The final goal, in accordance with the recommendations of the STAG-NTD, is to interrupt transmission of g-HAT by 2030. This sustainable, final step is defined as reduction to zero of the incidence of infection caused by g-HAT in endemic countries; noting that continued actions will be required to prevent re-establishment of the disease.

The elimination strategy is based on the four classical elements of g-HAT control:

1. Active case-finding through mobile teams,
2. Passive case-finding involving available health facilities,
3. Vector control to reduce the tsetse population,
4. Management of detected cases.

These elements must be appropriately combined and “dosed” according to:

- the intensity of transmission
- a precise understanding of the epidemiological setting, including geographical and demographic data,
- accessibility and capabilities of existing health facilities,
- knowledge of the vectors, the sites where vector control must be applied and the methods to be used.

HAT is a focal disease and the strategy must therefore be adapted to the situation in each focus rather than at country level. Moreover, the basic element for planning interventions is the village, according to its epidemiological status. The general framework for use of the strategy is summarized in Annex 4.

The strategy must be sufficiently flexible and dynamic to remain adaptable to different factors as the epidemiological situation evolves and changes affecting the local health services are made.

Implementation of the strategy will require a stable socio-political context, secure and turmoil free. Ownership by endemic countries of the objectives and process of elimination is crucial, as is long-term, appropriate funding from donors to implement elimination strategies, support operational research and develop new tools. The framework of elimination, control and surveillance must be integrated in the health system. Important challenges in addition to complex control tools are the weak capacity to implement control and surveillance activities, and low attendance and coverage of the health system in rural areas affected by HAT.

Elimination of g-HAT raises critical technical issues that require answers, and research must be orientated to solve these open questions:

- Estimation of the numbers and location of undetected and unreported cases, including areas where epidemiological knowledge is limited due to lack of surveillance and accessibility is difficult because of topographical or security constraints.
- The role of seropositive but aparasitaemic human carriers in maintaining transmission of g-HAT and the management of these cases.
- The role of animal reservoirs in transmission of g-HAT and reintroduction of the disease in humans.
- The role of vector control with affordable methods in the different elimination scenarios.
- The development and validation of new tools for diagnosis and treatment that are safer, less demanding, more affordable, robust and easier to use than existing tools. These include new screening tools (serological tests) that are easier to produce and cheaper; accurate and simple tests to confirm parasitology; less invasive staging tests; and safe, easy-to-use oral treatments effective against both forms and both stages of the disease.
- The development of tools for monitoring the elimination of g-HAT.
- Currently, clinical trials for new drugs are complex and long. Simplification and facilitation of clinical trials must be studied, while ensuring their scientific quality and the safety of the patients enrolled in them.
- Integration of g-HAT control and surveillance into routine activities of the health systems and maintaining staff motivation.
- Sustainability of elimination, risk of re-introduction and early detection of reintroduction.

6.4. Monitoring and evaluation of gambiense HAT elimination

Elimination as a public health problem

The elimination of g-HAT as a public health problem must be validated focus by focus. Endemic countries must build a validation file to be defined by a group of experts. It is foreseen that topics could include the standard operating procedures to detail key aspects of activities, such as epidemiological surveillance; coverage of activities; evidence of absence of cases; sustained control measures implemented; and presence of a functional detection and treatment system.

The validation file would be submitted to WHO for examination by a specific validation consultative group to verify that it is complete and complies with the standard operating procedure.

Based on the recommendation of the validation consultative group, the elimination of g-HAT as a public health problem in a country could be listed in the WHO statistic reports.

Elimination

The elimination of g-HAT as zero incidence must be verified. Eligible countries must build a verification file to be defined by a group of experts. It is foreseen that topics could include sustained epidemiological surveillance and its coverage; evidence of absence of cases; policy about healthy carriers and reservoirs of infection; situation of vector transmission; referral system for identification of cases and treatment; and post-elimination monitoring system.

The verification file would be submitted to WHO for examination by a specific verification consultative group to verify that the file is complete and complies with standard operating procedures, and to decide if a country visit is necessary at this stage.

Based on the recommendation of the verification consultative group, the elimination of g-HAT in a country could be listed in the WHO statistic reports.

Monitoring gambiense HAT elimination

The progress towards elimination will be continuously monitored in order to:

- Ensure the appropriateness and effectiveness of the strategy
- Adapt the strategy to the epidemiological situation
- Establish the timing for transitioning from one strategy to the next
- Ascertain the quality of control and surveillance activities
- Ensure sustainability and prevent re-emergence of the disease

Monitoring and evaluation will be essentially based on data collected by health facilities and mobile teams diagnosing and treating cases. Health facilities include HAT-specific health structures, HAT sentinel sites, and regular health facilities with integrated HAT case management. Mobile teams include regular mobile teams and reactive mobile teams.

These data are provided to WHO by countries and NGOs and entered in the global database linked to the HAT Atlas.

Progress will be measured via a set of indicators established in previous expert meetings (see section 6.5: *Recent progress in g-HAT elimination*)

At country level, the status of control and surveillance capacities will be followed by a qualitative assessment of different areas:

- Management of NSSCPs
- Epidemiological knowledge
- Active case-finding
- Passive case detection
- Case management
- Vector control
- Accessibility to populations
- Country ownership

6.5. Recent progress in gambiense HAT elimination

To measure the progress towards elimination of g-HAT, two quantitative indicators that are updated annually were selected and endorsed by the last WHO Committee of Experts on HAT in April 2013:

- the number of cases reported. This is a clear and simple indicator. However, it must be interpreted in the light of and assessment of the quality of the data and the circumstances other than epidemiology that have influenced its progress. This indicator relates to the coverage and accuracy of control and surveillance activities.

- the number of foci reporting annually less than 1 case per 10 000 inhabitants. This indicator has to be calculated from 2015 onwards. It requires to define the extent and population of each focus and to correctly allocate cases to their focus.

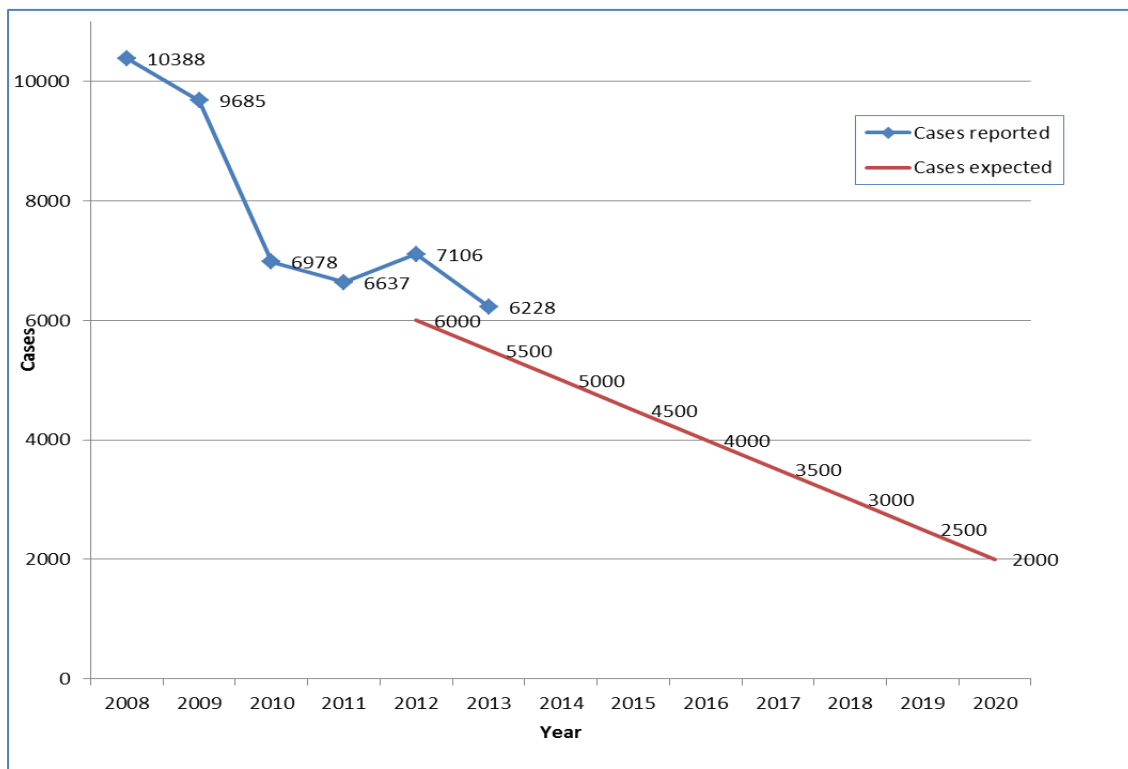
Additionally, secondary indicators are used to measure the quality and intensity of the elimination programme activities. These secondary indicators are updated every 2 years; their progress is assessed by comparing study periods of 5 years. They include:

- The geographical extent of the disease. This indicator shows the presence and absence of the disease at the village level in disease-endemic areas.
- The populations at different levels of risk. This indicator is calculated using an already defined method that takes into account the number of cases reported and the population estimated by Landscan^R.
- The proportion of the population at risk covered by control and surveillance activities. This indicator is based on the population at risk covered by active screening activities and their potential access to health facilities providing HAT diagnosis and treatment.

The basis for calculating the progress of these indicators is the database of the HAT Atlas, which is built according to the reports provided by field actors: the national sleeping sickness control programmes, NGOs and research institutions. This information is compared with the number of inhabitants in HAT areas using Landscan^R data.

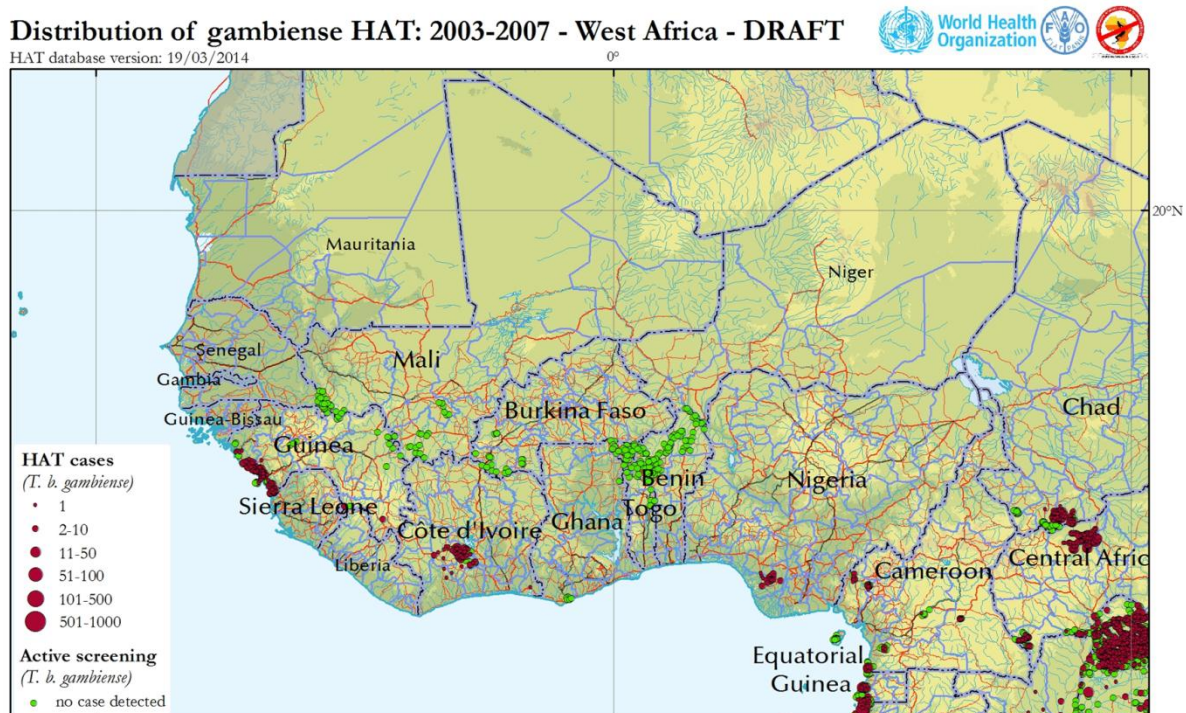
The number of cases reported in 2012 was 1106 more than expected. This excess was due mainly to improved security in Orientale Province (Democratic Republic of the Congo) and the Ouham focus (Central African Republic), which facilitated access to areas not visited for some years, and the detection of cumulated cases infected during several years. The deviation in 2013 from the expected benchmark improved and the divergence decreased to 728 cases (*Figure 2*).

