HAT Platform

PLATEFORME REGIONALE DE RECHERCHE CLINIQUE THA
TRYPANOSOMIASE HUMAINE AFRICAINE
HUMAN AFRICAN TRYPANOSOMIASIS
HAT REGIONAL PLATFORM FOR CLINICAL RESEARCH

NEWSLETTER
N° 9, July 2011

Steering committee members, Oubangui Hotel, Banguin, Central African Republic, 26th May 2011

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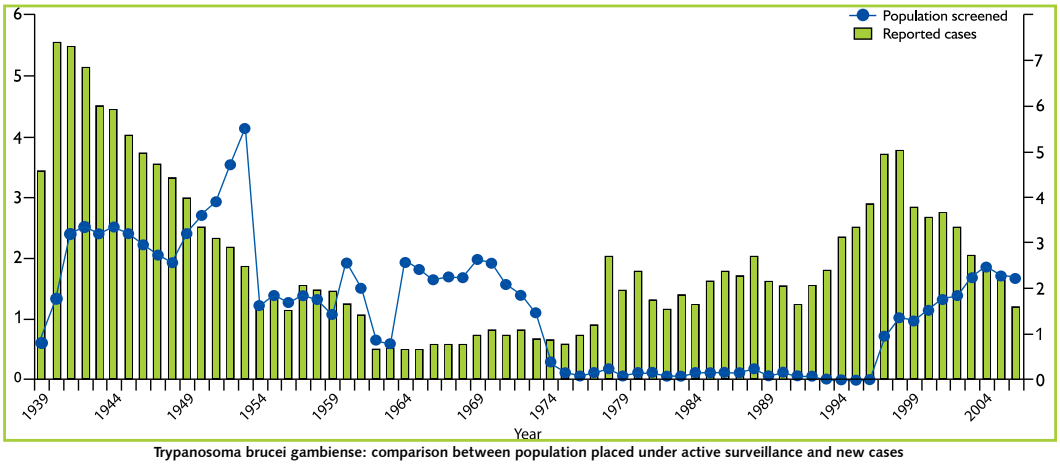
Editorial

Like in the previous issues, this ninth newsletter presents concrete and encouraging achievements resulting from a collaboration between different members of our HAT Platform.

However, behind these successes hides a worrying reality. The funding of scientific research in general, and of HAT control programs in particular, is sorely lacking. Governments of endemic countries invest little, and sometimes nothing at all in such activities, and the few foreign partners supporting sleeping sickness control are beginning to flag and have scheduled their withdrawal for the near future.

We are therefore appealing to all those concerned to find funds urgently to fight this neglected disease, and thus avoid that all the hard work accomplished so far is reduced to nothing. To ignore this cry for help would be tantamount to admitting that we have not learned the lesson of the famous WHO diagram showing the drop in number of cases reported in the 1960s, followed by a return in the 1980s to 1930 levels (see below). Our next Newsletter will be a special HAT advocacy issue, so that those who still doubt may be convinced.

I wish you an insightful read.



Trypanosoma brucei gambiense: comparison between population placed under active surveillance and new cases

2. Review of HAT epidemiology in 2010

Last year, we presented the figures for sleeping sickness per member country from 2005 to 2009 (see Newsletter n°7). In the current issue, we review the overall situation in the seven countries of the HAT Platform in 2010.

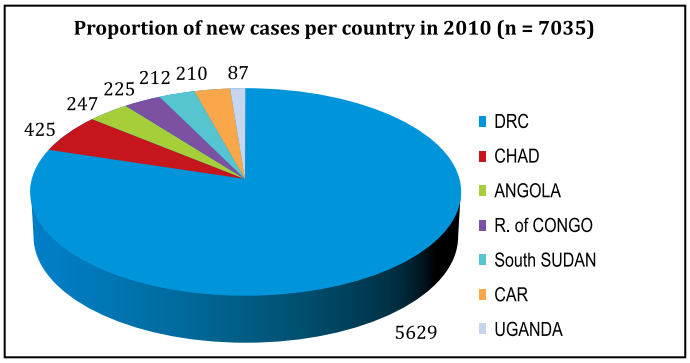
Between 2009 and 2010, the number of cases of sleeping sickness dropped by 25% in the HAT Platform member countries, particularly in the four countries most affected by the disease in 2009. The figures in Uganda, Chad, and Republic of Congo remained stationary.

Table 1 – Number of cases reported per country in 2009 and 2010

Country	Number of cases in 2009	Number of cases in 2010	Reduction in %
DRC	7183	5629	22
CAR	1054	425	60
South Sudan	353	247	30
Uganda	221	225	-2
Chad	215	212	1
Angola	295	210	29
Republic of Congo	87	87	0
TOTAL	**9408**	**7035**	**25**

The Democratic Republic of Congo (DRC) reported 80% of all cases (5629 /7035), followed far behind by the Central African Republic (CAR) with 425 cases, i.e. 6%, Uganda reporting 4% of cases, Angola, Sudan and Chad each reporting 3% of cases, and the Republic of Congo 1% (see Diagram 1).

Diagram 1- Cases reported per HAT Platform country in 2010



The total population examined in all the HAT Platform countries (2,329,895 people) represents 44% of the target population indentified by HAT control programs (5,251,477). This low rate suggests that a non-negligible number of patients are not diagnosed.

In 2010, the number of patients in the early stage of the disease was similar to the number of those in the late stage, but this distribution varied from country to country.

Diagram 2 shows that the proportion of patients in the early stage was higher in DRC than in the other countries. In DRC, the PNLTHA, supported by the Belgian Technical Cooperation, has 35 mobile teams dedicated to the identification of cases working eleven months per year. And yet, despite having greater means at their disposal than in the other countries, these teams reach less than 20% of the target population.

Diagram 3 shows the distribution of cases in the countries other than DRC. The high proportion of cases detected

Diagram 2 - Comparison of cases detected in 2010 in DRC and in the rest of the HAT Platform countries, based on the stage of sleeping sickness

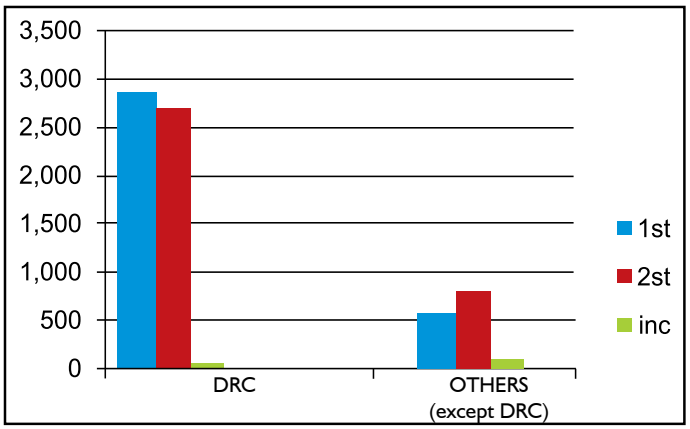
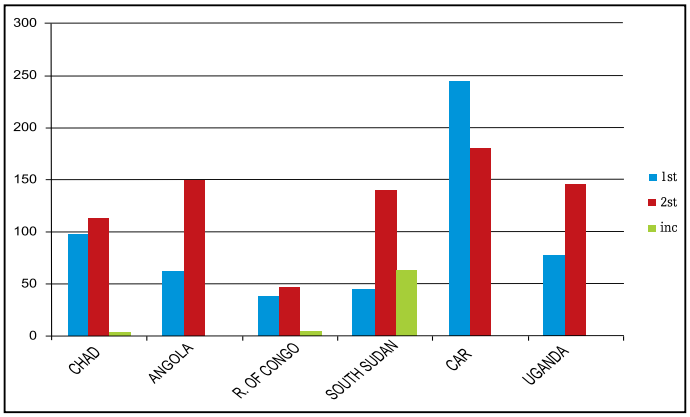


Diagram 3 – Case distribution per disease stage and per country (except DRC) for 2010



passively in Angola is due to the systematic screening of all patients attending healthcare centres in endemic areas, irrespective of the reason for their consultation. Active screening activities in Uganda and South Sudan are reduced.

