

C.A.S.A. Project

Cohort of African people Starting Antiretroviral therapy

C.A.S.A. Activity plan 2014

Edited by the C.A.S.A. Project partners (January 2014)

C.A.S.A. Project partners



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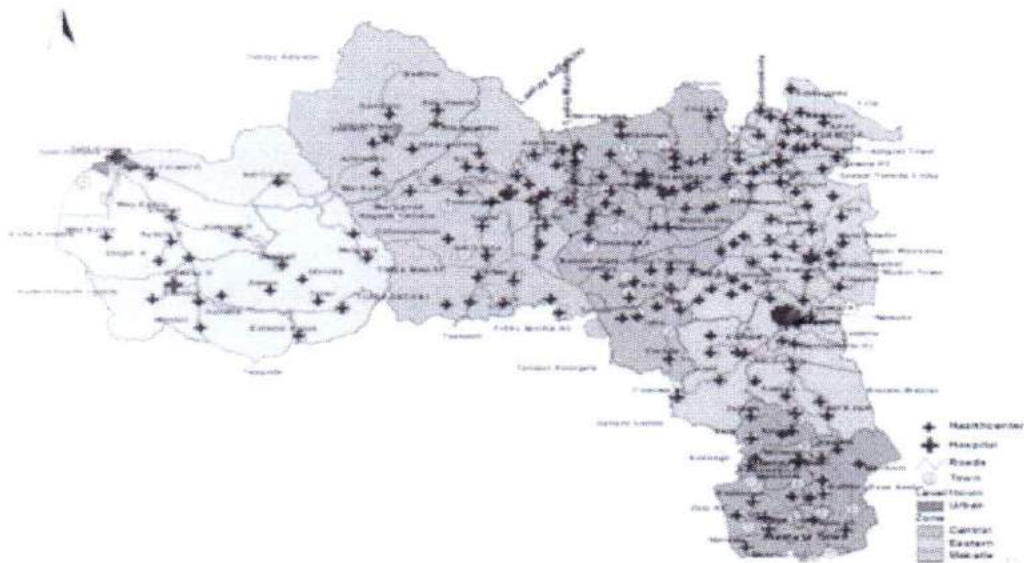
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The partners acknowledge the collaboration of all Health Facilities participating in the project.

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C.A.S.A. project operating area

Introduction

This document includes a brief description of the C.A.S.A. project and the activity planned for the year 2014.

To provide a more detailed description of the project we have included in this document also the English translation of an article on the C.A.S.A. project recently published in Italian in the monthly bulletin of the Istituto Superiore di Sanità (*Notiziario dell'Istituto Superiore di Sanità* (October 2013).

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The project in brief

The C.A.S.A. project (Cohort of African people Starting Antiretroviral Therapy), which started in early 2012, is an operational research for improving care of people with HIV infection. The C.A.S.A. Project is a partnership Project among Istituto Superiore di Sanità (ISS), Mekelle University (MU) and Tigray Health Bureau (THB).

The **THB** is the competent public body in charge of health planning and care management at regional level (Tigray). It represents the Ethiopian Institution of reference for this project, of which it has full ownership. THB provides the legal and administrative support to ISS.

The **MU** with its College of Health Sciences, is located in Mekelle, the largest city in Tigray. The MU provides its health care skills and prestige to support the project. The University guarantees the availability of specialized personnel as well as a work-space dedicated to the project.

The **ISS** is the main technical-scientific body of the National Health Service in Italy. ISS coordinates the CASA project and supports it providing both human and financial resources.

The fight against HIV/AIDS in Ethiopia is for Italy a major commitment in the context of international cooperation programs. The CASA project is in line with the *Growth and Transformation Plan* (GTP), which describes the five year plan (2011-2015) for the economic development of the Nation. In particular, the general objective of this project is to contribute to halting and reversing the spread of major communicable diseases (CDs) such as HIV/AIDS, TB and Malaria.

The specific objective, which the project aims to reach within five years, is to contribute to improve the quality of care of patients with HIV-infection and related co-infections and comorbidities in Tigray. The achievement of this objective needs a holistic approach including training for health workers (HWs), strengthening of the laboratory services, involvement of patients and community based organizations (CBOs) and the optimisation of the use of antiretroviral therapy (ART).

The direct beneficiaries of the project will be the HWs (physicians, nurses, laboratory technicians, health-officers, data-managers, case-managers) participating in this project who will be able to acquire better competency to manage the care of HIV/AIDS patients in a setting of clinical practice. The final beneficiaries will be people with HIV/AIDS who will gain medium and long term benefits from the results of the project, in terms of reduced probability of mortality/morbidity and improvement of the quality of life.

The CASA project has been funded by the Italian Ministry of Health and additional funds are expected by the Italian Cooperation.



Project Activity 2014

Currently four health facilities (HFs) are participating in the CASA project.

In 2014, the extension of the project to additional HFs is expected.

They will include four Health Centers (HCs) and four Hospitals. Below the list:

1. Alamata Health Center
2. Alamata Hospital
3. Mehoni Health Center
4. Machew Hospital
5. Mekelle Health Center
6. Mekelle Hospital
7. Ayder Hospital
8. An additional Health Center to be selected by THB

The activities of the project currently in progress will continue in 2014 and further activities will also be added. The project activities will include: A. Training activities; B. Equipment of HFs; C. Activities of health communication and therapeutic education for patients; D. Multi-site epidemiological data collection on HIV/AIDS treated patients.

A. Training activities

Training activities will be addressed to the local HWs including physicians, nurses, health officers, laboratory technicians, data-managers and case managers. Training activities will have the objective of reinforcing clinical and laboratory skill as well as improving collection, analysis and management of epidemiological data on HIV/AIDS patients in clinical practice. Training activities will include: 1. e-learning training; 2. on-site training; 3. participation in international meetings/conferences/congresses by local HWs.