Figure 2. Cases of g-HAT reported in 2008–2013 and targeted milestones for g-HAT until 2020 as established in the WHO Roadmap



Concerning the geographical extent of the disease in West Africa, HAT transmission has stayed at the same level in Guinea during the past 5 years despite sustained active case-finding surveys in mangrove foci. Vector control activities have started to complement medical surveys. In Côte d'Ivoire, the decrease in the number of cases reported could be due to less active surveillance during social disturbances in the first decade of the 21st century. However, when active case-finding surveys resumed, no increase in the number of cases was observed. An in-depth field study in all foci to improve knowledge of the status of the disease in this country is planned. A similar decrease in the number of cases was reported in Nigeria, although this decrease may not reflect the reality in the field due to the lack of sufficient passive or active case-finding. *Figure 3* shows the disease distribution in West Africa for the periods 2003–2007 and 2008–2012.

Figure 3. Distribution of g-HAT in West Africa, 2003–2007 and 2008–2012



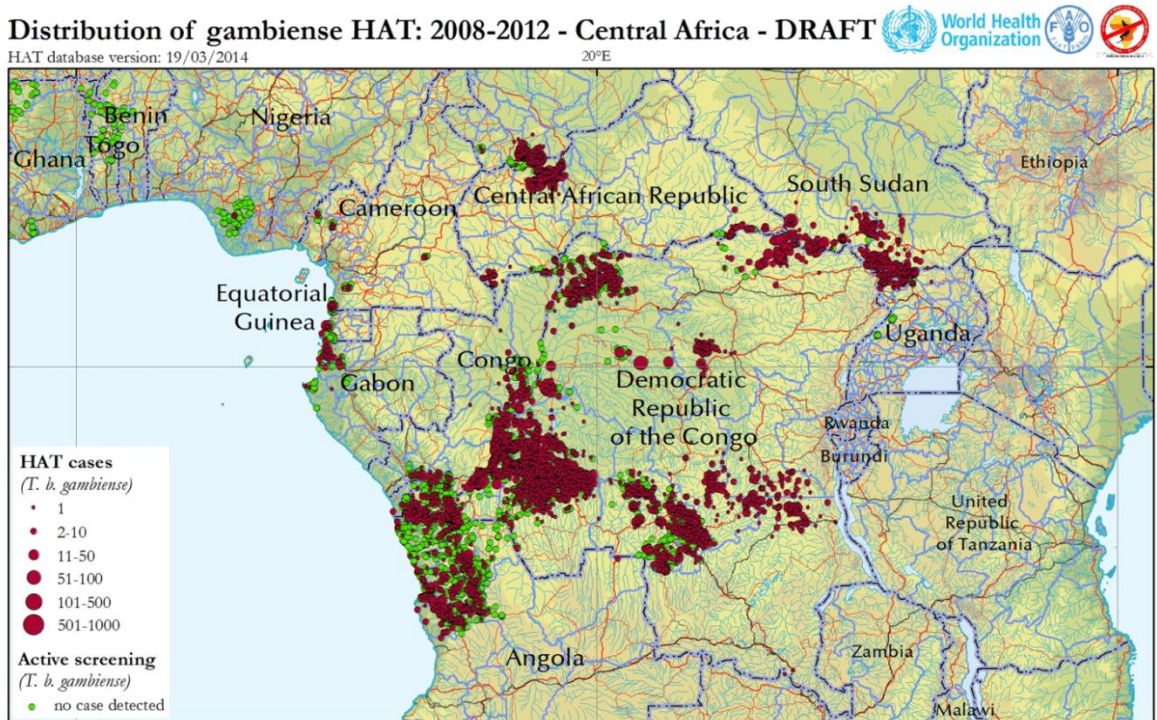
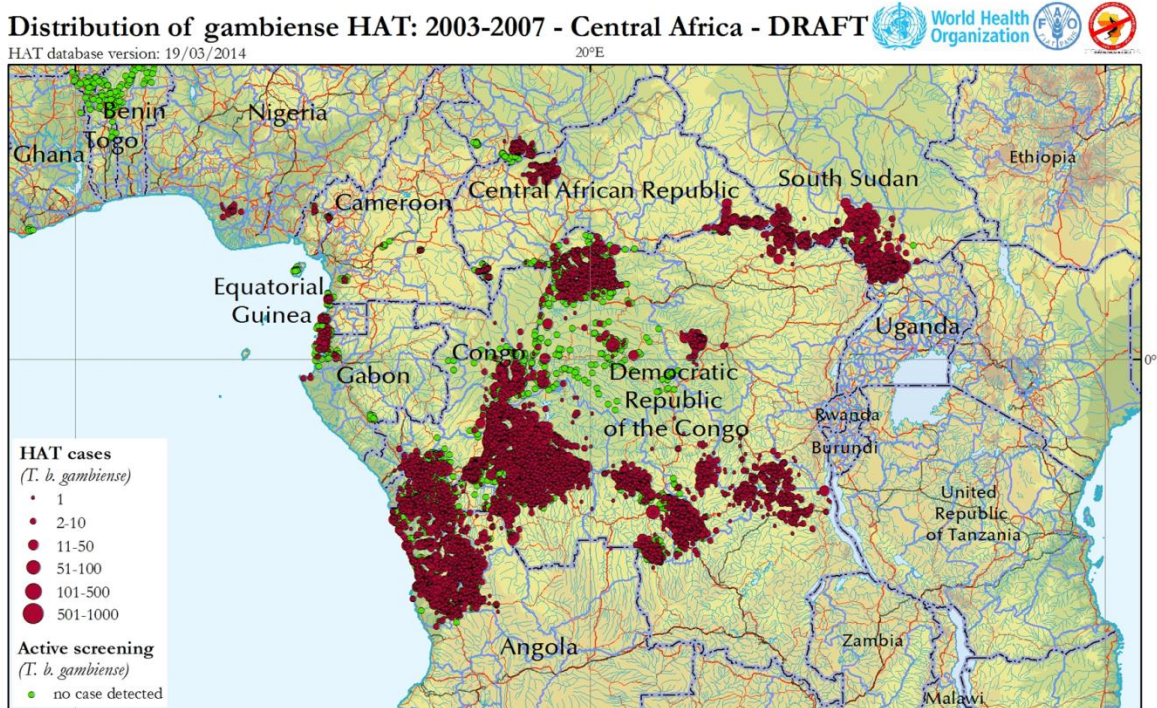
Distribution of gambiense HAT: 2008-2012 - West Africa - DRAFT

HAT database version: 19/03/2014



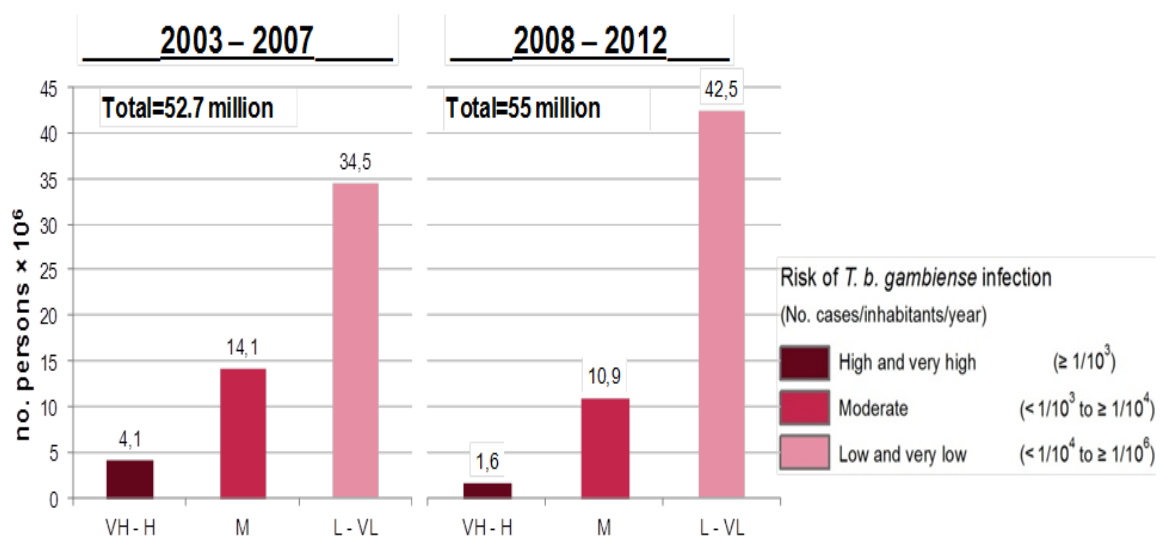
In Central Africa, social stability has permitted access to foci in Cameroon, Equatorial Guinea and Gabon as well as in the Congo. Sustained active screening in these countries has led to a significant decrease in the number of cases reported. In Chad, despite active screening being regularly applied in the most active focus, the Mandoul, the number of cases reported has not decreased as expected. Vector control activities to complement medical surveys are ongoing. In the Central African Republic, although an overall decrease in the number of cases is registered, the difficulties of accessing foci in Haut Mbomou due to logistic and security constraints as well as the complex and dangerous situation for mobile teams working in the Ouham focus may mean that the current data do not reflect the real status of disease transmission. In South Sudan and Uganda, a significant decrease in the number of cases has been reported. Whereas in Uganda extensive active and passive screening has been applied, in South Sudan it needs to be reinforced. Angola has also reported an important decrease in the number of cases. Finally, in the Democratic Republic of the Congo, despite being the country reporting the most cases, a major decrease has been registered while maintaining active screening intensity and reinforcing passive screening; however, logistic and security constraints still make it difficult to have an accurate knowledge of the epidemiological extent of the disease in all the foci registered in the country. *Figure 4* illustrates the difference of disease distribution in Central Africa, comparing the 2003–2007 and 2008–2012 periods.

Figure 4. Evolution of g-HAT distribution in Central Africa, 2003–2007 and 2008–2012



The evolution over time of the population living at different levels of risk for g-HAT infection has been calculated applying the methodology described elsewhere.⁷ Comparison of the 2003–2007 and 2008–2012 periods shows that the number of people exposed to high or very high risk has decreased by 61% from 4.1 million to 1.6 million; the number of people living at moderate risk has decreased by 23% from 14.1 million to 10.9 million. The number of people living at low or very low risk for g-HAT infection (i.e. less than 1 case per 10 000 inhabitants) has increased by 23% from 34.5 million to 42.5 million. This increase is due to two factors: (i) people who were previously at a higher level of risk who are now at a lower level of risk; and (ii) population growth, which is more rapid in settings at low level of risk. It is important to note that of the 55 million people considered at risk for g-HAT, 77% have reached the epidemiological status where the disease is considered eliminated as a public health problem (i.e. less than 1 case per 10 000 inhabitants per year) (*Figure 5*).

Figure 5. Evolution of the population at risk for g-HAT during the past decade



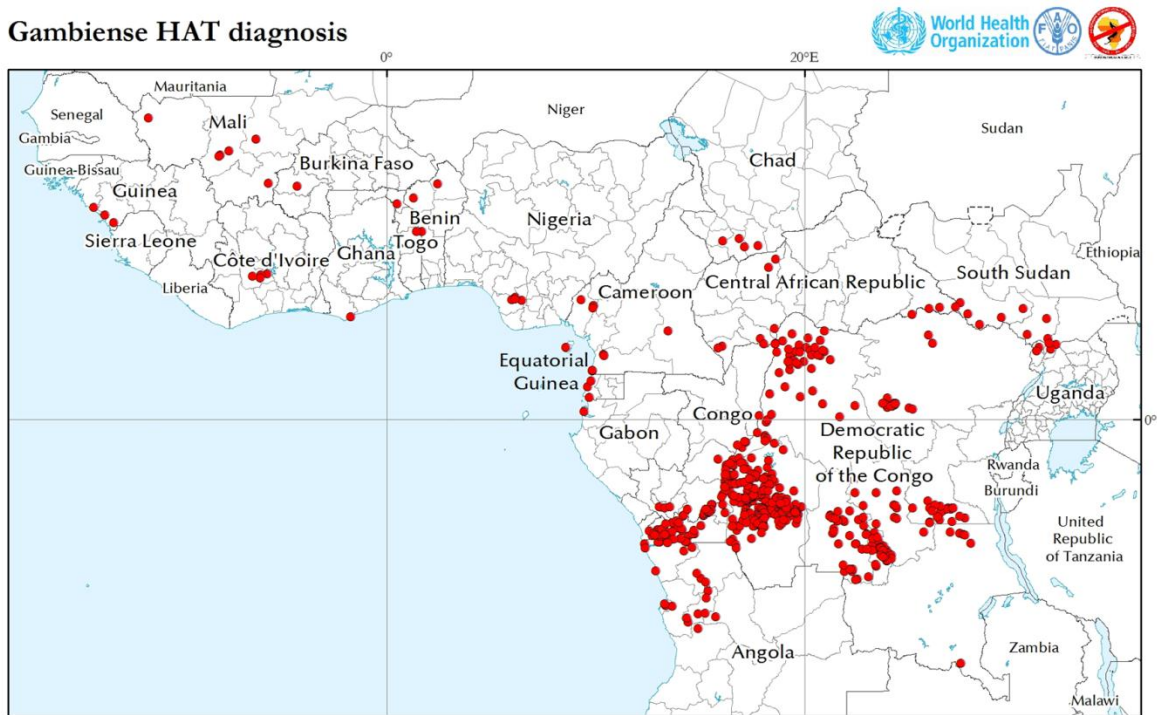
From December 2012 to August 2013, an inventory of fixed health facilities involved in diagnosis and treatment of g-HAT in disease-endemic countries having reported cases or having conducted active screening activities during the period 2000–2012 was done. There are 622 health care facilities performing diagnosis and 495 providing treatment. These facilities are spread across almost all transmission areas (*Figure 6*). The combined information on fixed health facilities, the distribution of the population at risk and the African Continental ‘friction’ map of the cost-time to travel from one pixel of 1 km² to another generates the number of people at risk who are covered and the cost-time to access a centre offering g-HAT diagnosis or treatment.⁸ *Table 1* shows that around 40% and 80% of people at high or very high risk for g-HAT infection are potentially covered by a centre offering diagnosis at 1 or 5 hours’ travel time respectively. The coverage rate for people at lower levels of risk (moderate and low) is slightly lower. For treatment coverage (*Table 2*), despite coverage of first-stage treatment for 87% of people at high or very high level of risk within 5 hours’ travel time, access to second-stage treatment with NECT is lower due to its complex administration demanding skilled staff who are not always available.