Active screening helps detect a higher number of patients in the early stage of the disease (2380 out of 3425, i.e. 67%), whereas passive screening detects more patients in the late stage (2388 out of 3610, i.e. 66%). The stage of the disease was unknown in 2% of patients, all countries combined, either because they refused the lumbar tap, or because the sample taken could not be analysed.

The figures on screening activities per country are shown in the two tables below. For Angola, the sources of the figures are not specified and hence only the totals per activity are given.

Table 2 – New cases detected by active screening (2010)

Country	Active screening of new cases			
	Early stage	Late stage	Unknown	Total
DRC	2,016	734	52	2,802
Chad	79	53	3	135
Angola	0	0	0	51
Republic of Congo	22	14	4	40
South Sudan	0	0	0	0
CAR	235	111	0	346
Uganda (Tbg)	23	21	0	44
Uganda (Tbr)	5	2	0	7
TOTAL	**2,380**	**935**	**59**	**3,425**

Table 3- New cases detected by passive screening (2010)

Countries	Passive screening of new cases			
	Early stage	Late stage	Unknown	Total
DRC	849	1,964	14	2,827
Chad	18	59	0	77
Angola	0	0	0	159
Republic of Congo	15	32	0	47
South Sudan	44	140	63	247
CAR	10	69	0	79
Uganda (Tbg)	20	52	0	72
Uganda (Tbr)	29	72	1	102
TOTAL	**985**	**2,388**	**78**	**3,610**

The results above show that the efforts of all the parties involved are bearing fruit, and that we are heading towards the elimination of this scourge in a large number of countries.

Nevertheless, the situation in DRC and in certain areas of the other countries remains worrying. The lack of updated information on the active monitoring of certain foci, the continuing insecurity in certain areas hampering screening activities, and the general lack of technical and especially financial means to cover the activities programmed at the beginning of the year threaten all the achievements accomplished so far, and may lead to a resurgence of the disease.

We believe that the eradication of sleeping sickness requires more research on new diagnostic tools and new treatments to simplify the management of the disease. Our platform must therefore intensify its efforts so that the synergies put in place may be used to quicken the pace towards meeting these objectives.

Dr Kadima Ebeja Augustin
HAT Platform Coordinator

Dr. Olaf Valverde Mordt
DNDi Medical Manager

Antoine Tarral, Head of HAT Clinical Program, DNDi

Dr. Antoine Tarral joined DNDi as Head of HAT (Human African Trypanosomiasis) on November 2010. Dr. Tarral, who most recently served as Head of Clinical pharmacology at NOVEXEL SA, in charge of development of new antibiotics (phase I and phase 2), has around 15 years of Clinical pharmacology experience in pharma industry, as well as in CROs. From 1991 until 2006, Dr. Tarral held various positions at Sandoz (now Novartis) and Biotrial as investigator in healthy volunteers studies and Chief Medical Officer of phase I units. Dr. Tarral completed post-doctoral pharmacology at La Pitié Salpetrière hospital, Paris, in neuro-psycho-pharmacology after earning his M.D. degree at the university of Nancy.

Nathalie Strub Wourgaft, Medical Director, DNDi

Dr. Nathalie Strub Wourgaft joined DNDi as Clinical Development Director in February 2009. Dr. Strub, who most recently served as Director, Clinical Development at Trophos, has over 15 years of clinical development experience, including with Pfizer from 2000 to 2003, and Lundbeck from 1995 to 1999. She also served as Medical Director for a CRO from 2004 to 2005 as well as for the French office of Aspreva from 2005 to 2008. Dr. Strub graduated as Medical Doctor from Necker Hospital, Université René Descartes in Paris in 1983.

3. Atlas of human African trypanosomiasis

Background and rationale

The World Health Organization (WHO) is committed to support the efforts of human African trypanosomiasis (HAT) endemic countries to eliminate this public health concern. Mapping the disease distribution is a key element in this support, because updated, accurate and comprehensive information on the distribution of the disease helps plan and monitor the activities.

For this reason, the WHO launched in 2008 the Atlas of HAT jointly with the Food and Agriculture Organization (FAO), as part of its Programme Against African Trypanosomiasis (PAAT). The aim of this WHO initiative is to geo-locate the information on HAT occurrence and non-occurrence. This Atlas is a dynamic tool, updated regularly and showing the changes in the geographical distribution of the disease.

Methodology

The WHO and FAO developed a methodology based on Geographic Information Systems (GIS) to map out the precise distribution of the disease in space and in time. New HAT cases, due to T.b. gambiense or T.b. rhodesiense, and the people screened within a defined geographic entity were chosen as the key variables to map the disease.

Over the past ten years, scaled-up control and surveillance activities produced a vast quantity of information on the occurrence and non-occurrence of the disease. The epidemiological data collected and reported by the National Sleeping Sickness Control Programmes (NSSCPs), Non-Governmental Organizations (NGOs), and research institutes form the cornerstone of the Atlas of HAT. This information, unpublished for the most part, has been screened, harmonized, stored in a central repository (epidemiological database), and analysed through a database management system.

At the same time, a database of locations was created. Many geographical data were available in the reports in form of geographical coordinates from global positioning systems (GPS) and sketch maps. Other sources of geographical coordinates were used to complement and verify the geographical coordinates available in the reports (different public gazetteers and maps). The experience of health workers and mobile teams in affected areas also contributes to the geo-referencing process.

Finally, by matching epidemiological data with geo-referenced named locations, the Atlas of HAT geo-references the disease cases with unprecedented accuracy, at the village level.

The final outcomes as well as the input data used for the Atlas will be available to the public through WHO and FAO/PAAT websites, for the benefit of national health services, scientists, concerned communities, policy makers and donors.

The data management capacity of NSSCPs will be strengthened to enable regular updates and ownership of the Atlas at the national level.

Results

A total of 25 sub-Saharan countries reported HAT cases in the 2000-2009 period. The data of 23 countries (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Ghana, Guinea, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, Sudan, Togo, Uganda, United Republic of Tanzania, Zambia and Zimbabwe) has been fully processed and mapping is now completed. Data processing for the two remaining countries, i.e. Angola and DRC, is ongoing.

Currently the epidemiological database contains:

- The results of active screening of over 2.2 million people, and
- Cases detected in healthcare facilities engaged in passive surveillance.

To date, approximately 1,500 documents and files (epidemiological and activity reports, maps, databases and spreadsheets) from these 23 endemic countries have been analysed. Out of the 42,235 HAT cases reported in the 2000-2009 period, 90% (38,139) have been mapped, with an average accuracy estimated at 900 m. The reports contain information on approximately 6,035 different localities, of which 91.4% have been mapped.

In DRC, 102,961 cases have been entered in the database and 64.4% (66,307) have been mapped.