1. E-learning training

In 2014, a key of CASA training activities will be the implementation of an E-learning platform. The advantages of a E-learning platform compared to traditional training systems are many, in particular time optimization and cost savings. Users will be able to have lessons at any time and in any place provided with internet connection. A specific software, installed and activated in ISS, will allow to communicate via web with similar software located at the MU. The software will also contain the material necessary to the formative activities and an e-learning platform for distance learning .

Lessons on clinical and epidemiological topics will be periodically provided by ISS team (about once in a month). After each lesson, learners will be asked to do an assessment test on the lesson contents. The assessment results will be immediately made available.

2. On-site training

In 2014, on site three month short courses are expected. The course will be aimed at transferring the ISS know-how to the local HWs. In addition to this, it will be also used *"train the trainer approach"*. The MU personnel, previously trained, will be able in turn to train the HWs working at the HFs involved in the CASA project. In 2014, the local HWs working at HFs will benefit of periodic on-site assistance in their clinical practice by Italian physicians, as per previous agreements stipulated with the School of Specialization in Infectious Diseases and Tropical Medicine, University of Genoa. The presence of two infectious diseases specialists is foreseen on site throughout 2014. Two physicians are expected to stay for two months two times in a year.



3. Participation in international meetings/conferences/congresses

The formative program will include the integration of the on-site training activities with further initiatives to be implemented through HWs participation in meetings, conferences or congress at international level. This training will be ensured to a maximum of 5 persons in 2014. Among these international activities it is scheduled the participation in the AIDS Society (IAS) congress (July 2014) of two people partners of CASA project.

B. Equipment of HFs

The eight HFs participating in the project will be adequately equipped with basic furniture, hardware and software necessary for collection and management of HIV/AIDS patients data in clinical practice. Four out of the eight HFs have previously been equipped by ISS.

Besides, each HF (if it's lacking) will be provided with an instrument for CD4 cell count. Seven out of eight HFs already have CD4 machine (four CD4 machine have previously been purchased and delivered by ISS). In addition to the CD4 instruments, HFs will also be provided with consumables necessary for their use (KITs and reagents) and technical training for using CD4 machines.

C. Activities of health communication and therapeutic education for patients

In 2014 the CASA project will still rely on the collaboration of local CBOs, which they will be essential to carry out communication and therapeutic education of patients through seminars, events (coffee ceremonies, theater) and dissemination initiatives (posters, brochures).



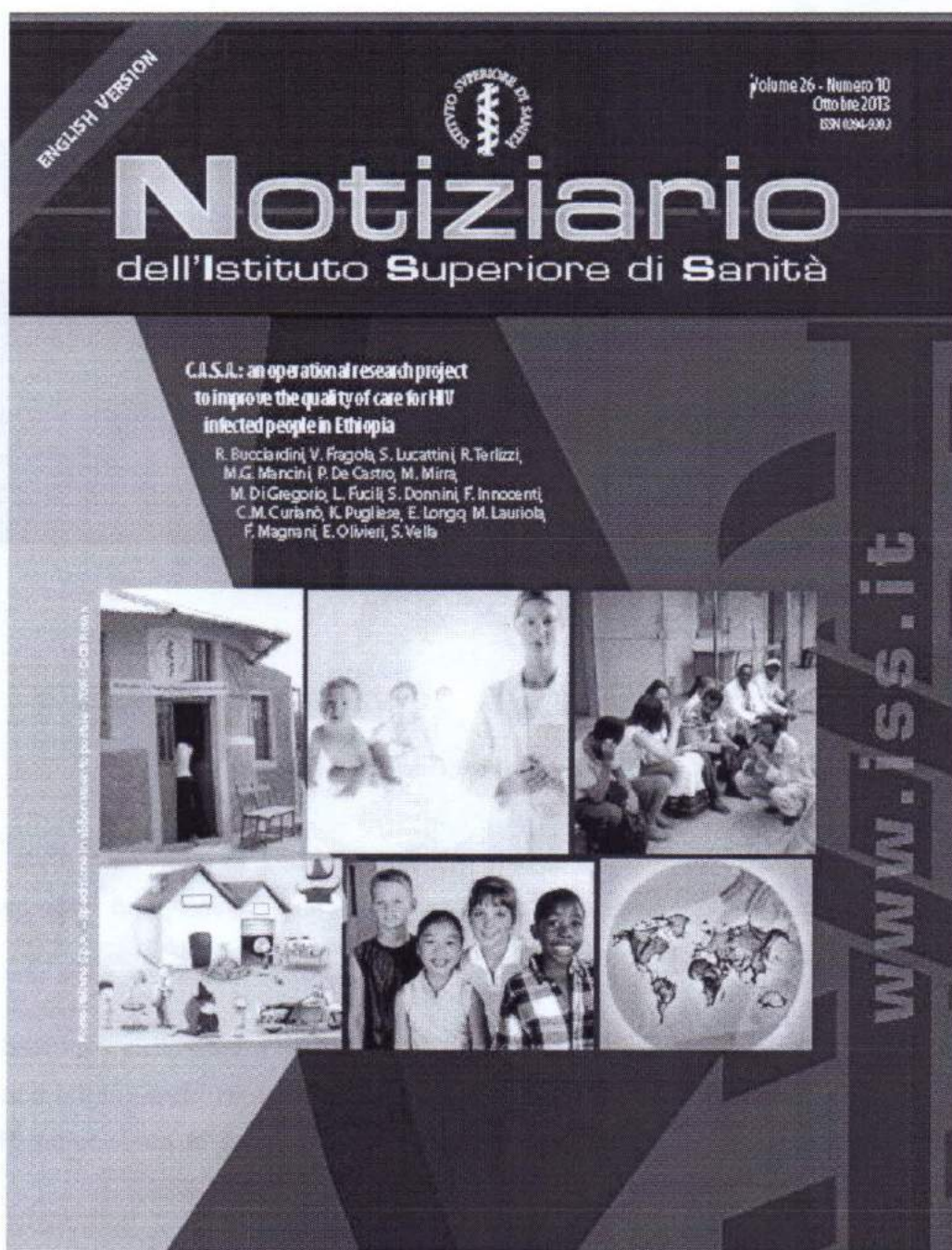
D. Multi-site epidemiological data collection on HIV/AIDS treated patients

In 2014 the collection of epidemiological data will be extended to eight HFs. Data on demographic and clinical characteristics, medical care and clinical and laboratory outcomes will be collected on HIV-infected patients taking ART at each HF.