⁷ Simarro PP et al. Estimating and mapping the population at risk of sleeping sickness. *PLoS Negl Trop Dis*. 2012;6(10):e1859.

⁸ Simarro et al. Mapping the capacities of fixed health facilities to cover people at risk of gambiense human African trypanosomiasis. *Int J Health Geogr*. 2014;13: 4.

Figure 6. Distribution of health facilities providing diagnosis and treatment of g-HAT (as of August 2013)

Gambiense HAT diagnosis



Gambiense HAT treatment

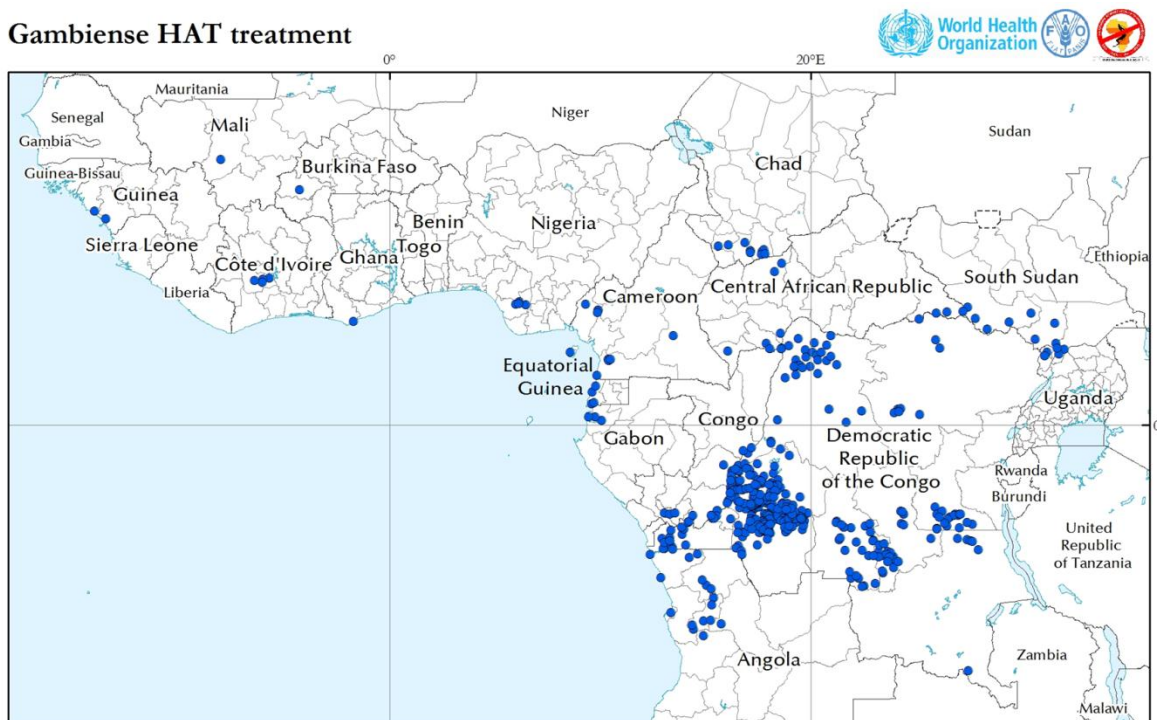


Table 1. Population at risk potentially covered by g-HAT diagnostic facilities

Type of diagnosis	At-risk population potentially covered (%)								
	≤ 1 hour travel time			≤ 3 hours travel time			≤ 5 hours travel time		
	VH-H	M	L-VL	VH-H	M	L-VL	VH-H	M	L-VL
DxC	48	41	40	77	72	69	87	84	82
DxS	41	38	37	73	70	65	86	83	79
DxP	41	37	37	73	69	64	85	82	78
DxPh	41	35	35	72	68	63	85	81	78

VH-H: very high and high risk; M: moderate risk; L-VL: low and very low risk; DxC: clinical diagnosis; DxS: serological diagnosis; DxP: parasitological diagnosis; DxPh: disease staging

Table 2. Population at risk potentially covered by g-HAT treatment facilities

Type of treatment	At-risk population potentially covered (%)								
	≤ 1 hour travel time			≤ 3 hours travel time			≤ 5 hours travel time		
	VH-H	M	L-VL	VH-H	M	L-VL	VH-H	M	L-VL
Tx1P	47	39	36	76	71	66	87	83	80
Tx2M	38	34	27	70	66	62	84	81	76
Tx2E	38	33	32	70	66	59	84	80	72
Tx2N	31	30	26	62	63	52	74	77	64

VH-H: very high and high risk; M: moderate risk; L-VL: low and very low

Tx1P: treatment of first-stage infection with pentamidine; Tx2M: treatment of second-stage infection with melarsoprol; Tx2E: treatment of second-stage infection with eflornithine; Tx2N: treatment of second-stage infection with nifurtimox–eflornithine combination therapy.

7. Control and surveillance tools: state of the art and challenges

7.1. Screening and diagnosis

As the elimination of *T. b. gambiense* advances, the needs and challenges for screening, diagnosis and staging take on a new profile.

- For screening and surveillance, tools that improve the ease, accuracy and timeliness of initial detection are needed which must be suitable for use within the routine health system, such as individual serological tests with thermostable reagents. For surveillance to be feasible in low prevalence settings, serological screening with sensitivity and very high specificity is important.
- For diagnosing infection, more sensitive methods of parasitological confirmation are needed.
- For staging, more accurate, hopefully less invasive tools are needed until a simple, safe and effective treatment to cure both stages of the disease becomes available.
- Finally, a test of cure remains an important missing tool for patient management and for therapeutic research.

Diagnostic algorithms must be flexible and adaptable to the different epidemiological settings. The inclusion of clinical elements in the algorithms has been proposed in order to improve their feasibility in peripheral rural health facilities.

Serological suspicion

The card agglutination test for trypanosomiasis (CATT) for detecting *T. b. gambiense* antibodies was the only screening test available until 2013. Its widespread use, however, is limited by its presentation in 50-tests vials and the need for cold storage, power for the rotator plus specific training, as the manipulation involves several elements and steps. The production of CATT is currently limited to a maximum capacity of 3 million tests per year.

Recently, individual serological tests, also for detecting antibodies, have become available for field testing on a large scale. These tools are simpler to use and stable at typical field temperatures. Although called “rapid diagnostic tests” (RDTs) – the generic name for this type of test – they do not determine diagnosis of g-HAT.

Two products are currently available as first-generation RDTs based on the same two trypanosoma native antigens: the LiTat 1.3 VSG (the same as the CATT) and the LiTat 1.5 VSG.

- The SD BIOLINE–HAT (produced by Standard Diagnostics with support from FIND), uses two antigens placed in separate bands. The current subsidized price is US\$ 0.5 per unit. It is being piloted in the Democratic Republic of the Congo, where more than 16 000 people have been screened to date.
- The HAT Sero-K-SeT and HAT Sero-Strip (produced by Coris with support from ITM) is undergoing phase II trials with good preliminary results in the Democratic Republic of the Congo: performance is equivalent to that of CATT and trypanolysis. The current price is €1.30 per unit.

Second-generation RDTs are being developed by these same two groups. The innovation consists in using recombinant antigens or synthetic peptides (combined or not with *T. b. brucei* native antigens). They offer a key additional advantage as these antigens are easier and cheaper to produce in large quantity.

Consideration is also being given to production of RDTs combining malaria and g-HAT as a possible strategy for surveillance in low prevalence areas.

The trypanolysis (TL) test was developed in the 1990s by ITM. Capacity to perform the technique was transferred to CIRDES in Burkina Faso and is now planned for the Institut National de Recherche Biomédicale (INRB) in the Democratic Republic of the Congo. This will enhance the capacity for g-HAT surveillance and research.

Confirmation of HAT infection

The new model mini Anion Exchange Centrifugation Technique (mAECT) continues to be produced at the INRB Kinshasa; quality control is ensured by ITM. In 2013, 8011 units were produced. The mAECT produced in INRB takes 500 µl of blood, which improves the analytical sensitivity of the test up to 50 tryps/ml. The mAECT has shown higher sensitivity and is cheaper than all the molecular diagnostic tests such as PCR, RT-PCR and NASBA. The cost of mAECT depends mainly on the price of the gels needed for its elaboration. In order to decrease the cost, a donation of gel by GE Healthcare for the production of 20 000 units per year is under consideration.

The LED fluorescence microscope (manufactured by Carl Zeiss and supplied at a preferential price after agreement with FIND) has been proposed to facilitate visualization of parasites in blood after

staining with acridine. It is already in use in pilot programmes or implementation studies in the Democratic Republic of the Congo, Guinea, Malawi and Uganda; its introduction in Angola, Chad, the Congo, Nigeria, and South Sudan is planned next. The cost per microscope is €1250.

The LAMP (co-developed by Eiken Chemical and FIND) is a molecular test that detects parasite DNA. Blood or buffy coat lysed with SDS can be stored on Whatman filter papers for delayed examination. It is currently under field evaluation in the Democratic Republic of the Congo, Guinea and Uganda; evaluation projects in Nigeria, Chad and South Sudan are planned. The cost per test is estimated at US\$ 3. Nevertheless, it is important to note that the last (2013) WHO Expert Committee on HAT control and surveillance did not recommend the use of molecular tests for disease confirmation.

Staging

A rapid test for staging has been proposed using detection of neopterin in CSF as a biomarker of second-stage disease (co-developed by Concile GmbH in Germany, Shenzhen Kang Sheng Bao in China and FIND). There is currently a prototype at validation stage, with the first field evaluations planned for the near future.

The University of Geneva and the University of Glasgow are working on a possible test for disease staging and follow-up using blood instead of CSF, but it is still at the discovery stage of development.

Other research

FIND is carrying out a project to characterize health facilities in HAT foci for HAT activity, diagnostics capacity, context and georeference. This inventory is ongoing in the Democratic Republic of the Congo, Guinea and Uganda, and is planned for extension to Angola, Chad, the Congo, Nigeria, and South Sudan.

The ITM is working on other biomarkers for infection, stage determination and treatment outcome, mechanisms of drug resistance and animal models.

The INRB is conducting research with diverse partners on markers for follow up, drug resistance of *T. b. gambiense* parasites, diagnostic work-up for neurological syndrome, human susceptibility to African trypanosomiasis and follow up of serological suspects.

Challenges

- Funding for HAT diagnosis must be reinforced to reach the expected goals.
- To ensure access to screening and diagnosis of the population at risk, a programme for financial support to produce and distribute all current screening and diagnostic tools is needed.
- The importation of materials into some endemic countries is hampered by cumbersome procedures and excessive taxes.
- In some countries, patients pay fees to access diagnosis, which could create an access barrier.
- New technologies and tests should be properly and independently evaluated before they are recommended and implemented for routine use.
- Monitoring of the quality of diagnosis is not done. It should be done in the field, at fixed health centres and at national reference laboratories, including regular check-up of equipment and infrastructure, and assessment and training of personnel.