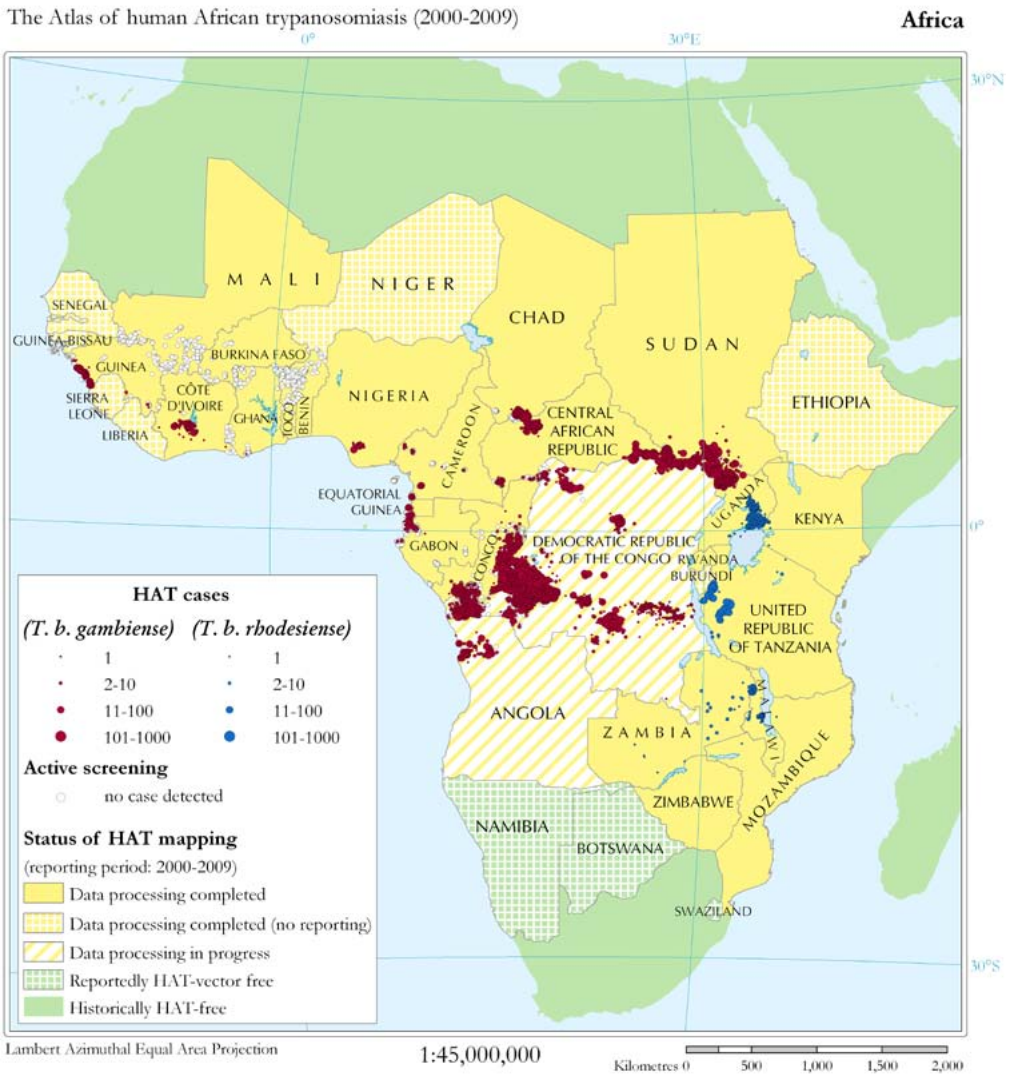
Conclusion

GIS tools and epidemiological data geo-referenced at the village level help produce maps that substantially improve the spatial quality of HAT cartography.

The commitment of NSSCPs, NGOs, and research institutes in building the Atlas of HAT has greatly contributed to the efficiency of the mapping process, and guarantees the quality of the collated information and the accuracy of the outputs.

The comprehensive, village-level mapping of HAT control and surveillance activities over a ten-year period provides a detailed and reliable representation of the known geographical distribution of the disease and its epidemiological trends. The Atlas will help identify the areas that still require further collection of data.

The Atlas of HAT is expected to become an important



tool for making informed decisions to plan and evaluate control and surveillance activities, as well as a useful advocacy tool.

The Atlas of HAT will also lay the basis for novel, evidence-based methodologies to estimate the population at risk and the burden of disease, leading to more efficient targeting of interventions. The spatial quality and reliability of the HAT database will also provide scientists with a robust tool to explore the relationship between sleeping sickness and demographic, landscape, climatic and other ecological dynamics that are bound to impact heavily on the future course of the disease. This research could help enlighten the complex interactions between host, parasite, vector, environment, and socio-economic setting.

The database, core of the Atlas of HAT, could also act as a valuable safe repository of key epidemiological information, and a back-up for NSSCPs.

The Atlas will be a dynamic and regularly updated tool that will assist the WHO and its partners in their efforts to curb sleeping sickness. Technical support and capacity building will facilitate future regular updates of the Atlas by the NSSCPs, while also reinforcing the sense of ownership of this tool in HAT-affected countries.

Acknowledgements

The Atlas of HAT is an initiative of the WHO Department of Control of Neglected Tropical Diseases, implemented through a technical collaboration between WHO and FAO, as part of the Program Against African Trypanosomiasis (PAAT).

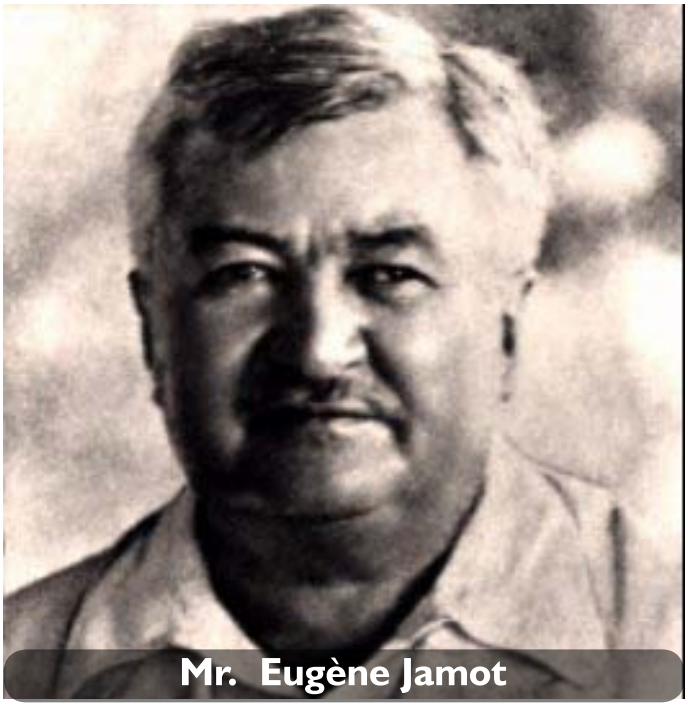
Epidemiological data used as input of the Atlas was provided by the National Sleeping Sickness control programmes and national health authorities of Angola, Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Gabon, Ghana, Guinea, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, Sierra Leone, Sudan, Togo, Uganda, United Republic of Tanzania, Zambia and Zimbabwe; the NGOs Médecins sans Frontières, Epicentre, Malteser and Merlin; and the Research Institutions Institut de Recherche pour le Développement, Institut Pierre Richet (Côte d'Ivoire), Projets de Recherches Cliniques contre la Trypanosomiase (Côte d'Ivoire), Centre International de Recherche-Développement sur l'Élevage en zone Subhumide (Burkina Faso), the Centre for Infectious Disease, College of Medicine and Veterinary Medicine, and the University of Edinburgh. The work also benefited from the HAT mapping activities carried out by Dr. P. Bureau and Mr. P. Lucas in Central Africa.