Currently around 700 patients have been enrolled in the CASA project. It is expected to reach more than 1000 patients at the end of 2014. In next mission in Tigray (at the end of January) ISS team will show the first report of CASA data collected at participating HFs and an abstract will be written to be submitted to IAS Conference (July 2014).

Annex 1. English version of the Article published in Italian in the
Notiziario dell'Istituto Superiore di Sanità (October 2013)

Available from http://www.iss.it/binary/publ/cont/PROGETTO_CASA_INGLESE.pdf



C.A.S.A.: AN OPERATIONAL RESEARCH PROJECT TO IMPROVE THE QUALITY OF CARE FOR HIV INFECTED PEOPLE IN ETHIOPIA



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SUMMARY - HIV infection is still a major threat to the health of people living in less economically developed countries. According to the estimates by the World Health Organisation, in 2012 there were 35 million people living with HIV, mostly (30 million) in the low- and medium-income countries. Sub-Saharan Africa, according to the most recent estimates (2012), is still the region most severely affected by the HIV/AIDS pandemic, with over 24 million people living with HIV. The fragility of health systems in Sub-Saharan Africa, as well as poor integration of services and the lack of adequate funding, are the main obstacles for the population to access to healthcare and prevention services, and to achieve the same standards of care of the more economically developed countries. In a context of extreme fragility and poverty, such as Sub-Saharan Africa, the role played by operational research is central in optimizing the use of available resources and improving the effectiveness of interventions. The C.A.S.A. Project aims to provide a contribution to improve the quality of patient care through a holistic approach including training of health personnel, strengthening of laboratory facilities, patient involvement in their own care and activities to maximize the effectiveness of antiretroviral therapy.

Key words: operational research; AIDS; HIV; training; cooperation

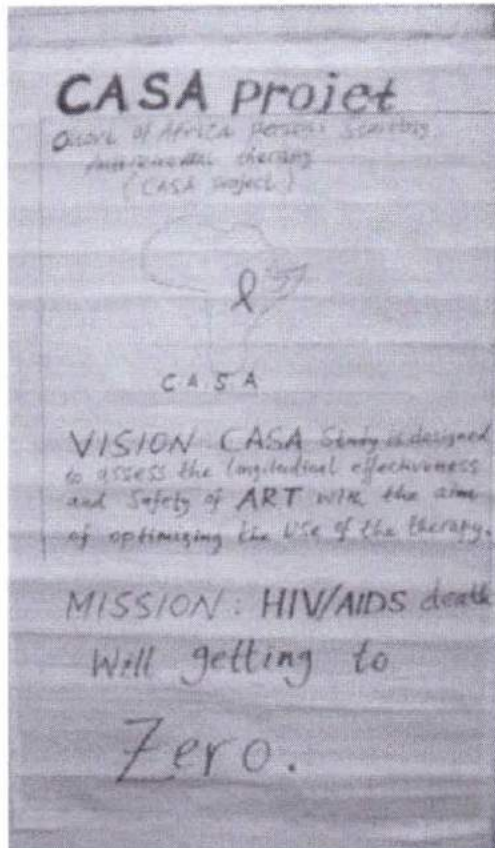
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Riassunto IC.A.S.A.: un progetto di ricerca operativa per migliorare la qualità della cura delle persone con infezione da HIV in Etiopia. - Nel 2012, secondo le stime dell'Organizzazione Mondiale della Sanità, 35 milioni di persone erano affette dal virus dell'HIV, di cui più di 30 milioni nei Paesi a basso e medio reddito. Nella terza decade della pandemia, nonostante i notevoli sforzi da parte delle iniziative internazionali per la lotta all'HIV/AIDS, l'Africa subsahariana rimane la regione maggiormente colpita con più di 24 milioni di persone (adulti e bambini) che vivono con l'HIV. La fragilità dei sistemi sanitari dell'Africa subsahariana, la scarsa integrazione dei servizi e la mancanza di finanziamenti adeguati sono i principali ostacoli alla possibilità di garantire all'intera popolazione l'accesso ai servizi di prevenzione e cura e assicurare gli stessi standard di cura dei Paesi economicamente più sviluppati. In un contesto di estrema fragilità e povertà, come quello subsahariano, è centrale il ruolo assunto dalla ricerca operativa, il cui obiettivo è l'ottimale utilizzo delle risorse disponibili per una maggiore efficacia degli interventi. Il Progetto di ricerca operativa denominato C.A.S.A. (Cohort of African people Starting Antiretroviral therapy) si propone di fornire un contributo al miglioramento della qualità della cura del paziente con HIV/AIDS attraverso un approccio olistico che comprende la formazione del personale sanitario, il potenziamento delle strutture laboratoristiche, il coinvolgimento dei pazienti e delle Associazioni dei pazienti e l'utilizzo tempestivo ed efficace della terapia antiretrovirale.