- All current specimen collections are pre-selected with CATT, which limits the possibilities of developing tests to detect all strains of *T.b. gambiense*.
- Parasite strains undetected by the current arsenal of diagnostics may emerge due to selection by diagnostic pressure (e.g. *T. b. gambiense* type II; *T. brucei brucei/gambiense* hybrid wearing a *T. evansi* glycoprotein coat).
- The process leading to endorsement of new tests and global policy must be better defined.
- There is a need for a coordination group for laboratory research and development.

7.2. Treatment

All the current HAT medicines are donated to WHO by Sanofi and Bayer, the only manufacturers, in sufficient quantity to cover all needs. These needs are forecasted periodically to adjust the timing of production. The manufacturers ensure the quality of the medicines. The commitment of Sanofi (eflornithine, melarsoprol, pentamidine) is until 2017 and that of Bayer (suramin) until 2017. The nifurtimox donation agreement ends in September 2014 but an extension is under discussion.

Medicines are distributed by WHO up to the end user through the services of MSF-Logistique, and at the field level through the national programmes. The responsibility for their use is assumed by the ministries of health. WHO supplies also the treatments for exported cases in non-endemic countries.

To ensure access to the recommended first-line treatment for second-stage disease (NECT), WHO distributes the medicines in kits, including all the materials needed for their administration, and provides practical training to health personnel. Owing largely to this strategy and the support of partners in the field, the implementation of arsenic-free treatments for second-stage was rapid. In 2013, more than 98% of patients diagnosed with second-stage g-HAT were treated with NECT. At the same time, WHO set up a programme of active pharmacovigilance of NECT in 9 countries with 22 centres: since 2000, over 3000 treated cases have been monitored, with <1% lethality and 1.8% relapses.

Challenges

The classic needs for new HAT medicines include improved safety, simple administration (oral, short duration), CNS penetration (efficacy against both disease stages) and affordability.

As the development of new therapies requires clinical trials in the field, and HAT is an eminently rural disease with a highly focal distribution, the challenges to conducting clinical trials were highlighted. These include:

- Difficulties in finding sufficient numbers of patients who meet study criteria. As elimination progresses and the number of cases decrease, there will be fewer patients available to enroll in clinical trials.
- Problems with referring patients detected by mobile teams to treatment centres because of difficulties with transportation and the need to ensure food and provisions.
- Limited resources in available facilities in areas where patients are diagnosed and treated yet clinical trials requiring high clinical and laboratory standards.
- Long post-therapeutic follow-up to assess treatment outcome and losses to follow-up frequently due to the hardship context, distance, migrations and feared lumbar puncture, among others. Because efficacy measurements depend on follow-up, clinical trials must invest significant resources in this aspect.

The drug candidate at the most advanced stage of development (involving DNDi and Sanofi) is fexinidazole, given orally for 10 days, once a day with food. By December 2013, the phase II/III clinical trial had treated 241 patients (of whom two-thirds received fexinidazole and one-third received NECT) and 40 patients had been followed for 12 months. The developers wish to submit a request for scientific opinion to the EMA in mid-2015 for treatment of second-stage and first-stage g-HAT under *article 58*. The response could be obtained by 2016.

The second candidate, oxaborole SCY7158, could be given in a single oral dose because of its long half-life. It is currently in phase I studies. Phase II/III studies are scheduled to begin in the third quarter of 2014. Conditional or full registration for second-stage and first-stage HAT will not be sought before 2017.

If these new drugs have insufficient efficacy, combination therapy trials could be envisaged. Studies are planned to investigate synergistic effects between fexinidazole and oxaborole SCY7158. A planned alternative is the investigation of compounds from other families.

There is concern that fexinidazole must be taken orally for 10 days and with enough food to ensure appropriate absorption of the drug. This could pose problems for treatment compliance and drug absorption, with subsequent reduced efficacy and risk of generating parasite resistance not only to fexinidazole but also to other drugs in use.

It was stressed that these clinical trials present good opportunities for synergy to implement other studies; for example, the screening of 200 000 people each year could be coupled with the testing of new RDTs and/or other diagnostic strategies.

7.3. Epidemiological tools

The HAT Atlas (WHO and FAO) is a major recent advance in the spatial analysis of the disease. It allows monitoring of changes in distribution and epidemiology and estimation of the size and location of populations at risk using spatial analytical methods. Disease distribution can be presented on various scales, from local to continental.

The Atlas database includes data on new HAT cases reported, active screening activities implemented and health facilities performing HAT activities from the year 2000 onwards. Currently, it contains 196 667 reported cases (86% mapped) and 30 321 locations (86% mapped). Data are being updated for the period 2000–2012, with 24 countries (out of 25) completed. Updating for the Democratic Republic of the Congo is still in process (updated up to 2009); once it is completed, it is estimated that 94% of cases and 95% of locations will be mapped.

The Atlas can be used to monitor and evaluate the elimination process by following the relevant indicators in time and space.

These data can be combined with other geospatial datasets to study the relations between HAT distribution and livestock population, vegetation and tsetse distribution. Via modelling, it is possible to generate maps of predicted prevalence, fill gaps in epidemiological knowledge and assess uncertainty, estimate disease burden, and analyse the impact of activities as well as environmental and socioeconomic variables.

The data can be accessed at the WHO and FAO/PAAT websites⁹ or, if more details are needed, requested from WHO. WHO plans to gradually transfer this technology to NSSCPs, providing training and equipment (hardware and software) to optimize its use at country level, and to provide regular updates.

⁹ http://www.who.int/trypanosomiasis_african/country/foci_AFRO/en/;
<http://www.fao.org/ag/againfo/programmes/en/paat/infosys.html>

The ITM and the PNLTHA-RDC are evaluating an alternative active case-finding and surveillance strategy to address the resource-intensiveness and cost-effectiveness of the current active case-finding strategy based on mobile teams. In this study, a health worker goes from house to house and conducts a census using a PDA (personal digital assistant), and examines the population with RDTs. If an RDT is positive, a blood sample is collected on filter paper, which is tested at a district or provincial laboratory by LAMP and at the ITM by immune trypanolysis (TL). All suspects (LAMP and/or TL positive) are called for a full diagnostic workup, including an mAECT. The results, including feasibility and efficiency of the strategy, are expected in late 2014 (preliminary) and late 2015 (final).

The IRD is working in different areas:

- Tsetse population genetics, which can serve as a decision tool for launching tsetse control versus tsetse eradication strategies. Genetics studies can determine if a tsetse population is isolated, so that eradication is possible.
- A tool for prioritization of places to be surveyed, or identification of villages at risk (IVR), consists of three steps:
 1. IVR in the office. A list of villages is produced by combining six geographical information layers (history of HAT distribution, ancient and current human settlements, population and landscape, distribution of tsetse species, hydrological network, and health structures).
 2. IVR in the field. A mobile team collects medical (serology, microscopy, filter paper) and socio-demo-geographical data (census, ecosystem, coordinates) from those villages.
 3. IVR to be surveyed. Field data are imported into a geo-referenced database, and villages most at risk are selected by discussion integrating all the information.
- Recent data on the animal reservoir were presented from Cameroon (4 foci), where HAT prevalence is low in humans but high (>6%) in domestic and wild animals. On the other hand, in a mangrove focus in Guinea, g-HAT prevalence is high in humans but was not found in 300 domestic animals tested. Similar research is ongoing in Côte d'Ivoire.
- Recent data on "human trypanotolerance" from Côte d'Ivoire and Guinea show that g-HAT is not 100% fatal. From a cohort of 600 cases, 14 patients diagnosed with but not treated for g-HAT showed evidence of spontaneous cure, with serological traces slowly fading 13 years later. Also, among patients with positive serology including TL (highly specific for g-HAT) who were followed for 24 months or more, some became positive to parasitological exams while others remained negative, but the behaviour of serology followed different patterns. This finding suggests that some patients could actually remain as healthy carriers. In one case, a patient who developed g-HAT in the United Kingdom after receiving immunosuppressive medication had not been in an endemic area for more than 25 years.

Different groups are working on models for the disease:

- The Spatial Ecology and Epidemiology Group (SEEG), University of Oxford, is modelling the proportion of undetected HAT cases based on the Gaussian Process method, which maps uncertainty using a number of epidemiological and environmental covariates.
- The Erasmus University Medical Center, Rotterdam, is modelling disease evolution using a technique called micro-simulation, which is useful in elimination situations, particularly in estimating the impact and costs of a given strategy. The group has applied the technique in lymphatic filariasis, onchocerciasis and HIV elimination programmes. Micro-simulation allows for the inclusion of individual heterogeneities, of social networks and household structures, and other necessary details such as vector dynamics, disease and immunity development, and attendance to control and processes within health systems. The project aims to produce a tool

for practical decision support on the choice of strategies and indicators of progress, according to local situations.

- The Swiss TPH is modelling HAT elimination using the Eradication Investment Case (EIC) method, which assesses elimination strategies from an economic perspective. Alternative scenarios are analysed for the investment needed; the outcome is expressed in the number of cases and DALYs averted over time.

Challenges

The epidemiological challenges to elimination of g-HAT include:

- a) Gaps in scientific knowledge
 - What is the role of an animal reservoir at a low prevalence of human disease?
 - Do asymptomatic human carriers play a role in maintaining transmission?
 - How many cases are missed by current control and surveillance activities?
- b) Programmatic needs
 - Solving gaps in mapping, including old foci with no surveillance or areas that are difficult to reach or insecure.
 - Integrating control and surveillance into health systems, which means strengthening health systems; training and training materials; quality assurance.
 - Monitoring and evaluation through adequate sampling methods, active case detection, sentinel surveillance, definition of criteria to assess the adequacy of surveillance; additional tools; and potential of xenomonitoring for monitoring.
 - Defining specific criteria for validation of elimination.

7.4. Vector control

The two main needs and challenges identified for vector control were: highly effective vector control methods (easy to deploy and maintain, less costly than current approaches) and the feasibility of xenomonitoring for monitoring and evaluation of elimination of g-HAT.

a) New vector control methods

The Vector Group (a collaboration of researchers from academic, government and private institutions) presented the results of field trials using “Tiny Targets” for riverine tsetse control in Kenya, Guinea and Uganda, showing 75–99% reduction of tsetse populations. In Guinea, after a g-HAT “screen and treat” campaign, the annual incidence of g-HAT was 20 times lower than in an adjacent area where no targets were deployed. Compared with traditional traps, Tiny Targets are twice as effective, 10 times cheaper, longer-lasting (6 months) and easier to deploy. The annual cost of deployment and maintenance is estimated at US\$ 26/km² and US\$ 62/km² respectively, including community sensitization and monitoring of tsetse. The Group is planning additional trials in different types of environment: marsh/swamp (Chad – Mandoul and Moissala foci), mangrove (Guinea – Boffa and Dubreka foci), degraded forest (Côte d’Ivoire – Bonon focus) and riverine savannah (Uganda – Arua, Maracha, Koboko, Yumbe and Moyo foci). Furthermore, it plans to produce a guidance document for national programmes on use of tiny target control, identify SSNCP support needs, and extend work on effective means of community sensitization, cost analysis and epidemiological impact.

B) Xenomonitoring

The role of xenomonitoring as a tool to determine the presence of *T. b. gambiense* in an area was discussed. In field tsetse flies, when rates of mature infection are 0.1–0.5%, the midgut infection rates are typically higher (often 5–10-fold), and often with high trypanosome loads. Flies could be processed by batch on whole flies (no dissection), probably using LAMP or qPCR in standardized laboratories. In an active HAT focus, screening 7500 flies may yield 37–75 positives; but traps often catch less than 5 flies per day, therefore needing 60 traps per day for 25 days, four staff and two vehicles. An alternative is to collect flies locally over longer periods and preserved with a stabilization reagent (e.g. RNAlater). A rough cost estimate was given of US\$ 20 000 vs US\$ 10 000 per 7500 flies for active vs passive collection. Laboratory methods being developed include:

- (1) Screening tests: lateral flow method (US\$ 1/test) for *T. brucei* and Pan Tryp-LAMP (US\$ 5/test) for *T. brucei*, *T. congolese* and *T. vivax*; and
- (2) Confirmatory tests: TBR-PCR and RIME-LAMP for identification of *T. brucei* subgroup, and TgSG-PCR for identification of *T. b. gambiense*.

Extensive evaluation of the developed tests is now required.

8. WHO Network for gambiense HAT elimination¹⁰

Collaboration is a key element in the progress towards HAT elimination and the coordination of activities required to synergize efforts, avoid overlap and harmonize activities.