Further reading

Cecchi G, Paone M, Franco JR, Fevre EM, Diarra A, Ruiz JA, Mattioli RC, Simarro PP (2009) **Towards the Atlas of human African trypanosomiasis** Int J Health Geogr 2009, 8:15 (http://www.ij-healthgeographics.com/content/8/1/15)

Simarro PP, Cecchi G, Paone M, Franco JR, Diarra A, Ruiz JA, Fèvre EM, Courtin F, Mattioli RC, Jannin JG (2010). **The Atlas of human African trypanosomiasis: a contribution to global mapping of neglected tropical diseases.** Int J Health Geogr 2010, 9:57 (http://www.ij-healthgeographics.com/content/9/1/57)

4. From past to present


Mr. Eugène Jamot

4.1 Jamot's assumptions

Books have been and will continue to be written on the eminent scientist Eugene Jamot. In this newsletter, we present the theories postulated by this epidemiologist approximately one hundred years ago.

a. Who was Jamot?

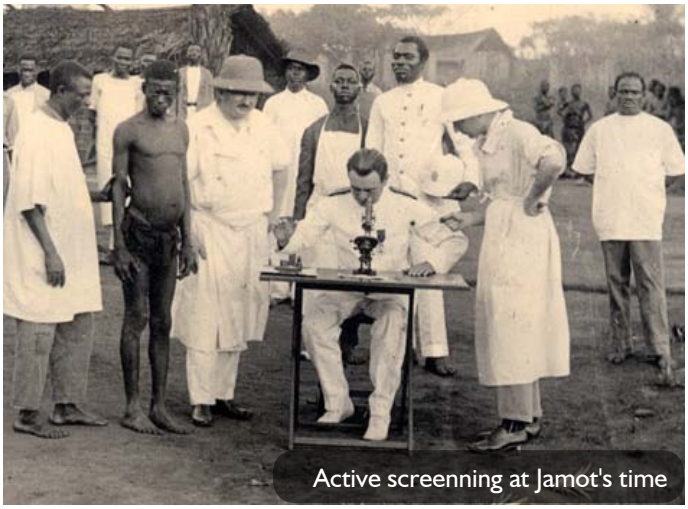
As described in the free encyclopaedia Wikipedia, "Eugène Jamot (1879–1937) was a French entomologist who played a major role in the prevention of sleeping sickness in Cameroun.

He was born in the hamlet of La Borie, part of the commune of Saint-Sulpice-les-Champs, in the Creuse département of central France. Jamot trained as a medical doctor at the University of Montpellier. In 1909, he enrolled at the Marseilles School of Tropical Medicine and a year later, in 1910 he went to Cameroon with a French colonial hygiene group. They joined German scientists who had organised a Sleeping Sickness Treatment Research Group. Jamot discovered that the tsetse fly was the vector of the trypanosomes causing the disorder. Implementing measures taken against insect borne diseases during the construction of the Panama Canal, Jamot's team eradicated the tsetse fly in Cameroun and hence the disease. Later Jamot was made director of the Pasteur Institute at Brazzaville. He died on the 7th April 1937, in the village of Sardent, Creuse, in France.

b. His assumptions (as reported by General René Labusquière)

1. In territories with low medical density, huge distances, scattered populations, and fatal endemic diseases, static medicine cannot produce appreciable results.
2. No precise information on the level of endemicity can be expected from the examination in fixed establishments of patients who come forward spontaneously. Only surveys including vast sections of population can produce exploitable data.
3. A prerequisite for the success of such surveys is a comprehensive population census and high turnout rates during the prospection tour, whether people attend willingly or are forced to do so.
4. One of the first tasks to accomplish is to prioritise all existing problems, without losing sight of the fact that the objective is not to conduct fundamental research in smart institutes, but to work on an urgent task, i.e. prevent human beings from dying!
5. Among the available means of control (sterilisation of virus carriers, eradication of vectors, protection of healthy individuals), that vary according to the endemic, those with proven efficacy and usable on a large scale must be chosen.
6. The results must be monitored using indices, established as rigorously as possible.
7. The control instrument will be a specialist service able to carry out mass prophylaxis for major endemics in a rural environment, using mobile teams.
8. This service will have to meet the following criteria:
- Financial, administrative and technical autonomy;
- Management unit;
- Elimination of administrative barriers;
- Specialised staff;
- Staff with a team spirit, committed and efficient.
9. A ninth assumption would be the necessity to have a doctor present at all times to lead all operations.

When defining these assumptions, Jamot was behaving like an epidemiologist. His approach is further confirmed by his taste


Active screenning at Jamot's time

for biological diagnoses, precise case reporting, accurate statistics, medical geography, and for a review of the situation as clear and as up to date as possible. Likewise, he offered solutions that are also typical of epidemiologists, including immediate sterilising injection, prophylactic use of drugs with slow elimination, vaccination, and vector destruction.

c. Jamot's heritage

Although we cannot cling to the past, we must admit that some of these assumptions are still applicable today to the strategies aiming to eradicate sleeping sickness. We must adapt them to our current environment and reformulate them, taking into account progresses achieved in diagnostic techniques, and the availability of new drugs or new dosage regimens.

We are all (researchers, political decision makers, and actors in HAT control alike) invited to use this information to hasten the eradication of this disease.

4.2 Aerial spraying campaign in Angola and in Zambia

Sequential aerial spraying operations in Angola and Zambia to eradicate tsetse flies and trypanosomiasis in the Kuando-Zambezi region

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Experts from Angola, Namibia, Botswana, and Zambia met in 2003 in Kasana (Botswana) and in 2005 in Luanda (Angola) to address the problem of trypanosomiasis and tsetse flies. Recommendations were issued after the meetings and an agreement was signed by the four countries, setting up a regional tsetse and trypanosomiasis eradication project in the common region of Kuando-Zambezi, under the auspices of the Pan African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC) of the African Union Commission.

The project's secondary objectives include improving the socioeconomic conditions of rural populations, protecting the fauna, promoting an expansion of tourism in the sub-region, and establishing an example of sub-regional cooperation and collaboration.

Spraying team in Angola, July 2009

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Sequential aerial spraying technique (SAT) with the pyrethrinoid insecticide deltamethrin 0.35% ultra-low volume was chosen as the control method in this region affected by Glossina morsitans centralis. The operations were based out of the Katima Mulilo airport, Caprivi, Namibia.

The first operations were launched in 2006 with two aerial spray cycles in Namibia and Botswana, along the Kuando, Zambezi, and Linyanti Rivers.

The aerial spraying operations, which took place from 14 May to 29 July 2009, targeted the two banks of the Kuando River, in the municipality of Rivungo, province of Kuando Kubango, southeast Angola, and the districts of Shangombo and Senanga in southwest Zambia. Five spray cycles were used to treat an area of 5,000 Km2 in each of the two countries.

These operations in Angola and in Zambia required five planes, one helicopter, and six pilots. One of the planes crashed but there were no fatalities. The government of Angola paid US$ 3,383,493 for these operations.

The experts recommended repeating these operations in 2010, northwest of the municipality of Rivungo, in the Kuando Kubango province in Angola, as well as in southeast Zambia. They also suggested that a feasibility study should be conducted for the same operations in northern Angola, where tsetse flies as well as human and animal trypanosomiasis are a major health concern.