Parole chiave: ricerca operativa; HIV; AIDS; formazione; cooperazione

After over 30 years from its initial outbreak, HIV infection is still a major threat to the health of people living in less economically developed countries (LDCs). According to estimates of World Health Organisation (1), in 2012, 35 million people were living with HIV (PLWH),

of whom over 30 million in low and medium income countries. Sub-Saharan Africa, according to the most recent estimates (2012) is still the region most affected by the HIV/AIDS pandemic, with over 24 million people (adults and children) living with HIV infection. ►



Posters made by health workers of Alamata health center (Ethiopia)

Since 2000, many initiatives aimed at supporting the fight against the so-called diseases of poverty (AIDS, tuberculosis-TB and malaria) have been undertaken, including those launched by Global Fund, PEPFAR (U.S. President's Emergency Plan for AIDS Relief) and UNAIDS (Joint United Nations Programme On HIV/AIDS). Despite such interventions, there are still many challenges to be faced in order to achieving one of the Millennium Development Goals (2000-2015), i.e. "halting by 2015 and begin to reverse the spread of HIV/AIDS". It is a priority to optimize the use of antiretroviral therapy (ART) with new drugs and innovative therapeutic strategies as well as to have adequate laboratory services for monitoring of therapy and control of disease. In addition, the low retention of patients in care represents one of the main obstacles to treatment success in Africa (2-5). Interventions aimed at improving patient involvement in the management of their own care are extremely necessary.

Besides, integration of health interventions for prevention and treatment of infections most associated to HIV (co-infections) is also needed. TB, for example, remains one of the most common infectious diseases (Communicable Diseases - CD) and the main cause of death among PLWH (6). An additional difficulty is the lack of health workers (HWs) adequately trained to give care to the patients.

In a context of extreme fragility and poverty, like that of Sub-Saharan Africa, the role played by operational research is central. The operational research, in fact, shows us "how to do" to improve the effectiveness of interventions. To date, there is still much to learn about the correct use of ART and how to optimize its efficacy and reduce costs in LDCs context.

Health situation in Ethiopia

Healthcare system in Ethiopia significantly suffers of the limited economic resources. Poverty, low education level, inadequate access to drinking water contribute to worsen health problems in this country (7-10). The CDs, including TB, malaria, HIV/AIDS, respiratory infections, diarrheal diseases and nutritional deficiencies contribute to the high disease burden in Ethiopia (11). HIV/AIDS is still one of the



Structure used for the Project meetings at Mehoni Health Center (Ethiopia)

main health challenges to be faced. Although HIV prevalence is not very high, and the country recently experienced a major reduction in new HIV infections, it has still a large number of PLWH, with some 800,000 case of infection and about 1 million AIDS orphans (11).

In addition, TB infection in Ethiopia is one of the major public health problems ranking this country among those with higher rate of TB (12,13). The high number and severity of TB cases are attributable to the high presence of people with HIV infection (co-infection HIV/TB).

Although over 80% of adults but only 20% of children are under ART treatment (11), only some antiretroviral drugs are currently available in Ethiopia for the treatment of HIV infections and especially for first-line treatment. Health facilities (HFs) in Ethiopia, in line with other sub-Saharan countries, suffer from lack of adequate laboratory services for routine laboratory tests (hematology and biochemistry) as well as virological and immunological tests to monitor the progression of the disease and the efficacy of treatment. In addition to this, HWs are numerically insufficient and not always adequately trained.

The CASA project

The CASA project (Cohort of African people Starting Antiretroviral Therapy) is an operational research for improving care of people with HIV infection. Coordinated by Istituto Superiore di Sanità (the National Institute of Health in Italy, ISS) since 2012 and funded by the Italian Ministry of Health, this project is designed to provide a contribution to the improvement of HIV/AIDS patient care through a holistic approach including training for HWs, strengthening of the laboratory structures, involvement of PLWH and community based organizations (CBOs), and the optimization of ART. The first country involved in the project is Ethiopia. The Italian contribution to the fight against poverty in Ethiopia has been remarkable. The fight against HIV/AIDS in Ethiopia is one of the main challenges which Italy has faced, with interventions in sectors of crucial importance such as education, energy, organization of healthcare services. The fight against HIV/AIDS epidemics in Ethiopia is part of the priority objectives that Italy intends to reach.

The CASA project is in line with the healthcare priorities established by Ethiopian Government (14), which recognizes a close correlation between health improvement and economic development of the country. This Project, which will have a minimum duration of 5 years, is a partnership-Project among ISS, Makelle University (MU), and Tigray Health Bureau (THB). This latter has full ownership of the Project.

The general objective of this Project is to contribute to halt and reverse the spread of major CDs such as HIV/AIDS, TB and malaria. The specific objective is to contribute to improve the quality of care of patients with HIV-infection and related co-infections and co-morbidities in the HFs participating in this Project.

Figure 1 shows the general objective, the specific objective and the expected results. The activities of the CASA Project to achieve the expected results are grouped into four groups, schematically listed and described in Figure 2.

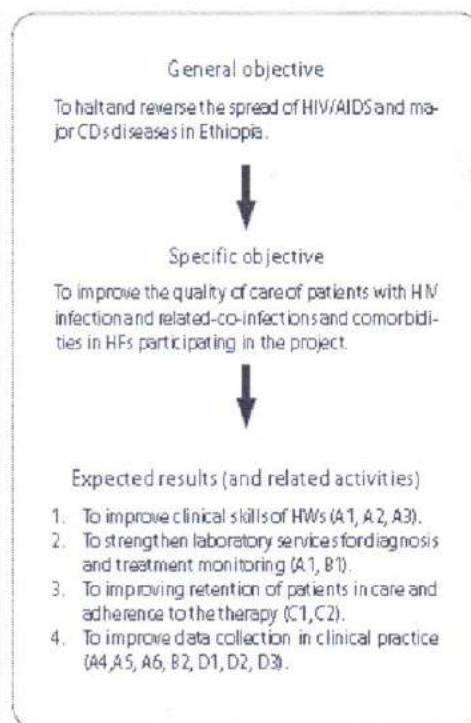


Figure 1 - CASA Project. General objective, specific objective and expected results. In brackets the activities related to the results