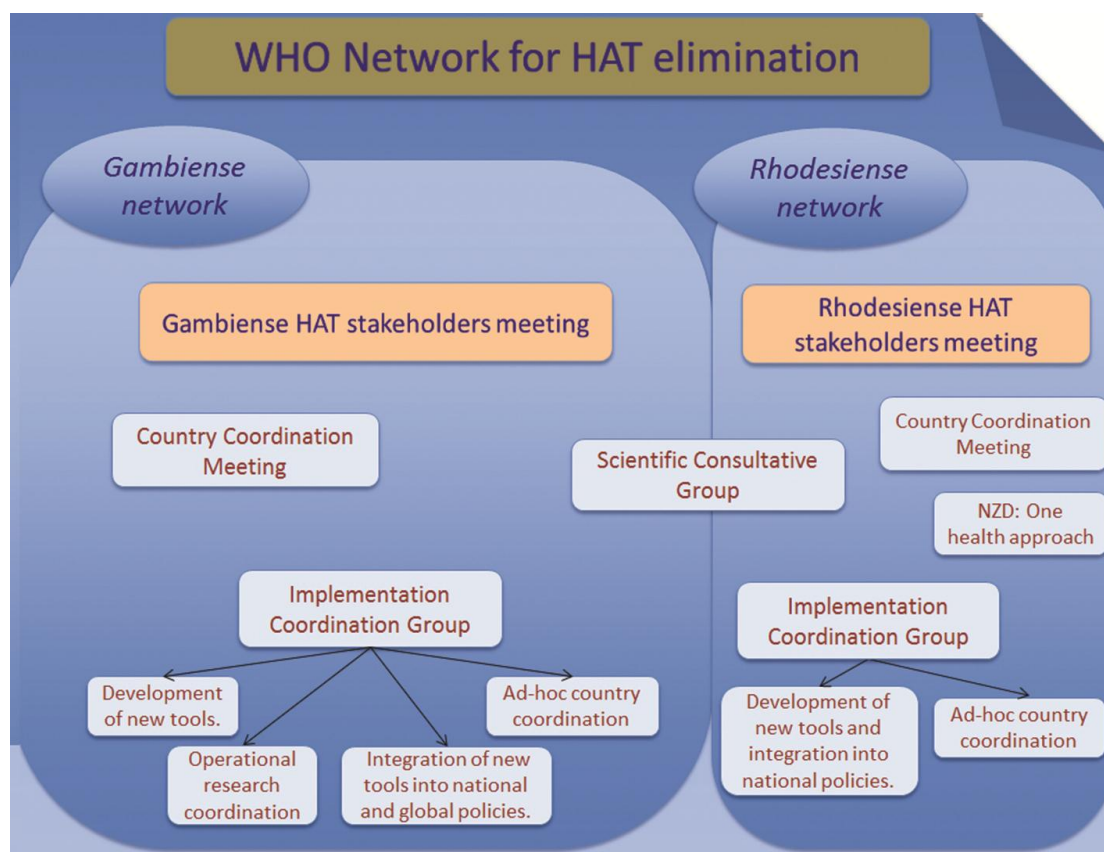
The WHO Expert Committee on the control and surveillance of human African trypanosomiasis recommended in 2013 that coordination be strengthened among people involved in control and research in order to facilitate the development and validation of new control tools.

The network for g-HAT elimination plans to hold a general forum: the stakeholders meeting. Three groups (*Figure 7*) will provide effective support for driving activities during the interval between meetings, with more groups added according to identified needs.

- Scientific and Technical Consultative Group
- Country Coordination Meeting
- Implementation Coordination Group

¹⁰ This section was completed after the meeting through further communication with the participants.

Figure 7. WHO's Network for HAT elimination



^(*)Rhodesiense HAT stakeholders meeting scheduled for 20–22 October 2014.

1. WHO gambiense HAT elimination stakeholders meeting

This meeting convenes all the stakeholders involved in the elimination of g-HAT in its different aspects, including:

- national sleeping sickness control programmes;
- scientific institutions and platforms developing new tools to control g-HAT;
- international and nongovernmental organizations involved in g-HAT control; and
- public and private donors.

It is an open forum where progress in g-HAT elimination is reported and important advances, difficulties and gaps are discussed. The different groups included in the WHO network for g-HAT elimination report to this meeting.

Meetings provide a tool for advocacy of HAT elimination. Donors are also involved in the meeting in order to share information on progress and discuss financial gaps in the road to elimination.

WHO convokes meetings every 18–24 months at its headquarters in Geneva and ensures the Secretariat.

2. Gambiense HAT Scientific and Technical Consultative Group

This group of individuals has vast experience on different aspects of g-HAT. It advises on strategies, tools and evaluation of outputs of activities; answers specific scientific and strategic questions and issues; identifies possible barriers to elimination; and proposes technical and strategic solutions.

Members are selected from WHO's panel of experts and, according to the agenda, they may also include other specialists in specific areas.

The Group meets on request at WHO's headquarters in Geneva and WHO provides the Secretariat. It reports to the WHO g-HAT elimination stakeholders meeting.

3. Country Coordination Meeting

This is a general meeting of WHO and all the g-HAT focal points of endemic countries. Occasionally, other implementers (NGOs, international agencies), WHO collaborating centres or other experts may be invited.

The meeting updates the g-HAT country situation and the results of control and surveillance in the framework of the elimination process. It reviews and advises on policies, strategies and implementation.

This meeting with all the g-HAT focal points is organized every year by the WHO Regional Office for Africa in an African country.

4. Implementation Coordination Group

Given the complexity and specificity of the topics to be treated, this working group is split into several specific thematic subgroups. The first stakeholders meeting identified the following themes requiring subgroups:

- Development of new tools
- Integration of new tools into national and global policies
- Operational research
- Ad-hoc country coordination

The subgroups include representatives of g-HAT focal points from selected disease-endemic countries, research institutions and institutions developing new tools or implementing activities in the field. Serving as a member of a thematic subgroup does not preclude membership of another subgroup.

Each thematic subgroup identifies areas of work and reports the outcomes to the WHO g-HAT elimination stakeholders meeting. These subgroups are closely interconnected and coordinated.

Meetings are held according to needs, either face-to-face or virtually via the Internet. One annual face-to-face meeting is recommended of each subgroup, with the date and venue decided according to needs and participants.

Donors are also invited to participate in any subgroup as observers. WHO ensures the Secretariat of each subgroup.

4.1 Development of new tools subgroup

This group addresses research mainly concerning the development of epidemiology, diagnostics, treatment and vector control tools. It facilitates answers to the main knowledge gaps identified during

the elimination process, disseminates advances in research, and can also identify funding gaps in research and advocacy to donors.

It includes the research institutions working to reconcile identified knowledge gaps, representatives of disease-endemic countries and WHO.

The activities identified and covered by the group are to:

- Identify and categorize the knowledge gaps that need to be filled.
- Identify relevant institutions working in those recognized gaps.
- Advocacy with donors to support research needed to fill the identified gaps.
- Disseminate advances in research.

4.2 *Integration of new tools into national and global policies subgroup*

This group works to facilitate the inclusion of newly developed tools into national and global policies as they become available. It covers regulatory issues to introduce new tools where necessary and adapts strategies when needed; discusses the monitoring and evaluation of new tools being introduced; and works to ensure full access by populations at risk to the best available control tools.

Members includes representatives of g-HAT focal points from involved endemic countries, institutions working on the development of new tools, institutions working on control and surveillance, and WHO.

The activities identified and covered by the group are to:

- Facilitate regulatory processes at national and international levels for the introduction of new tools, coordinating any actions taken in this aspect.
- Enable the integration of new tools in HAT policies.
- Collaborate with countries to develop policies, guidelines and strategies accordingly, and harmonize and standardize procedures.
- Coordinate the close follow-up of new tools in use (pharmacovigilance for new drugs and performance monitoring of screening/diagnostic, vector control tools).
- Enable access to the best existing tools.

4.3 *Operational research subgroup*

This group follows the implementation of trials for new diagnostics, new drugs, new vector control tools and epidemiological research in the framework of control and surveillance activities in the countries concerned.

It coordinates research and development activities, avoiding duplications and overlap; aims to synergize and improve the coverage of control and surveillance activities; and facilitate operational research.

Members include the g-HAT focal points from disease-endemic countries, institutions implementing control activities in the field, institutions developing new tools, and WHO.

The activities identified and covered by the group are to:

- Provide updates on activities performed in the framework of clinical trials and identify the sites involved.

- Help to identify new sites for clinical trials, including resources available and needs.
- Coordinate field research activities and current control and surveillance strategies to avoid overlapping.
- Synergize coverage of control activities with operational research.
- Facilitate integration of research activities into the control and surveillance programmes.

4.4 Ad hoc country coordination

This group is convened on demand to coordinate activities when different partners are interested and/or involved in implementing control and surveillance activities in the same country.

For instance, there is a coordination group for the Democratic Republic of the Congo co-organized by the NSSCP, ITM and WHO.

4.5 Advocacy and financial resources mobilization

Although this topic was discussed at the meeting, it may not be needed as a specific group at the present time. Currently, donors meet regularly and the general stakeholders meeting could cover this aspect.

9. Conclusions

The participants in the First WHO stakeholders meeting on g-HAT elimination launched a final declaration (Annex 5) and concluded that:

1. The achievements in the control of HAT for the past 10 years are remarkable.
2. The strategy and goals for elimination of g-HAT are accepted and all the participants confirm their commitment to the target of elimination and the WHO Roadmap.
3. It is expected that new diagnostic tools for screening and surveillance will make significant contributions to the elimination strategy.
4. The existing diagnostic and treatment facilities should be maintained.
5. Questions remain over asymptomatic carriers, possible animal reservoirs and confirmation of cure.
6. An independent evaluation of new diagnostics tests is recommended.
7. The recent developments in new treatments offer many advantages over existing therapies and are considered highly encouraging.
8. As the number of clinical cases decreases, there will be major challenges in organizing future clinical trials.
9. The new “tiny targets” have shown successful results at relatively low cost, and they have an important potential for vector control in HAT areas.
10. There is a clear distinction between the concepts of “elimination as a public health problem” and “elimination at zero cases”.
11. Implementation strategies must be flexible and adapted to the evolving situation. Monitoring should be progressively fine-tuned to obtain robust data.
12. Countries issued a clear call for coordination to advance in coherence and cohesion.
13. There is consensus for moving forward as a network towards HAT elimination. The structure proposed by WHO for the network was globally accepted, with some fine-tuning to be done.
14. The coordination and leading role of WHO in the process of g-HAT elimination is recognized.

ANNEXES

Annex 1. Agenda

Time	Topic	Detail	Presenter
Tuesday 25 March 2014			
09:00–09:30	Welcome	- Addresses by WHO	ADG HTM/NTD Director DPC/AFRO Director NTD/HQ
09:30–11:00	Introduction	- Presentation of the meeting - Why to attempt elimination of g-HAT. Goals, indicators and milestones - Progress of g-HAT elimination	Coordinator IDM/HQ A. Moore P.P. Simarro
11:00–11:30	Coffee break		
11:30–12:30	Open floor for Stakeholders	- Statements and discussion	All
12:30–13:30	Lunch		
13:30–14:30	Gambiense-HAT elimination	- Strategy for HAT elimination Discussion	J.R. Franco/A. Diarra
14:30–15:30	Country and NGOs report (I)	- West Africa (Côte d'Ivoire, Guinea) - East Africa (South Sudan, Uganda) - MSF (MSF-CH, MSF-S, MSF-H)	National Coordinators Sleeping Sickness Programme NGO focal point
15:30–16:00	Coffee break		
16:00–17:30	Country and NGOs report (and II)	- Central Africa (Angola, Cameroon, Central African Republic, Chad, Congo, Democratic Republic of the Congo)	National Coordinators Sleeping Sickness Programme
Wednesday 26 March 2014			
09:00–10:30	Screening and diagnosis	- Introduction: identifying gaps and needs. - New tools - FIND - INRB - ITM Discussion	A. Moore J. Ndungu P. Buscher
10:30–11:00	Coffee break		
11:00–12:30	Treatment	- Introduction: identifying gaps and needs - Quality, access and pharmacovigilance of HAT drugs - The challenges for clinical trials for HAT - The development of new tools for g-HAT treatment Discussion	A. Moore J.R. Franco C. Burri B. Pécoul
12:30–13:30	Lunch		