Traping material in Angola, July 2009

©Photo VATUNGA

5. Latest scientific events and miscellaneous information

5.1 Training in pharmacovigilance

a) Terminology

The preclinical stages in the development of a drug do not provide sufficient information to characterise a new drug fully. Likewise, the data provided by preclinical studies cannot always be extrapolated to man, as the number of animals used and the duration of the studies are both too small.

During the clinical stages, the number of patients recruited is also limited, the studies are carried out in very controlled environments (different to real life), and concomitant treatments are highly restricted and controlled, which hinders the detection of rare adverse events as well as those related to drug interactions.

And yet, drug-related adverse events are a real public health concern. They have a negative influence on patient compliance and are associated with non-negligible morbidity and mortality.

Pharmacovigilance, defined as the science and activities related to the detection, evaluation, understanding and prevention of drug-related adverse events, is thus of paramount importance.

This is even truer for neglected diseases such as HAT, for which available treatments are either limited, old and toxic, or new and hence require an active pharmacovigilance.

This is why a course on pharmacovigilance was given to the actors of the HAT Platform, with the following objectives:

- Increase awareness on the importance of adverse events and their extent
- Inform about the existence of a Pharmacovigilance System dealing with drug-related adverse events
- Teach how to report drug-related adverse events

b) Description of the course

The course was organised jointly with the National HAT Control Program (PNLTHA) and the National Centre of Pharmacovigilance (CNPV) of DRC, at the Centre Catholique Nganda in Kinshasa on 18-21 April 2011. A total of 40 participants, including two from Chad, two from CAR and three from Angola, the rest being from DRC (Bandundu, both Kasai provinces, Eastern Province and Kinshasa), attended the course given by CNPV specialists and several professors from the University of Kinshasa.

The session started by a definition of pharmacovigilance and a description of its purpose. A comprehensive definition of adverse events was also given, for all drugs in general, as well as for different drug categories, and organ systems (nervous system, skin, kidneys, liver/digestive tract, etc.), with a particular focus on trypanocidal drugs.

The warning signs of adverse events were discussed before addressing the issues of notification and relation to the drug. The participants were then given practical exercises to perform in groups, and the role of pharmacovigilance actors was also discussed. A total of 29 presentations were made and discussed during these four days.

At the end of the course, the participants from DRC and the other HAT Platform countries decided to raise awareness in their own countries on this new and very important field, especially for clinical trials. Some proposed to act as focal

Facilitators and part of participants to the pharmacovigilance training, Kinshasa, DRC, April 2011

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One view of participants to the pharmacovigilance training, Kinshasa, DRC April 2011

©Photo A. EBEJA

points in their provinces and hospital establishments to pass on notifications to the CNPV.

Adverse events occurring during clinical studies are a special case, and must be notified to the study organisers and not to the CNPV. Each participant was given a CD containing all the presentations and specific documentation, as well as an attendance certificate.

Once again, our HAT Platform played the role of catalyst, providing an opportunity for countries that do not yet have a functional pharmacovigilance system to set up their own system. In DRC, the provinces have well-trained human resources motivated to expand this activity, which up until now had been limited to the capital (Kinshasa), and to a lesser extent Katanga. All the modules used during the course have been entered in our database, and a network has been created for all the participants, facilitators, and any scientist interested in this topic.

Dr. Kadima Ebeja Augustin
HAT Platform Coordinator

5.2 Training on GCP in Nairobi

Report on the course on Good Clinical Practice and Good Laboratory Practice for clinical monitors in Nairobi, Kenya

The course was held in Nairobi, Kenya from 16th -18th November 2010 at Olive Gardens Hotel in the Hurlingham suburb. Out of all the participants, seven came from Uganda, the rest from South Sudan, North Sudan, and Kenya.

Numerous professions were represented: doctors, nurses, laboratory technicians, and public health specialists.

The course facilitator was Prof. Sherry Armstrong from Clinical Research Africa, who was in charge of all the sessions for the three days.

Objectifs

Teach the participants the necessary skills to carry out clinical research in compliance with international standards, with a special focus on good clinical and laboratory practice.

Course Outline

- The course was given over three days from 9am to 5pm, with morning and afternoon tea breaks and a lunch break.
- Participants kept time and there were negligible disruptions to the sessions.
- Participants were allowed to ask questions between and at the end of the sessions.
- Participants also had time to share experiences.
- At the end of the three days, there was a written exam on the afternoon of the third day, followed by a visit of the KEMRI premises.
- The participants generally agreed that the course was well organized.

Challenges

- Most participants felt that there was not enough time for discussions, which had to be cut short.
- Some participants would have preferred to have more than one facilitator for three days, but they agreed that the facilitator had done really well by involving everyone in the participatory sessions.
- The first day was a little hectic for participants who had travelled by road in the night, as they had to go straight to the sessions in the morning.

Conclusion

The course was very relevant and the methods of teaching ensured that knowledge was passed on effectively. The professional mix of the participants also provided a wide variety of viewpoints. All invited participants were already actively involved in various research projects in their own country and were encouraged to put their newly acquired knowledge into practice.

The quiet atmosphere in and around the hotel was appreciated and allowed for maximum concentration.

However, it was generally agreed that further information on research practices and more courses on various topics were needed.

The participants thanked the organizers and the facilitator for their commitment and a job well done.

This report was compiled by Dr. Andrew Edielu (one of the participants).

Dr. Andrew Edielu is the Medical superintendent of Lwala Hospital, Uganda, and the HAT coordinator in Teso/Lango sub region.

5.3 HAT advocacy supported by the PATTEC/FIND collaboration

We will never repeat often enough that Human African Trypanosomiasis (sleeping sickness) is a neglected disease, and that advocacy is necessary to find solutions. However, the word 'advocacy', defined as an oral or written presentation defending an idea, a cause, etc., may never go

beyond a clever speech.
Fortunately, the PATTEC and FIND collaboration motto is to « move from decision to action ». The HAT Platform, PNLTHA, DNDi, CTB and the other partners all agree to move to concrete actions.
For instance, a workshop was held in Kinshasa (in accommodations next to the Flat Hotel LUNTU) on 23-24 February 2011 to review the first stage (2009-2010) of the strategic advocacy plan in DRC, with the support of PATTEC/FIND, and plan the mapping of healthcare facilities involved or not in HAT control in DRC.
All PNLTHA technical managers participated in this workshop. The HAT Platform was represented by its Coordinator, and the FIND team included Salome Bukachi, Lakshmi Sundaram, Joseph Ndung'u, Paul Bessell, and Sylvain Bieler.
The first part was seen as very positive and provided many communication tools to:
- Harmonise HAT control
- Increase the index of suspicion for HAT among healthcare professionals
- Improve healthcare facilities
- Improve HAT diagnosis and monitoring
- Increase HAT awareness and commitment at the local, regional and international levels

PNLTHA admitted that more new tools need to be created and existing ones must be validated.
By November 2010, 66% of the US$ 97,950 budget allocated to this project had been used.
The PATTEC/FIND team presented the strategy proposal for the characterisation and mapping of healthcare facilities in DRC.
This project is totally different from the HAT map produced by the WHO (Atlas of HAT).
We are basing our approach on the fact that very little is known on healthcare facilities, the type of personnel, and the available equipment (electricity, microscopes, centrifuge machines, reagents, etc.) and drugs, etc.
Knowing where the various healthcare facilities are located and the specifications of their equipment is important for advocacy, and is used to plan studies on diagnostic tools as well as clinical studies.
The proposed strategy is to collect data in all HAT endemic provinces, starting with Bandundu as a pilot stage. Existing data on the facilities (with GPS records) and on their equipment will be used as a basis.
This strategy uses the advocacy project to collect data by involving HAT provincial coordination structures. This mapping and characterisation will then be extended to the other provinces.
Activities started at the end of March so that the pilot stage (Bandundu) can be finished by 1 July 2011. The strategy will then be refined and extended to the other provinces over the following five months, bringing the study to an end by 1 December 2011.