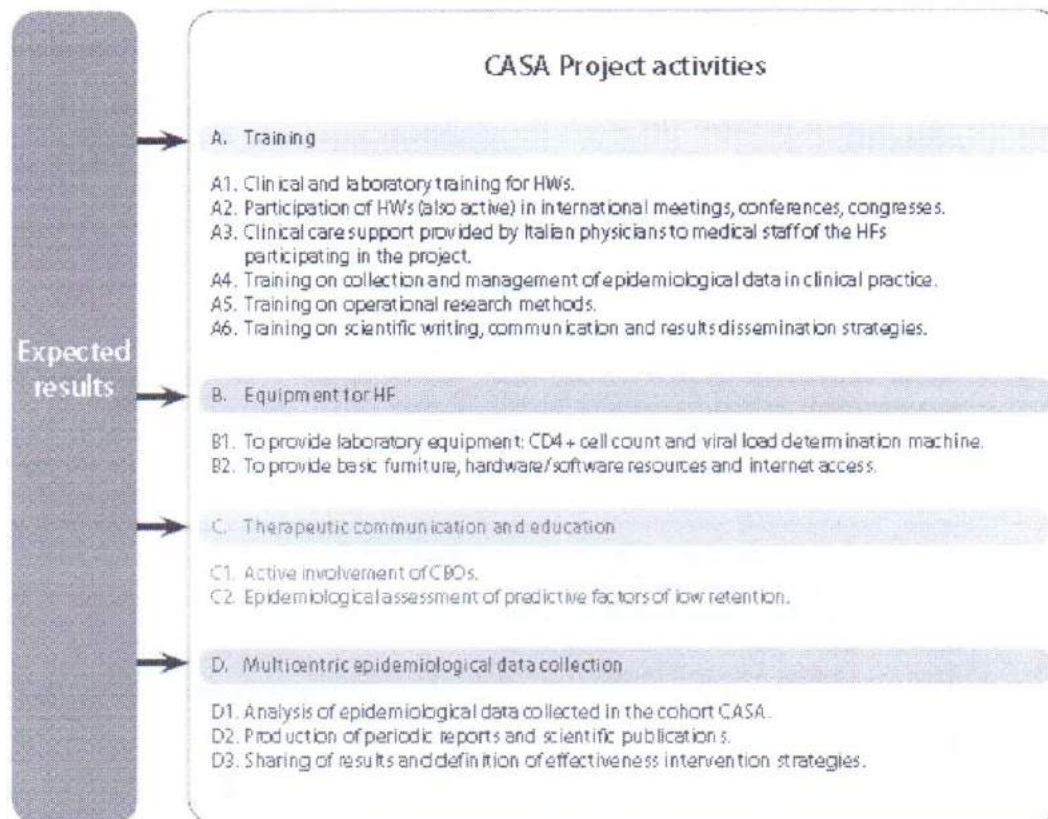


Figure 2 - CASA Project activity related to expected results

Training activities

Training activities fall into different typologies, involving different sectors and addressing different targets. They include on-site training courses provided by the ISS team as well as the participation of local HWs in international meetings, conferences and congresses on specific issues related to the Project objectives. Besides, on-site clinical assistance provided by Italian physicians to the HFs participating in the Project is periodically planned. Training activities are also carried out through E-learning platform that will allow to manage distance learning for all the duration of the project. Teaching activities have the constant support of an ISS information technology unit (IT), also responsible for the implementation and management of a website specifically designed for CASA Project.

Equipment for HFs

The ISS is responsible for the basic equipment as well as for laboratory facilities of each participating HF. ISS also guarantees technical support, hardware and software to carry out the project.

Activities of health communication and therapeutic education for patients

The project involves local Community Based Organizations (CBOs) working in the social context where the patient lives. CBOs initiatives provide counselling to the patients, contribute in increasing knowledge of HIV/AIDS and understanding the importance of adherence and retention. CBOs initiatives also contribute to assist patients in dealing with the social problems of the community where they live, such as stigma, with positive effects on adherence and

retention. In addition, CBOs receive periodic training sessions by ISS team specialized in editing, communication and strategies for information dissemination. Besides, periodic short courses are organized to discuss how communication on HIV/AIDS can be delivered to the patients.

Multi-site epidemiological data collection on HIV/AIDS treated patients

The project includes also the longitudinal collection of epidemiological data of patients with HIV infection taking ART. Data on demographic and clinical characteristics, medical care and clinical and laboratory outcomes are collected on HIV-infected patients receiving ART for the first time at each participating HF.

The analysis of the data will be able to provide evidence about how to support the successful implementation of ART in the setting of routine care. In addition, data analyses will also assess how the activities proposed in this project are translated into benefit.

Beneficiary groups

The direct beneficiaries of the project are the HWs (physicians, nurses, laboratory technicians, health-officers) participating in this project. They can increase their competence in managing of the care of HIV/AIDS patients in a setting of clinical practice. Direct beneficiaries are also the HWs playing in the project technical and operational roles, ie case managers and data managers. They have the opportunity to acquire knowledge on methodology in epidemiological research, data analysis, interpretation of results and dissemination of scientific information. The final beneficiaries are people with HIV/AIDS referring to each participating HFs who gain medium and long term benefits in terms of reduced probability of clinical events (mortality and morbidity) as well as of improvement of the quality of life.

Activities results

The CASA project began in Ethiopia in early 2012. After a start-up period, in which a "Memorandum of Understanding" was signed by partners (THB, MU and ISS), planned activities have begun.

Below is a brief summary of the results achieved for each activity.



Meeting at Alamata Health Center (Ethiopia)

Training activities

The training activities are carried out on-site by ISS team on a quarterly basis.