13:30–16:00	Epidemiological tools	<ul style="list-style-type: none"> - Introduction: identifying gaps and needs - The Database of the Atlas of HAT and potential of passive coverage - New approaches for screening - Improve epidemiological knowledge in historical foci Assessment of zones at risk, grey areas: IVR approach - Role of animal reservoir to maintain g-HAT transmission - Role of healthy carriers as human reservoir of g-HAT - Modelling proportion of undetected HAT cases - Modelling disease progress considering new scenarios - IEC for g-HAT Discussion 	<p>A. Moore</p> <p>J.R. Franco</p> <p>E. Hasker V. Lejon</p> <p>V. Lejon</p> <p>B. Bucheton N. Golding</p> <p>S. deVlas</p> <p>STI representative</p>
16:00–16:30	Coffee break		
16:30–18:30	Vector control	<ul style="list-style-type: none"> - Introduction: identifying gaps and needs - New tools - Xenomonitoring as a tool for disease elimination - Role of FAO and PAAT in tsetse and trypanosomosis control - Role IAEA on tsetse control - Role of PATTEC on advocacy and coordination of tsetse control Discussion 	<p>A. Moore</p> <p>S. Torr M. Lehane/J. Enyaru</p> <p>G. Cecchi</p> <p>R. Argilés H. Mahamat</p>
Thursday 27 March 2014			
09:00–11:00	Elimination of gambiense-HAT	<ul style="list-style-type: none"> - Guiding principles - Monitoring and evaluation Discussion 	<p>P. Holmes</p> <p>J.R. Franco</p>
11:00–11:30	Coffee break		
11:30–13:00	WHO Network for gambiense HAT elimination	<ul style="list-style-type: none"> - Mechanism for coordination Discussion 	<p>WHO/HAT programme</p>
13:00–14:30	Lunch		
14:30–16:00	Conclusions and outcomes	<ul style="list-style-type: none"> Meeting wrap-up 	<p>P. Holmes</p>
16:00	Farewell coffee		

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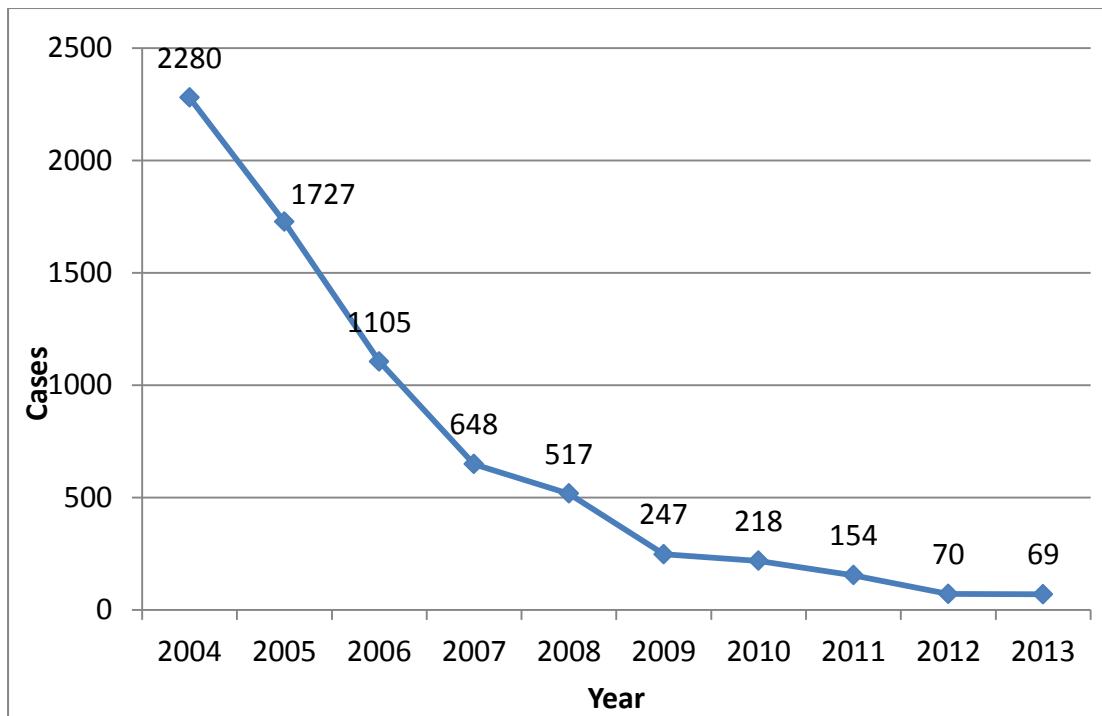
Annex 3. Country update

Angola

There are 7 endemic provinces (46 municipalities): Bengo, Zaire, Uige, Malange, Kuanza Norte, Kuanza Sul and Luanda.

The number of cases declared has shown an important and constant decrease during the past years.

HAT epidemic curve for the decade 2004–2013 as presented by Angola



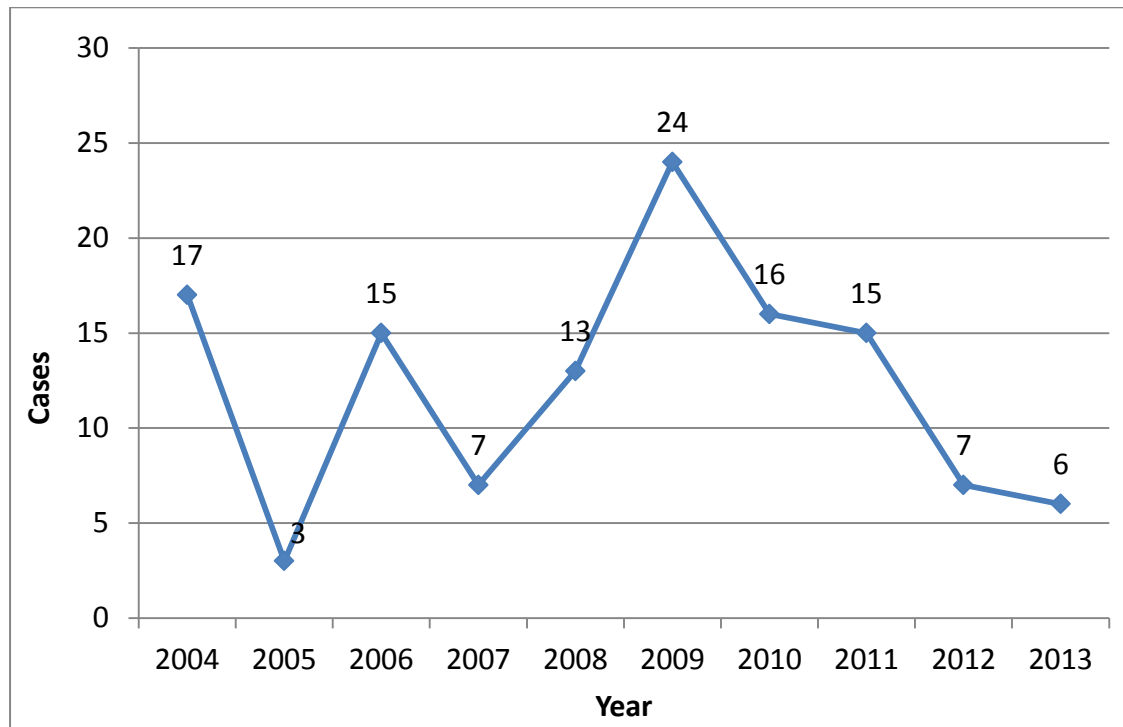
As strong points, the NSSCP underlines the ownership of HAT control by national authorities, the presence of a well-structured control programme and the availability of medicines.

As weak points, there is a lack of integration of HAT control in the health system and weak participation of the population in control activities. There is no support from international partners.

Cameroon

Currently, 5 HAT foci are considered active and a variable number of cases (always below 25 cases per year) are notified. These variations are mainly related to intensity of control activities.

HAT epidemic curve for the decade 2004–2013 as presented by Cameroon



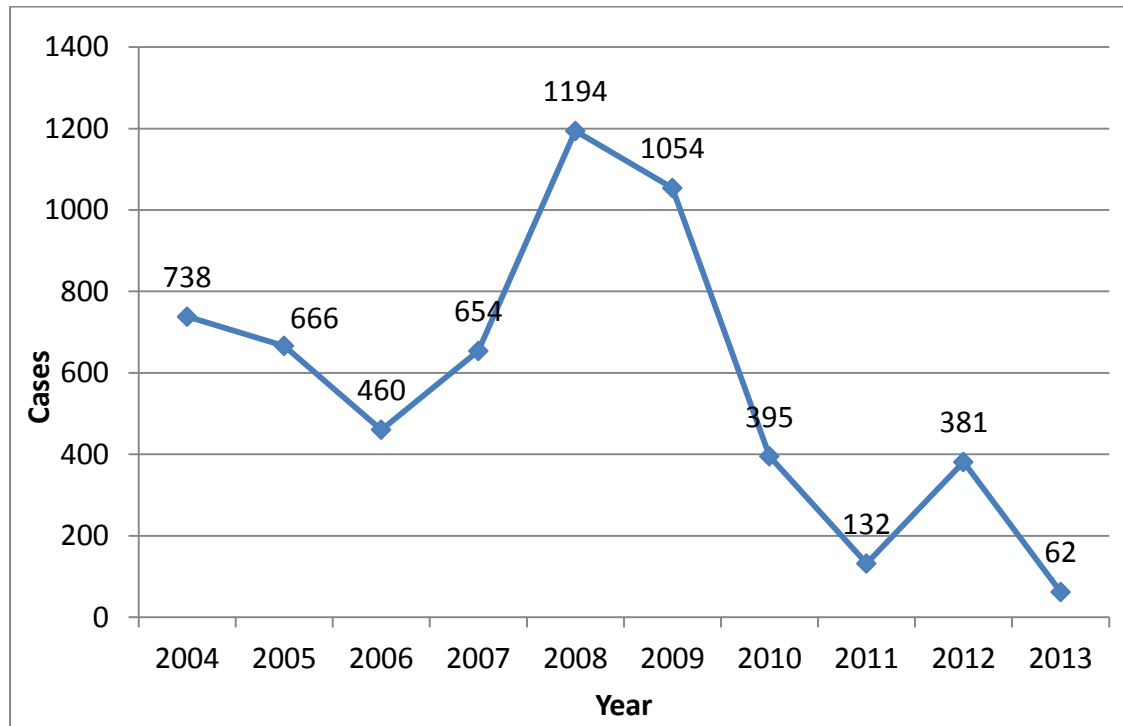
As strong points, the NSSCP has good epidemiological knowledge about the disease distribution in the country, experience and capacity to perform regular control activities with ensured availability of medicines and skilled staff.

As weak points, there is a lack of replacement for elderly staff, poor integration of HAT control in the health system, lack of motivation of the population to participate in control activities and absence of an autonomous budget for the programme.

Central African Republic

There are 4 active HAT foci. The number of cases is related to changing factors (linked to the security situation) that allow control activities to be carried out or not.

HAT epidemic curve for the decade 2004–2013 as presented by the Central African Republic

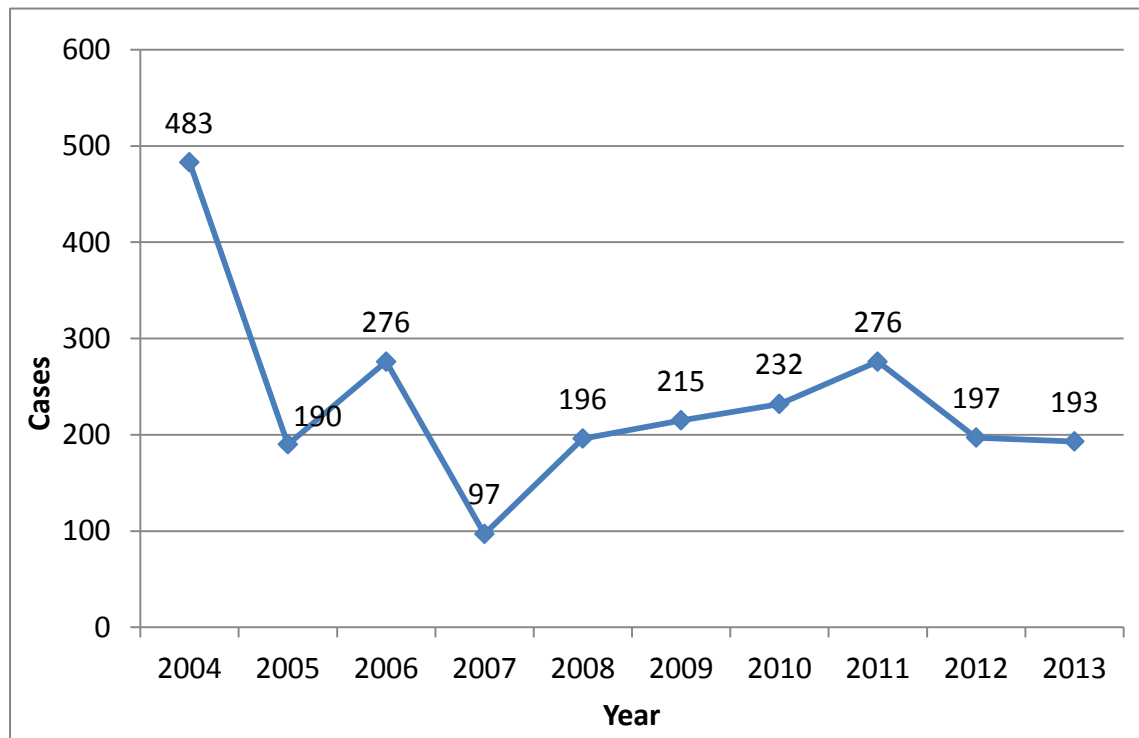


As positive elements, the NSSCP has strong support from partners for control activities and medicines are available. The main constraint is the severe insecurity situation of the country in the framework of a very weak health system, and problems of access, ownership and management of the NSSCP.