Kinshasa, **Dr. Kadima Ebeja Augustin**
HAT Platform Coordinator

HAT advocacy workshop participants, Kinshasa DRC, February 2011
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5.4 Target Product Profile for new drugs against human African trypanosomiasis

A Target Product Profile (TPP) was defined to determine the direction of research on new drugs against human African trypanosomiasis. Each new R&D project is selected, implemented and managed, using well-defined decision matrices based on these TPPs.

The TPP must be updated to take into account changes in the disease in the field, and the introduction of new drugs. The latest review was initiated during the scientific meeting in Nairobi in October 2010, and was finalised and approved by the steering committee of the HAT Platform during its meeting in Bangui on 26 May 2011. The final approved version is given below.

1. New drug for HAT stages 1 and 2

Ideal	**Acceptable:** Improvement compared to the current treatment for stage 2	**NECT**
Effective on stages 1 and 2	Effective on stages 1 and 2 (used only against stage 2)	Stages 1 et 2 (used only against stage 2)
Broad spectrum (gambiense and rhodesiense)	Effective only against *gambiense*	*gambiense*
Clinical efficacy > 95% after 18 months follow-up	To be determined by the experts	Clinical efficacy: 96.5% (ITT NECT study)
Effective in melarsoprol refractory patients		Effective
Drug related mortality <0.1%	Mortality possibly related to the drug <1%	Mortality possibly related to the drug 1.2% (NECT Field)
Also safe in pregnant or breastfeeding women and in children		No specific adverse events in babies born or breastfed after treatment (NECT Field)
Adult and pediatric formulations (rectal?)		Pediatric formulation DFMO + Nifurtimox 5 mg tablet to be cut
No monitoring for adverse events	Simple weekly lab test (in the field)	Hospitalisation required
≤ 7 days PO UID	10 days PO (up to TID)	7 days IV infusion (BID) + 10 days PO (TID)
< 7 days IM UID	< 10 days IM UID	
Stability in zone 4 for > 3 years	Stability in zone 4 for > 12 months	Stability in zone 4 for > 24 months
Trypanocidal	Trypanostatic	Trypanostatic DFMO + Trypanocidal Nifurtimox
Several targets	Single target (but uptake not exclusively via P2 transporter)	
< €30 /course* (cost of drugs only)	< €100* /course	222.5 €/ course (in 4 treatment kits; WHO)
	< €200* / course if the other criteria are very good	

2. Target Product Profile to develop solely if efficacy of a drug against stage 2 not demonstrated in advanced clinical trials

Ideal	Acceptable
Effective on stage 1	Effective on stage 1
Broad spectrum (gambiense and rhodesiense)	*Effective only against gambiense*
Clinical efficacy > 95% after 18 months follow-up	Clinical efficacy no worse than pentamidine
0% drug related mortality	0% drug related mortality
Treatment ≤ 3 days	Treatment ≤ 7 days
Also safe in pregnant or breastfeeding women and in children	Also safe in pregnant or breastfeeding women and in children
Adult and pediatric formulations	Adult and pediatric formulations
No monitoring for adverse events	No monitoring for adverse events
Single dose PO or IM	2-3 daily doses PO or IM
(single dose in animal models, long half-life)	
Stability in zone 4 for > 4 years	Stability in zone 4 for > 2 years
Trypanocidal	Trypanocidal
Several targets	Single target but resistance not readily inducible
< €10 / course	< €30 / course

5.5 HAT Platform Steering Committee meeting in Bangui

The HAT Platform Steering Committee is the governing body of the platform. It includes two representatives from each member country and representatives from partner institutions. The committee meets twice a year to review the activities and decide what is to come next.
Its presidency is rotating, and this time the presidency went to the Central African Republic. Consequently, the first meeting of 2011 was held in Bangui on 26-27 May 2011, in the meeting room of Hotel Oubangui. A total of 20 participants attended the meeting

First name and name	Country
Augustin Kadima Ebeja	Coordination
Gedeão Vatunga	Angola
Sylvestre Mbadingaï	CAR
Bénédicte Noëlla Mandakombo	CAR
Victor Kande betu Kumesu	DRC
Dieudonne Mumba Ngoyi	DRC
Stephane Ngampo	ROC
Intisar Elrayah	Sudan
Mustafa Mubarak	Sudan
Richard Laku	South Sudan
Jean Claude Peka Mallaye	Chad
Oumar Mahamt Saleh	Chad
José Ramon Franco	Switzerland
Nathalie Strub Wourgaft	Switzerland
Antoine Tarral	Switzerland
Olaf Valverde	Switzerland
Wilfried Mutombo	France
Laurence Flévaud	Spain
Enrica Picco	CAR
Didier Kalemwa	Switzerland

The event was sponsored by the government authorities, and the opening and closing sessions were chaired by Jean-Pierre Waboue, legal policy officer and personal representative of the Minister of Public Health, Population and Fight against AIDS, who was out of the country. The other officials included the Medical Director of DNDi Geneva, Nathalie Strub Wourgaft, and the HAT Platform Coordinator, Dr Augustin Kadima Ebeja, who is also the permanent secretary of the Steering Committee.
The epidemiological and therapeutic situation in the 6 countries represented was reviewed, along with the achievements and unmet needs at the first quarter 2011 (courses, workshops and on-going studies). The idea of creating a website for the HAT Platform and of connecting


Steering comittee workshop, Bangui CAR, May 2011

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the various ethics committees of the member countries was discussed and adopted. The Target Product Profile (TPP) to treat HAT was updated and adopted after improvements were made by the participants (see table in this Newsletter). The on-going research as development of fexinidazole, the FIND iLED study on fluorescence microscopy was presented.
Platform member countries presented a list of 32 sites (15 in DRC) as possible places for HAT clinical research. All those sites are located in health structures in known endemic areas of Sleeping Sickness. The list is available on request from the Coordination. Not all of them are ready to start a research. Each research institution remains responsible to evaluate the sites while preparing a precise activity. This preliminary evaluation must concentrate on different factors among those one of the main one is the latest detected prevalence in the site's coverage area. It is also necessary to consider the availability of trained staff (or staff that can be trained), infrastructure, accessibility, security and adequate telecommunication means.
The next steering committee meeting is scheduled in Bamako, during the meeting of CSIRLT (Conseil Scientifique International de Recherche et Lutte contre les Trypanosomiases) in September 2011. South Sudan was chosen to host the joint annual meeting with EANETT and the steering committee meeting in May 2012. All the participants expressed their satisfaction and a family photo was taken at the end of the workshop.