The local HWs, composed of physicians, nurses, health officers, laboratory technicians, data managers and case managers, regularly receive specific training in clinical, laboratory and epidemiology fields. Abroad training of local HWs were made in Italy by participation both in congresses on CDs and in meetings on methodological aspects of operational research.

Equipment for HFs

To date, four HFs in Tigray are involved in CASA Project. They are situated both in rural and urban areas. The HFs participating in the project have been equipped with basic furniture, hardware and software. Each HF has been also equipped with an instrument for counting CD4 (CD4 miniPOC Partec machine) permitting the counting of CD4 and evaluate a prompt starting of ART. Besides, laboratory technicians receive periodic training to properly use the CD4 instrument.

Activities of health communication and therapeutic education for patients

A CBOs called OSSA (Organization for the Support Service for AIDS) is actively involved in CASA project is, along with other smaller organizations situated in more remote rural areas. Such ►



Case manager of CASA project at Addis Ababa health center (Ethiopia)

contribution has allowed the implementation of activities aimed at patient therapeutic education and active involvement in their own care. The first follow-up data show an increased retention in patients due to the active intervention of the Associations.

Multi-site epidemiological data collection on HIV/AIDS treated patients

The systematic collection of epidemiological data is intended to assess the longitudinal effectiveness of ART as used in Ethiopia in a real-world setting. For this purpose, a CASA dedicated website has been realized. It allows to share data between ISS and MU (location of the centralized database). To date, about 700 patients (in four HFs) participate in the study with an average follow-up of 7 months. A first detailed assessment of collected data will be provided at the next International AIDS Conference (July 2014, Melbourne, Australia).

The Italian version of this article is available from www.iss.it/binary/publ/cont/onlineottobre2013.pdf

Conflict of interest statement

The Authors declare that there are no potential conflict of interest or any financial or personal relationship with other people or organizations that could inappropriately bias conduct and findings of this study.

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***An Intervention
to improve the Care of People with HIV
infection in Tigray***

Concept note, version 1.0

December 2013

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral
ART	Antiretroviral therapy
CBO	Community Based Organization
CDs	Communicable disease
CHWs	Community health workers
FHAPCO	Federal HIV/AIDS Prevention and Control Office
FMOH	Federal Ministry of Health
GTP	Growth and Transformation Plan
HBC	High TB burden countries
HC	Health Centre
HF	Health Facility
HIV	Human Immunodeficiency Virus
HW	Health Worker
ISS	Istituto Superiore di Sanità
IT	Information Technology
LDC	Economically- Less-developed countries
MDC	Economically- More-developed countries
MDG	Millennium development goal
MDR-TB	Multi Drug Resistant-TB
MU	Mekelle University
NCDs	Non communicable diseases
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH	People living with HIV
TB	Tuberculosis
THB	Tigrai Health Bureau
UNAIDS	Joint United Nation Programme on HIV/AIDS
WHO	World Health Organisation

1. PROJECT ESSENTIAL DATA

Title

An Intervention to improve the Care of People with HIV infection in Tigrai.

Short Title

CASA project

Duration of the intervention

3 years.

Country of intervention

Ethiopia (Tigrai).

Partners

The **Tigrai Health Bureau**⁽¹⁾ (THB) is the competent public body in charge of health planning and care management at the Tigrai regional level. It represents the Ethiopian Institution of reference for this project, of which it has full ownership. THB provides the legal and administrative support to Istituto Superiore di Sanità (ISS), and the permission to access to epidemiological data and to work at health facilities (HFs). THB will also recognize the ISS local representatives and give them the appropriate powers to act on behalf of the ISS.

The **Mekelle University**⁽²⁾ (MU) with its College of Health Sciences, is located in Mekelle, the largest city in Tigrai. The MU will provide its health care skills to support the project. The University will guarantee the availability of specialized personnel as well as a work-space dedicated to the project.

The **ISS**⁽³⁾ is the main technical-scientific body of the National Health Service in Italy. ISS will coordinate the project and will support it providing both human and financial resources.

HFs participating in the project

The HFs participating in the project will be situated in urban and rural area. They will include four Health Centers (HCs) and four Hospitals. Below the list:

1. Alamata HC
2. Alamata hospital
3. Mehoni HC
4. Machew hospital
5. Mekelle HC
6. Mekelle hospital
7. Ayder hospital
8. An additional HC to be selected by THB

2. BACKGROUND OF THE INTERVENTION

Health in Ethiopia significantly suffers of the limited economic resources. Communicable diseases (CDs), including tuberculosis (TB), malaria, HIV/AIDS, respiratory infections, diarrheal diseases and nutritional deficiencies contribute to the high disease burden in Ethiopia⁴. HIV/AIDS is still one of the main health challenges to be faced. Although HIV prevalence is not very high, and the country recently experienced a major reduction in new HIV infections, it still has a large number of people living with HIV (PLWH): in 2010 (latest estimated data) the adult prevalence was 1.5 percent, with some 800.000 PLHIV and about 1 million AIDS orphans⁵. In line with other sub-Saharan countries, Ethiopia has implemented numerous efficacious strategies to scale up antiretroviral therapy (ART) and improve the quality of HIV care. In 2003, the Government of Ethiopia introduced its ART programme with the goal of reducing HIV-related morbidity and mortality. In 2005, Ethiopia started to provide "free ART" with the support of the U.S. President's emergency Program for AIDS Relief (PEPFAR) and the Global Fund. In the third decade of the pandemic, despite numerous interventions in the fight against HIV/AIDS both by Governments and global health initiatives⁵⁻⁸, the gap between economically- less- developed countries (LDC) and economically-more-developed countries (MDC) with reference to universal access to prevention, care and treatment is still huge. This calls for a more robust and targeted response by Ethiopian Government, also in the light of the progressive switch from an emergency aid intervention to a locally sustainable response of some global initiatives and organizations like PEPFAR. In addition, the recent publication of the new "World Health Organization (WHO) guidelines"⁹ (June 2013) on *"The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection"* will put the country in front of a renewed effort to reach its progressive implementation. The 2013 guidelines reflect important advances in HIV responses during the past three years. Since 2010, new technologies, including CD4 point-of-care testing, and new service delivery approaches allow HIV testing and treatment monitoring to be diversified and decentralized. Simple, safer, once-daily, single-pill ARV regimens have become more affordable and more widely available in low- and middle-income countries. The new clinical recommendations promote starting HIV treatment earlier and expanded eligibility for ART with a CD4 threshold for treatment initiation of 500 cells/mm³ or less for adults, adolescents. Viral load testing is now recommended as the preferred approach to monitor ART success and diagnose treatment failure, complementing clinical and immunological monitoring.. The extended eligibility for ART and a wider range of options for using ARV drugs provide new opportunities to save lives, improve clinical outcomes and reduce HIV incidence but also poses challenges to policy-makers and implementers in many countries. New operational guidance in 2013 provides recommendations for strengthening key aspects of the continuum of HIV care and improving linkages across the health system.