Chad

Chad has 4 well defined foci of HAT, 2 of which are currently reporting cases, in a decreasing trend, but stagnant trend during the past 6 years.

HAT epidemic curve for the decade 2004–2013 as presented by Chad



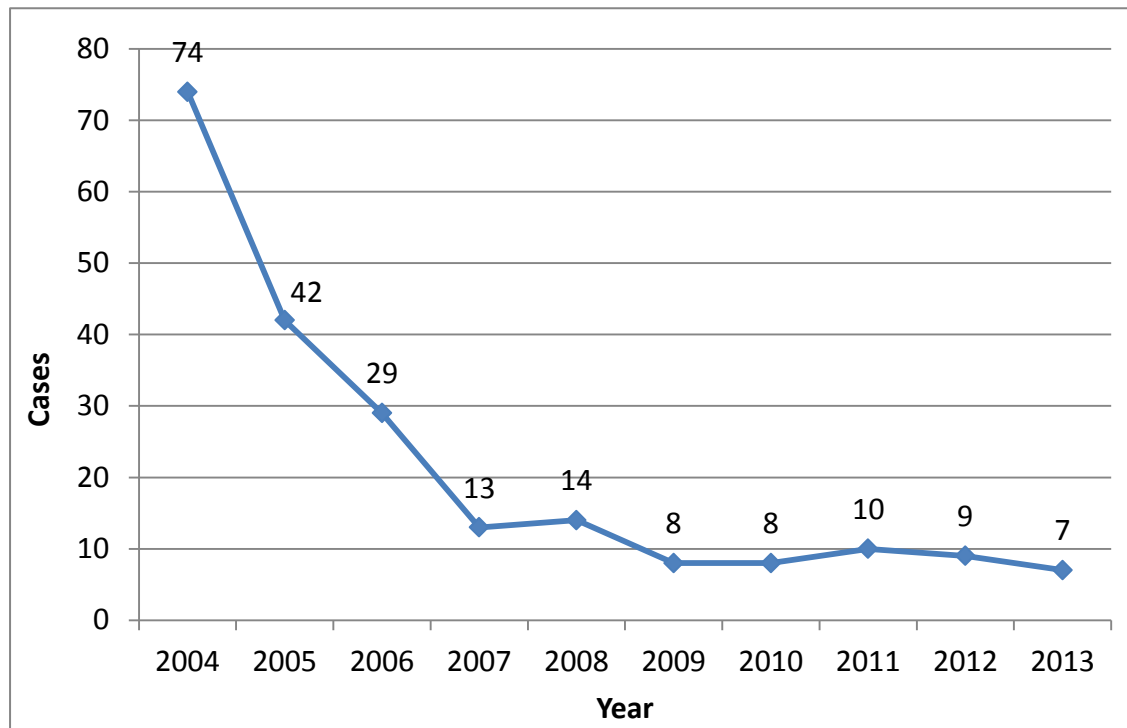
The strengths identified by the programme are good epidemiological knowledge about the disease distribution and regular, maintained control activities. There is a clear ownership of the NSSCP by the Minister of Health and medicines are available.

As weaknesses, there are difficulties to integrating control activities in the weak health system, worsened by the high turnover of health staff in the peripheral structures in endemic areas.

Côte d'Ivoire

Gambiense HAT is present in 12 health districts (Danane, Duekoue, Guiglo, Vavoua, Daloa, Bouafle (Bonon and Sinfra), Oume, Gagnoa, Soubre, Sassandra, San Pedro and Aboisso). The number of cases reported has followed a decreasing trend, flattening during the past 7 years to a low level of cases reported.

HAT epidemic curve for the decade 2004–2013 as presented by Côte d'Ivoire



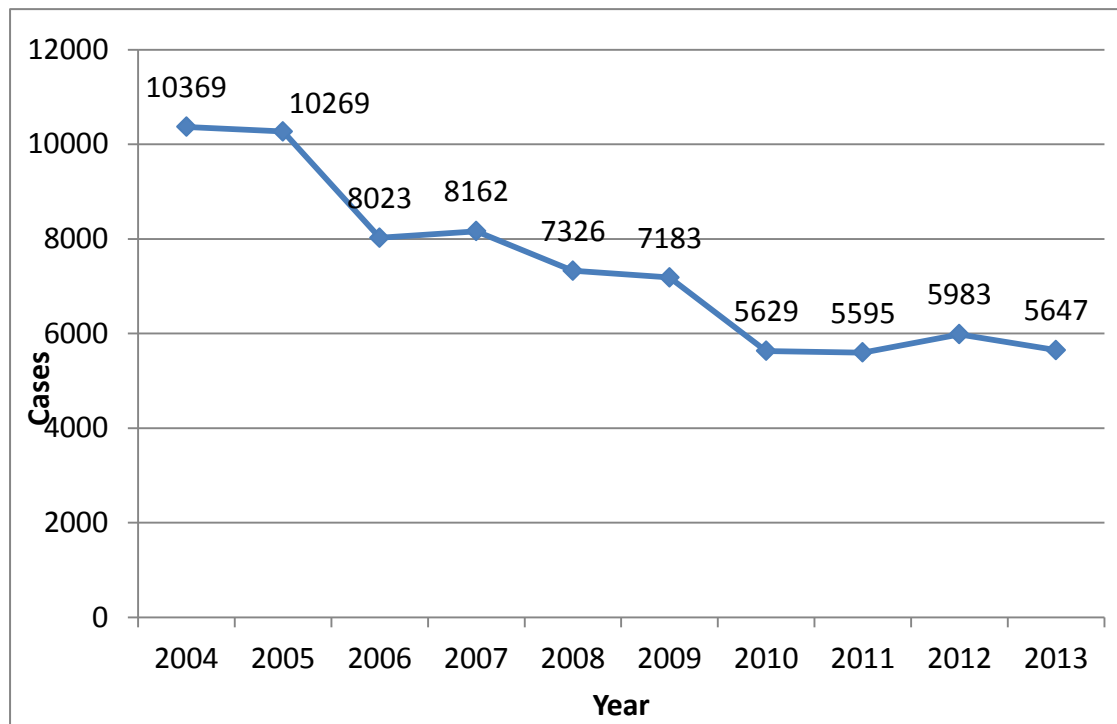
The advantages to control of HAT in Côte d'Ivoire are the ownership of control activities by the Minister of Health within the framework of an elimination programme, with the involvement of multiple national partners.

The disadvantages include the lack of epidemiological information in some areas and the integration of control activities in the health system.

Democratic Republic of the Congo

The disease is distributed throughout the country and is endemic in 247 of its 516 health districts. The number of reported cases shows a decreasing trend, stabilizing to below 6000 cases during the past 4 years.

HAT epidemic curve for the decade 2004–2013 as presented by the Democratic Republic of the Congo



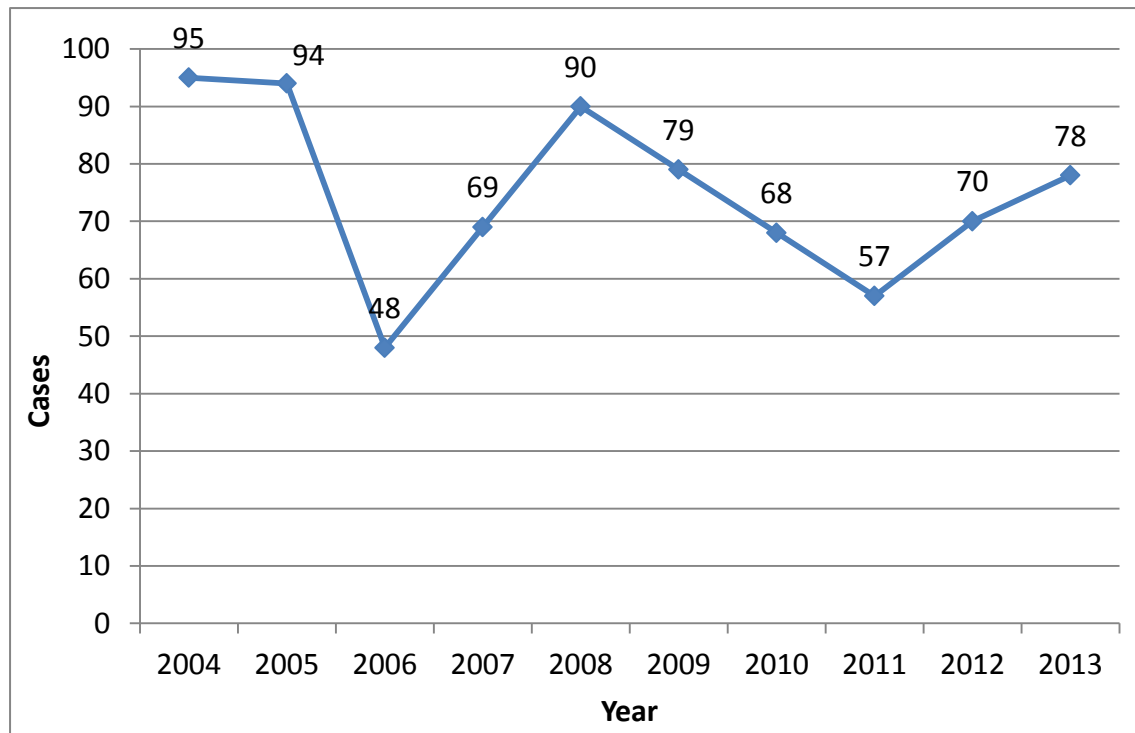
The strong points reported by the NSSCP are the good structure of the programme, dedicated and skilled staff and support from important partners. Medicines are widely available in all endemic areas.

Problems include gaps in epidemiological knowledge, with some grey areas and difficult access related to topographical issues or security concerns, linked to logistic weakness of the NSSCP. The health system in the country is weak, making the integration of activities difficult. The NSSCP has very limited funding and scarce resources.

Guinea

The endemic area for g-HAT is located in the littoral region (Boffa, Boke, Conakry, Coyah, Dubreka, Forecariah), with occasional cases in the south-eastern forest region (Guéckédou, N'zérékoré). Other areas previously considered as endemic have not reported cases during the past years. The number of cases reported is variable but always below 100 cases per year.

HAT epidemic curve for the decade 2004–2013 as presented by Guinea



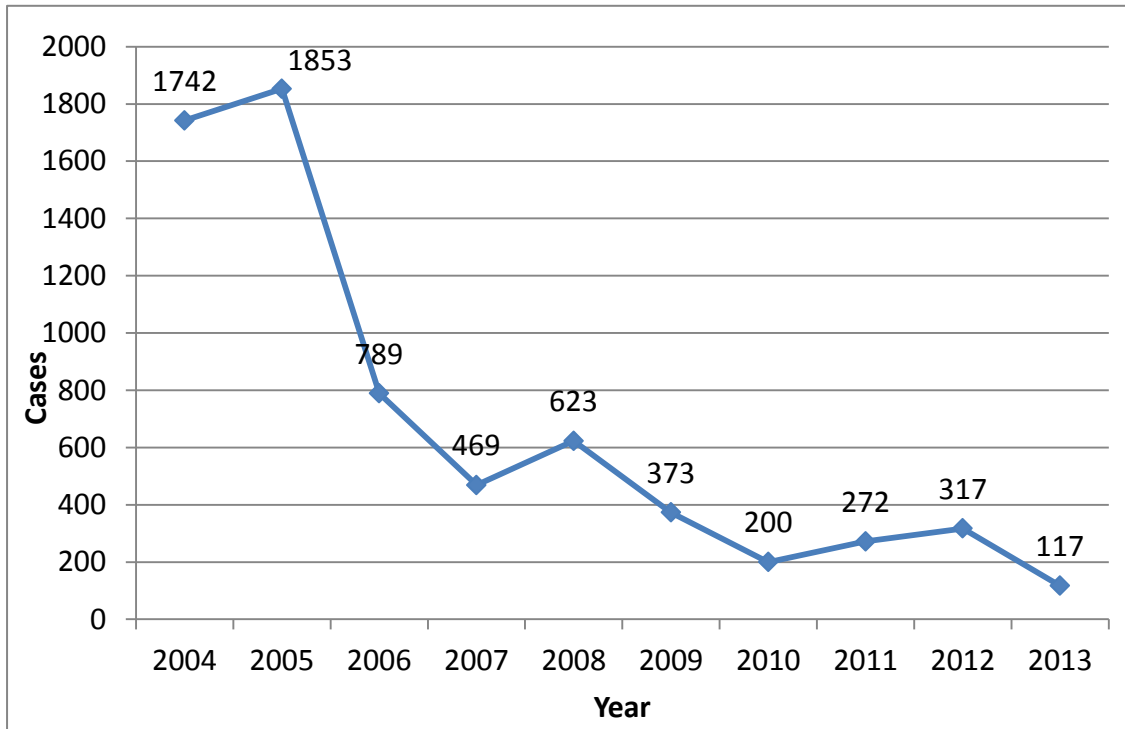
Strong points are the improved management of the NSSCP, with support from partners, allowing intensified active screening in most endemic areas. There is good epidemiological knowledge about the disease in the country and medicines are available.