Sylvestre Mbadingaï and Augustin Ebeja

5.6 Health research policy in South Sudan

In South Sudan, the Directorate of Planning and Coordination of the Ministry of Health is responsible for health sector research, which falls under the Division of Research, Monitoring and Evaluation .
Scientifically unsound research involving human subjects is by definition unethical as it may expose participants to risks or inconvenience for no benefit. Even if there is no risk of injury, the expenditure of subjects' and researchers' time in unproductive activities represents a waste of valuable resources.
Mechanisms do exist, however, to ensure the scientific validity of health research. This is usually the responsibility of research ethics committees. An ethics committee can verify that a competent body has judged the research to be scientifically sound.
The research department currently includes a research data hub, an ethical committee, and the research secretariats.
The National ethical committee includes seven people from various different fields, not necessarily all ministry staff. The national ethics committee (NEC) will undertake an independent, competent, and timely ethical review of research proposals.
There are two standard application forms for healthcare research conducted in South Sudan: one for social and behavioural research and the other for medical and clinical research. Researchers (principal investigators) also have to submit a covering letter from their academic institution, evidence of the approval of the ethics committee's of their own institution, a detailed research protocol, and information on the data collection tool. Seven hard copies of the application are required.
Conclusion
South Sudan is emerging from a decade of civil war, which has degraded the country's social and physical infrastructure. The Health Research Policy has provided the Government of South Sudan an opportunity to start building a nation and to regulate and monitor research in the country.
Keywords: Ministry of Health, Government of South Sudan, National Ethics Committee, and South Sudan.

Richard Laku

5.7 MSF project on sleeping sickness control in the Eastern Province, Democratic Republic of Congo

Catherine de Patoul, Bertrand Rossier, François Chappuis

In July 2007, MSF (Médecins Sans Frontières) Operational Centre, Geneva, initiated a HAT project in Doruma, in the district of Haut-Uélé close to the borders with South Sudan and the Central African Republic. The screening activities and treatment of infected patients were maintained in the health districts of Doruma and Ango, and started in Bili in January 2009 with a second MSF team. In March 2009, all the activities had to be stopped and the teams evacuated following the attack of the MSF base in Banda by LRA (Lord's Resistance Army) rebels, and the abduction of expat and Congolese staff. The activities were resumed in Doruma in December 2009, and initiated in Dingila and Bambesa in the Bas-Uélé in September 2010.
MSF HAT programmes in the Uélé districts were developed in a highly complex security environment. LRA rebels are still active and attack an already very vulnerable local population, making the access to healthcare very difficult. Apart from the town of Doruma where several screening rounds helped reduce the prevalence of HAT from 4.2% to 0.7%, the conflict has severely restricted the movements of the mobile teams and thus affected HAT control throughout the region. Moreover, massive displacements of people fleeing the conflict have probably contributed to the reemergence of HAT in Bas-Uélé.

A total of 770 patients were treated for HAT in Doruma, Gangala and Dingila in 2010, in addition to the 1570 patients treated between 2007 and 2009. This number would be much higher if screening activities could have been carried out normally. Screening is the only way to ensure that the disease is included in the national statistics, and yet it is non-existent in numerous remote or unstable regions of central Africa. In addition, the use of NECT (Nifurtimox/Eflornithine Combination Therapy) in patients in the late stage of the disease offers an effective (very few relapses), safe (mortality 0.3%), and simplified solution for the management of sleeping sickness. MSF strongly recommends an expansion of the use of NECT in DRC and elsewhere.

HAT patient in treatment in MSF centre in Province oriantale / DRC

©Photo MSF-CH

6. On-going research

6.1 Fexinidazole, a new oral compound for the treatment of HAT

Fexinidazole is a new, oral compound with in vitro and in vivo activity against the parasites Trypanosoma brucei rhodesiense and T.b. gambiense, the causative agents of human African trypanosomiasis (HAT). In preclinical studies on murine models, the oral administration of fexinidazole cured mice with acute or chronic HAT infection. Preclinical absorption, distribution, metabolism, and elimination (ADME) studies show that fexinidazole is well absorbed and readily distributed throughout the body, including the brain. In all investigated animal species, fexinidazole was rapidly metabolized, resulting in the formation of at least two active metabolites (fexinidazole sulfoxide and sulfone), responsible for most of the compound's pharmacological activity.

Regulatory toxicology studies, including safety pharmacology and 4-week repeated-dose studies in rats and dogs, have shown that fexinidazole is well tolerated up to 800 mg/kg/day, with no particular safety issues identified.

Like many nitroimidazoles, fexinidazole was shown to be mutagenic in the Ames test, but it is not genotoxic to mammalian cells in vitro or in vivo, and therefore is not expected to pose a genotoxic risk for humans. Based on these results, fexinidazole was introduced to first in man studies. To date, 96 healthy volunteers of sub-Saharan origin have been included and randomized to receive either a single oral dose or repeated fasting doses increasing up to 3600 mg/day for 14 days. The drug is metabolised the same way in man and in animals, resulting in high plasma concentrations of fexinidazole sulfone (M2), which peak at around 24h with a half-life of 24 hours, leading to a single dosing per day. In man, the free fraction of this pharmacologically active metabolite (M2) is about 43%, which suggests that is crosses the blood-brain barrier easily, as demonstrated in animal studies.

Fexinidazole demonstrated a good tolerance and safety profile, and only one subject had elevated liver enzymes. The liver function will be explored in the next repeated dose study in volunteers.

Single dose studies of food interactions have shown an interesting increase in blood concentrations. This effect will be used in healthy subjects to determine the best and most compliant oral dosing regimen for the next clinical pivotal study in patients. Our goals are to finalize the studies in volunteers during the 4th quarter 2011, and start the pivotal phase II/III study early 2012.

DNDi has thus started looking for adequate trial sites in DRC and in other affected countries. The study protocol is being finalised and a training course for future investigators will be organised soon. This trial will be carried out in close coordination with the HAT Platform, so that it may contribute to improving the practical experience of African researchers.

Antoine Tarral, DNDi

Fexinidazole prototype tablet

©Photo DNDi

6.2. The NECT was adopted as the first-line treatment for late stage gambiense trypanosomiasis in 2010.

During that year in five of the seven HAT Platform countries, oral nifurtimox and injectable eflornithine were administered as a combination treatment for a shorter duration, and with a reduced dosage regimen compared to previous protocols based on eflornithine alone. The HAT Platform supports and monitors carefully the use of NECT in HAT member countries. The results are shown in Table 1 below:

Table 1: Number of late-stage HAT patients treated in 2010 per endemic country from the HAT Platform countries.

Treatment	Arsobal	DFMO	NECT	Other	Total
DRC	347	707	1'767	4	2'825
RoC	6	42	0	0	48
Uganda	0	13	57	0	70
Angola	0	149	0	0	149
Chad	11	0	101	0	112
CAR	0	0	180	0	180
South Sudan			71	69	140
Total	364	911	2'176	73	3'524
%	10.3	25.8	61.8	2.1	100

The data on the treatment of late-stage HAT patients presented in this table was supplied directly by the member countries. The 3426 patients diagnosed with early-stage HAT (treated with pentamidine) were not included in this table. Melarsoprol (arsobal) was used before the formal introduction of NECT as first-line treatment in 2010. In DRC, arsobal was administered to 341 patients in the Bandundu province. In December 2010, healthcare personnel had attended a training session on the use of NECT, organised by the PNLTHA with the financial support of DNDi (North Bandundu, 29 people) and of Coopération Technique Belge (South Bandundu, 76 people). The instructors were trained by the WHO during an international course in Kinshasa in 2009.

Arsobal was administered to 75 patients with rhodesiense trypanosomiasis in Uganda, because NECT or eflornithine are not effective on this form of sleeping sickness.

Following the agreement signed between the manufacturers Sanofi and Bayer and the WHO, HAT treatments will be supplied free of charge to the countries requesting it.

Among the two countries that had not yet used NECT in 2010, Angola applied to the WHO for the use of NECT on 31 December 2010 and started using it in 2011. In the Republic of Congo, the Pharmacy, Drug and Laboratory Directorate of the Ministry of Health authorised the use of NECT on 27 April 2011. NECT supplies will be made available as soon as the official request, signed by the Minister of Health, is made to the WHO.