Indeed, major challenges remain, which are summarised below:

1. To foster the introduction of better antiretroviral drugs and drug combinations for the treatment of HIV infection, also subsequently to the publication of the updated 2013 WHO guidelines.
2. To strengthen the laboratory services for the monitoring of antiretroviral therapy.
3. To scale-up the training and education of health workers (HWs).
4. To scale-up integrated interventions and to improve the management and the treatment of HIV-related comorbidities and of co-infections
5. To improve the retention of patients in care and treatment.

1. To foster the introduction of better antiretroviral drugs and drug combinations for the treatment of HIV infection.

According to a recent update (year 2010) from the Federal HIV/AIDS Prevention and Control Office (FHAPCO) over 80% of adults but only 20% of children are under treatment⁵. Although the ART coverage is high, only some antiretroviral (ARV) drugs are currently available in Ethiopia for the treatment of HIV infections and especially for second line treatment¹⁰. Current first and second-line ART regimens may be further improved with the introduction of new and safer drugs and of innovative strategies. Treatment simplification should be progressively introduced to allow further antiretroviral therapy scaling-up and to support long-term retention in care.

2. To strengthen the laboratory services for the monitoring of antiretroviral therapy

In Ethiopia many HFs do not have a sufficient number of equipped laboratory services for conducting basic biochemistry analysis as well as virologic and immunologic tests for HIV testing and therapy monitoring. Because of this, the diagnosis and treatment can be inaccurate and as a result the care of patient is impaired. Scaling-up laboratory services will be also necessary to be in line with the new WHO guidelines⁹. In fact, one of the major challenges will be the progressive implementation of the new guidelines which highlight: 1. earlier initiation of ART (moving to 500 CD4 the threshold for treatment starting) and 2. monitoring for ART efficacy and toxicity, with emphasis on the progressive introduction of HIV-RNA measurement as the standard of care to define therapeutic failure. In this contest, the health system will have to be equipped to conduct more HIV tests, CD4 count and viral-load determinations.

3. To Scale- up the training and education of HWs

The HWs are numerically insufficient and not always fully qualified. Ethiopia, like other sub-Saharan countries, is adopting a task-shifting strategy to overcome the lack of physicians. To ensure the access to HIV prevention and cure services, including provision of ART, the government has decentralized HIV patient care, which it has been transferred from physicians in hospitals to mid-level HWs (nurses and health officers) in health centres (HCs). The HWs involved in the task-shifting strategy, in order to successfully provide the care to the patients, need to be supported with continuous training and education activities.

4. To scale-up integrated interventions and to improve the management and the treatment of HIV-related comorbidities and of co-infections

Since the 1950's, TB has been considered one of the most important public health problems in Ethiopia. The most recent estimates (year 2011) rank the Ethiopia among the 22 high TB and the 27 high multi-drug resistant TB (MDR-TB) burden countries (HBCs) in the world^{11,12}. The elevated number of cases of TB is also observed due to the presence of a significant number of PLWH. According to the 2012 TB/HIV Surveillance report, 91.2% of HIV infected patients newly enrolled in HIV-care were screened for TB; of these 8.6 % were found to have active TB. According to the same report 87% of TB patients have undergone HIV test and 19.7% out of these were tested HIV positive¹¹⁻¹². The Federal Ministry of Health (FMOH) in Ethiopia, with support from development partners, in line with TB related millennium development goal (MDG) and Stop TB partnership targets, has developed a guideline for scaling up integrated management of TB and HIV infections¹³. The main specific goals include: 1. to address adequately TB/HIV interventions in

order to reduce burden of TB among PLWH and to reduce the burden of HIV among TB patients; 2. to increase the proportion of notified MDR-TB cases; 3. to promote program based on health operational interventions.

To manage the care of PLWH suffering from other diseases, in addition to HIV/AIDS, is another key challenge. People with HIV have a major risk of having comorbidities than people not infected with HIV. This causes serious implications for health care costs, as many of these conditions result in hospitalization and extended use of health care services. More information are necessary to better understand the impact of comorbidities in PLWH and provide evidence to support preventive health interventions and disease management.

6. To improve retention of patients in care and treatment

According to *UNAIDS report on the global AIDS epidemic 2010*¹⁴ there is new evidence that high ART retention rate is achievable. Of the countries with the highest number of PLWH, Botswana, Brazil and Cameroon report that at least 90% of people are still receiving treatment one year after initiating ART. Ghana, India, Kenya, Lesotho, Thailand, Uganda, Ukraine, and Vietnam report that about 80% of people are in treatment for at least one year. A recent study conducted in Ethiopia¹⁵ has estimated that 80%, 74% and 68% of patients are still in ART at 6, 12 and 24 months, respectively. These data show that ensuring a good retention in care is still a major challenge for ART programs. This is also more difficult because of different retention rates among health facilities (HFs), with high, medium and low retention rates.