The main weakness is the important logistic problem in accessing disease endemic populations.

South Sudan

There are 9 endemic counties for HAT in South Sudan. There is a decreasing trend in the number of reported cases.

HAT epidemic curve for the decade 2004–2013 as presented by South Sudan

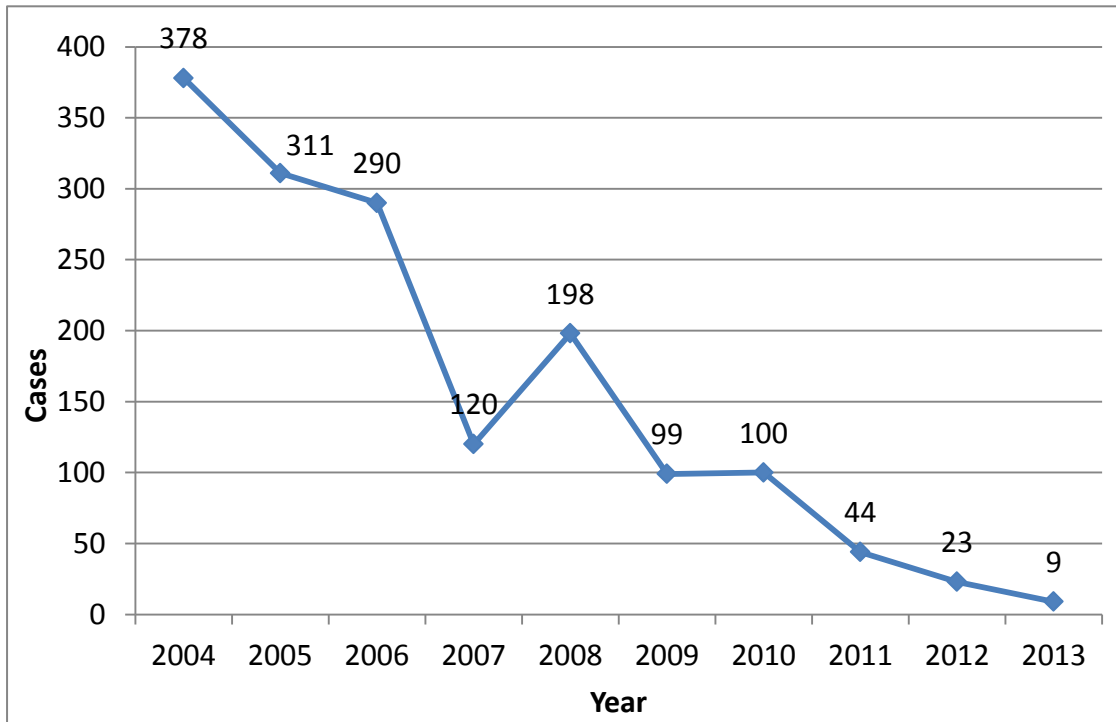


There is good epidemiological knowledge about the disease distribution and medicines are available, but an important problem is the lack of a national control programme and a lack of ownership by national authorities. The health system is very poor and there is worrying social instability with important population displacements.

Uganda

There are 8 endemic districts for g-HAT in Uganda, located in the north-west (West Nile Region). The number of reported cases shows a remarkable decreasing trend, reaching less than 10 cases per year.

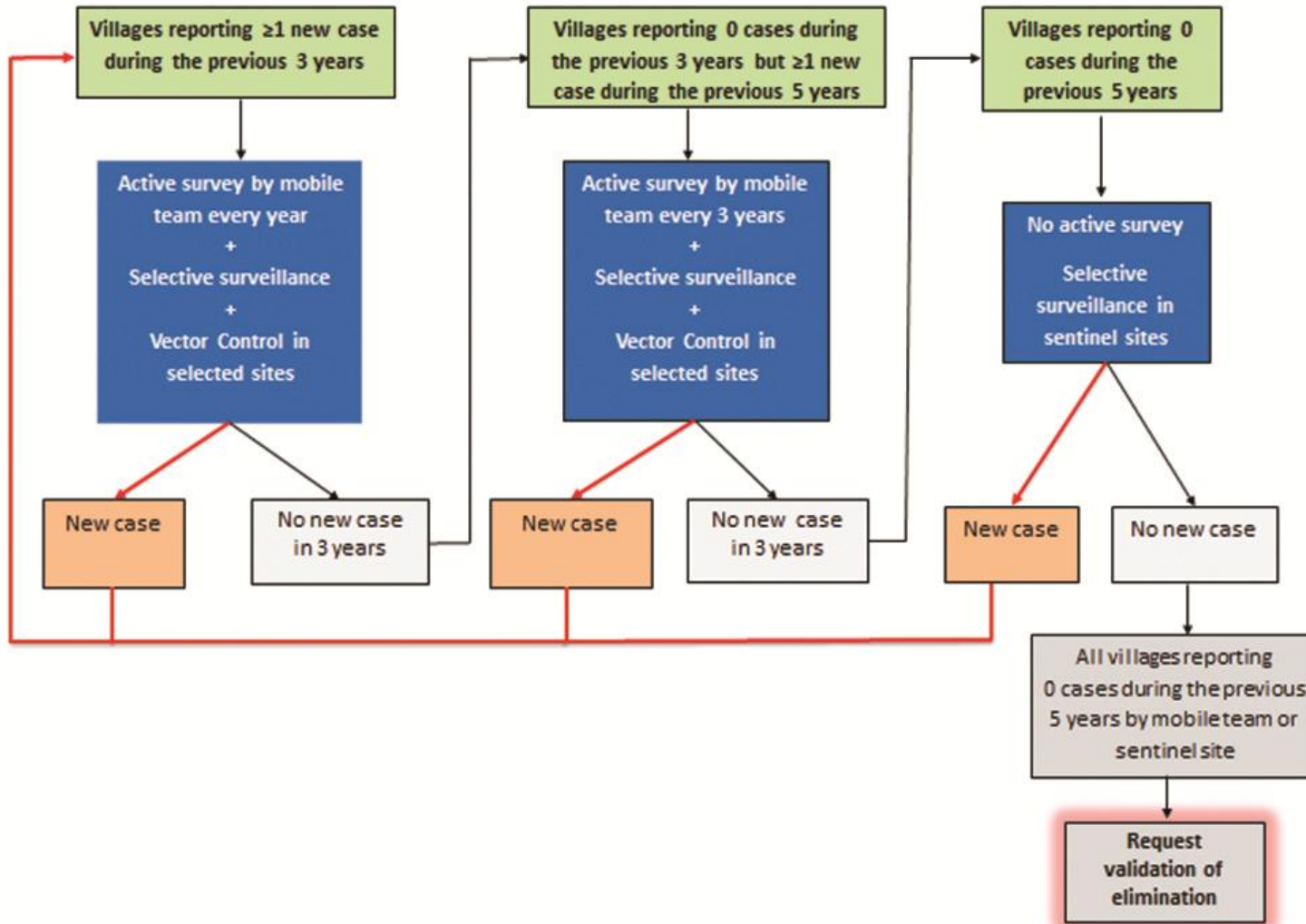
HAT epidemic curve for the decade 2004–2013 as presented by Uganda



The NSSCP reports as positive points the good epidemiological knowledge about the disease, with a clear decreasing trend in the number of reported cases. Important advances have been made to integrate activities in the health system. Medicines are available and the social situation is stable.

The weaknesses highlighted are the lack of ownership by national authorities, low levels of community awareness, a porous border with neighbouring endemic countries and the risk of overlap of the two forms of HAT.

Annex 4. General strategy to be applied by village to define interventions



Annex 5. Declaration on the elimination of gambiense human African trypanosomiasis

The First WHO stakeholders meeting on gambiense human African trypanosomiasis (g-HAT) elimination held in Geneva, Switzerland, on 28 March 2014 decided to establish a WHO-led network to ensure a coordinated, strengthened and sustained effort to eliminate g-HAT, and they agreed the following declaration:

First WHO stakeholders meeting on gambiense human African trypanosomiasis elimination

Declaration on the elimination of gambiense human African trypanosomiasis

Geneva| 28 March 2014.

Human African trypanosomiasis (HAT), commonly known as sleeping sickness, has been one of the great scourges of mankind. The incidence of gambiense HAT, which had been brought to virtual elimination in the 1960s, surged to epidemic proportions by the end of the 20th century. Efforts towards intervention in this disease over the past decade have enjoyed remarkable success with incidence falling by over 90%. New tools to diagnose and treat the disease and to control the vector are becoming available, and unprecedented political will has led to the World Health Organization (WHO) declaring a programme of global elimination of this disease at a meeting in Geneva on 25-27 March 2014.

WHO included HAT in its roadmap for elimination and control of neglected tropical diseases in 2012, setting a date of 2020 to eliminate the disease as a public health problem. An Expert Committee met in April 2013 and approved a strategy to eliminate the disease, subsequently endorsed by the World Health Assembly in a resolution adopted in 2013 (WHA66.12), providing an international mandate to work towards elimination.

The stakeholders present at the meeting making this declaration included national sleeping sickness control programmes, groups developing new tools to fight HAT, international and non-governmental organizations involved in control and donors. The meeting decided to establish a network under WHO leadership to ensure coordinated, strengthened and sustained efforts to eliminate the disease. The stakeholders appeal to the international community and disease endemic countries for their commitment, political support and essential resources to achieve the elimination goal.

Organizations represented at the first stakeholders meeting on gambiense HAT elimination having adopted this declaration:

- National Sleeping Sickness Control Programmes (NSSCPs) of the Ministries of Health of:
 - Angola
 - Cameroon
 - Central African Republic
 - Chad
 - Côte d'Ivoire
 - Democratic Republic of the Congo
 - Guinea
 - South Sudan
 - Uganda

- International organizations:
 - African Union Commission (AU)/Pan African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC)
 - Food and Agriculture Organization of the United Nations (FAO)
 - International Atomic Energy Agency (IAEA)
 - Programme Against African Trypanosomosis (PAAT)
 - World Health Organization Strategic and Technical Advisory Group for Neglected Tropical Diseases (WHO STAG-NTD)
 - World Health Organization (WHO)

- Donors:
 - Bayer HealthCare
 - Bill & Melinda Gates Foundation (BMGF)
 - Sanofi
 - The Wellcome Trust, London

- Foundations and NGOs involved in HAT:
 - Drugs for Neglected Diseases Initiative (DNDi)
 - Foundation for Innovative New Diagnostics (FIND)
 - Médecins Sans Frontières (MSF), including MSF Access Campaign

- Scientific institutions developing new tools to fight HAT:
 - Erasmus MC, Department of Public Health, University Medical Centre, Rotterdam, The Netherlands
 - Institut National de Recherche Biomédicale (INRB) Kinshasa, Democratic Republic of the Congo
 - Interdepartmental Research Centre for Neglected Diseases, Institute of Tropical Medicine, Antwerp, Belgium
 - Institut de Recherche pour le Développement (IRD), Montpellier, France
 - Institute of Infection and Global Health, University of Liverpool, U.K.
 - Liverpool School of Tropical Medicine (LSTM), Liverpool, U.K.
 - Makerere University, Kampala, Uganda
 - Spatial Ecology & Epidemiology Group (SEEG), University of Oxford, U.K.
 - Swiss Tropical and Public Health Institute (STPHI), Basel, Switzerland
 - University of Glasgow, U.K.