Information collected by: Olaf Valverde, DNDi and Augustin Kadima Ebeja, HAT Platform Coordinator

6.3 Two HAT endemics in Uganda

Uganda is in a unique situation regarding Human African Trypanosomiasis (HAT) or sleeping sickness, as it is the only country reporting active foci of both Trypanosoma brucei gambiense (chronic HAT) and T.b. rhodesiense (acute). Over the past decade, T.b. rhodesiense has spread continuously northwards, from Southeastern Uganda (traditional foci) towards T.b. gambiense endemic districts in Northwestern Uganda. Outbreaks in areas where HAT had never before been associated with drug resistance problems, as seen in the north, have serious implications in terms of diagnosis and treatment, and complicate the control of the disease. In such a situation, characterization of trypanosome isolates from patients, tsetse flies, and domestic animal reservoirs in the interface districts of Northern Uganda is of prime importance. Dr. Enock Matovu and Dr. Anne Kazibwe from Faculty of Veterinary Medicine at Makerere University received a grant to carry out these activities in the Kaberamaido, Dokolo, Lira, Gulu and Amuru districts, as part of the Postdoctoral Fellowship Programme "Neglected Communicable Tropical Diseases and Related Public Health Research". The sum of €150,000 over 3 years was donated jointly by the Volkswagen, Merieux Foundation, Nuffield and Calouste Gulbenkian Foundations. "We are grateful to the European Foundations for this opportunity to map out areas of the two HAT forms in Uganda, and to shed light on the feared co-existence of the two diseases in the same foci. This should help the concerned institutions set up relevant control measures in the affected districts," said Dr. Enock Matovu, PI of the project. Dr. Anne Kazibwe, a postdoctoral fellow at Makerere University and co-investigator is equally delighted. "This is an opportune moment for us to consolidate the gains in HAT control in Uganda, achieved through the concerted effort of many players in the national control programme over the past decades," said Dr. Kazibwe. Other objectives of this project include the determination of drug susceptibilities of the parasites circulating in these districts, and the surveillance for genetic markers of trypanocidal drug resistance.

REVIEW ON BIOETHICS

Promoted by Prof. Kiyombo Mbela and Prof. Okitolonda Wemakoy, the Public Health School of the University of Kinshasa in the Democratic Republic of Congo initiated a joint project with the University of North Carolina, Chapel Hill, USA, and the Catholic University of Louvain, Belgium, to create a Bioethics Interdisciplinary Centre. The Centre will be involved in all aspects of bioethics, but those that require the most urgent attention are clinical ethics, ethics in biomedical research, environmental ethics, and ethics in healthcare policy.

Objective of the Bioethics Centre

To become a centre of excellence in bioethics training, research, and intervention in French-speaking Africa, based on a growing partnership with persons and institutions interested in the welfare and dignity of human beings.

Mission of the Bioethics Centre

To produce researchers, executives and contributors in all scientific, technological and professional specialties of French-speaking African countries, committed to change the situation of men and women through research and actions in healthcare and development, taking into account their rights, their dignity and their welfare, where inequality, marginalisation, and lack of means prevail.

A few achievements

- The centre was created in Kinshasa in September 2006.
- Seminars on bioethics and research ethics given to students of several departments of the University of Kinshasa every Saturday from 2.00 to 5.00 pm.
- Participation of a CIBAF member to a training workshop to strengthen the capacities of ethics committee members in Malawi in 2006.
- Publication of articles on bioethics co-authored by CIBAF members published in renowned journals in French and in English.
- Organisation of training workshops for the members of the National Ethics Committees in DRC, RoC, and CAR.
- A diverse group of executive was set-up in Belgium and in the US to create the Centre at the Public Health School, University of Kinshasa.
- Participation of three CIBAF members to the Bioethics Days held in Dakar.

On-going work

- Development of curriculums to be included the Public Health Training Programme and in the programme of the School of Medicine of the University of Kinshasa.
- Research work on bioethics taking into account the local context.
- Organisation of local, regional, and international workshops on bioethics and research ethics for French-speaking African countries.
- Circulation of information on bioethics through publications, Internet sites, blogs, articles and works on the region.
- Training sessions based on short modules in clinical ethics, research ethics, management of a research ethics committee, management of an ethics committee attached to healthcare facilities, and in bioethics.

Projects

- Creation of a Masters' programme in Public Health with a special focus on bioethics.
- Introduction to the course on research ethics made compulsory for all Master of Public Health students.
- Strengthening of an inter-university network between the country's large cities, particularly Kisangani, Lubumbashi, Matadi, Goma and others, dealing with research ethics, public health, and ethics committees.
- Exchanges on bioethics experiences between 5 French-speaking countries, particularly Madagascar.
- Involvement in the creation of principles, laws, and regulations in medical ethics and research ethics on an international level.

Our partners

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Other Fogarty Bioethics programmes
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7. Scientific Events 2011-2012

2011 :

Date	Place	Event
12-16 September 2011	Bamako, Mali	International Scientific Council for Trypanosomiasis Research and Control (ISCTRC)
3 - 6 October 2011	Barcelona, Spain	7th European Congress on Tropical Medicine and International Health (ECTMIH)
24 - 27 October 2011	Addis Ababa, Ethiopia	ANDI meeting

2012 :

Date	Place	Event
11-14 March	Atlanta, USA	International Conference on Emerging Infectious Diseases
31 March /3 April	London, UK	22nd European Congress of Clinical Microbiology and Infectious Diseases
3-5 April	Glasgow, UK	BSP spring meeting - 50 years of Parasitology in the UK-2012
18-20 April	Geneva, Switzerland	Geneva Health Forum
8-11 May	Thessaloniki, Greece	30th Annual Meeting of the European Society for Paediatric Infectious Diseases
13-16 June	Bangkok, Thailand	15th International Congress on Infectious Diseases
16-18 June	Washington, USA	Global Health Council Annual Conference

Bioethics workshop participants, Adis Ababa, Ethiopia, March 2011

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8. Recent publications on HAT

Johon E. Chisi. Adamsons Muula et al. A retrospective Study of Human African Trypanosomiasis in three Malawian districts. Tanzania Journal of Health Research 2011.13(1): p 79-86

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Bucheton, B. et al. (2011) Human host determinants influencing the outcome of T.b. gambiense infections. Parasite Immunol Mar 8. (epub ahead of print)

Corbel, V. and Henry, MC. (2011) Prevention and control of malaria and sleeping sickness in Africa: Where are we and where are we going? Parasit Vectors, 4, 37

Deborggrave, S. et al (2011) Diagnostic accuracy of PCR in gambiense sleeping sickness diagnosis, staging and post-treatment follow-up: a 2-year longitudinal study. PLOS NTD, 5 (2), e972.

Hasker, E. et al (2011) Health care-seeking behaviour and diagnostic delays for Human African Trypanosomiasis in the Democratic Republic of the Congo. Trop Med Int Health. Mar 29

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Lang, T. (2011) Advancing global health research through digital technology and sharing data. Science. 331 (6018), 714-7

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Njiru, Z. (2011) Rapid and sensitive detection of human African trypanosomiasis by loop-mediated isothermal amplification combined with a lateral-flow dipstick. Diagn Microbiol Infect Dis. 69 (2), 205-209.

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Willyard, C. (2011) Putting sleeping sickness to bed. Nature Medicine. 17(1); 14-17.

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