This project, in line with the Growth and Transformation Plan (GTP)¹⁶, is designed to provide a contribution to the improvement of HIV/AIDS patient care through a holistic approach including training for HWs, strengthening of the laboratory structures, involvement of PLWH and optimisation of the use of ARV therapy. It appears increasingly clear that improving care of PLWH may also improve the care of the major CDs (eg, TB and malaria) and chronic non communicable diseases (NCDs), such as hypertension, cardiovascular diseases, diabetes and cancer. Ethiopia, like other sub-Saharan countries is experiencing the epidemiological transition in which CDs co-exist with the new NCDs. Although the CDs are still the prevalent health problem in Ethiopia, the chronic NCDs are becoming one the principal challenges to be faced¹⁷⁻¹⁹. According to the most recent data, NCDs are estimated to account for 34% of all deaths. The above measures call for an urgent intervention for policies for control of the new double burden of disease. HIV infection is characterized by being a chronic infection which impact throughout lifecycle, with periods of illness and periods of wellness, with multiple clinical and psychosocial needs, needing life-long care and treatment and secure supply of medicines and laboratory tests. The same picture is applicable to other chronic conditions, which requires demand and access to services, HWs training, support for adherence, infrastructure and equipment, drug and laboratory supplies, great attention to linkage to care and, finally, the need for an important community involvement and educational campaigns for people.

3. LOGICAL FRAMEWORK

	Intervention Logic	Objectively verifiable indicators of achievement	Sources and means of verification	Assumptions
General Objective	To contribute to halting and reversing the spread of major CDs such as HIV/AIDS, TB and Malaria (<i>Growth and Transformation Plan</i>)	Reduction of mortality related to HIV/AIDS and major co-infections	Regional and national mortality registers	Implementation of the Ethiopian Governments' political strategy of investment in the health sector pertaining to HIV/AIDS
Specific objectives	To contribute to improve the quality of care of patients with HIV-infection and related co-infections and comorbidities in Tigray	- Increase of 100 CD4 cell (average measure) after the first year of treatment - CD4 >200 cell after two years of treatment in all patients - CD4>350 cell after three years of treatment in all patients - Clinical non progression of the disease in all patients taking therapy - Reduction in mortality in each participating HF	- Periodic reports provided by project results - Regional HMIS report	Partnership between THB, MU and ISS Consolidated knowledge of the territory for the international partner HF's motivated to participate in the project
Expected Results		Objectively verifiable indicators of achievement	Sources and means of verification	Assumptions
1	To improve clinical skills of HWs (physicians, health-officers, nurses)	100% of HWs (physicians, health-officers, nurses) taking part in training activities pass the assessment test	- Certificate of attendance for participating in training sessions and assessment test - Certificate of attendance for participating in meeting/conference/congress	HWs motivated to improve their skills
2	To strengthen laboratory services for diagnosis and treatment monitoring	- Each HF involved in the project performs routinely blood chemistry analyses - Each HF involved in the project performs routinely CD4 test	- List of furniture acquired - Certificate of attendance for participating in training sessions	Delivery of furniture at the times foreseen HWs motivated to improve their skills

3	To improve retention of patients in care and adherence to the therapy	At least 85% of patients return to the routinely clinical visits at HF's involved in the project.	- List of activities provided by CBOs - Clinical database of enrollment and follow-up visits	Receptive approach in HIV/AIDS patients
4	To improve data collection in clinical practice	100% of data-managers and case-managers taking part in training activities pass the assessment test - Each HF involved in the project utilizes electronic treatment cards and registers to collect the epidemiological data in clinical practice on HIV/AIDS treated patients	- Certificate of attendance for participating in training sessions - Clinical database of enrollment and follow-up visits	HF's motivated to participate in the project
Activities		Means	Sources and means of verification	Assumptions
1.1	E-learning clinical training provided by ISS team to physicians, nurses and health-officers of MU	Human resources: 1 physician expert in CDs 1 epidemiologist 1 local coordinator 1 expert IT from ISS 1 expert IT from MU	Certificate of attendance for participating in training sessions	Local HWs motivated to improve their skills
1.2	On-site clinical training provided by ISS team to physicians, nurses and, health-officers of MU and HF's	Human resources: 1 physician expert in CDs 1 epidemiologist 1 local coordinator 1 logistic	Certificate of attendance for participating in training sessions	Local HWs motivated to improve their skills
1.3	On-site clinical assistance provided by physicians from Italy at HF's participating in the project	Human resources: 4 physicians in a year 1 logistic 1 local coordinator	List of Italian physicians providing on-site clinical assistance	Local HWs motivated to improve their skills
1.4	Participation of HWs (physicians/nurses/ health-officers) in international meetings / conferences / congresses	Human resources: 1 local coordinator 1 logistic	Certificate of attendance for participating in meeting/conference/congress	Local HWs motivated to improve their skills
1.5	On-site training, in scientific writing, provided by ISS team to MU personnel (physicians, nurses, health-officers).	Human resources: 1 expert in communication activities 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	HWS motivated to improve their skill

2.1	On-site laboratory training provided by Partec team to laboratory technicians of MU and HFs	Human resources: 1 laboratory trainer 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	Laboratory technicians motivated to improve their skills
2.2	On-site laboratory training provided by MU team to laboratory technicians of HFs	MU trainers 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	Laboratory technicians motivated to improve their skills and to implement "train the trainer approach"
2.3	To provide laboratory equipment at each HF involved in the project: laboratory service for blood chemistry analysis; CD4 machine	Human resources: 1 logistic 1 local coordinator	List of furniture acquired	Delivery of furniture by the time foreseen
3.1	Active involvement of local CBOs	Human resources: Local CHWs 1 expert in communication 1 logistic 1 local coordinator	List of CBOs participating in the project List of CBOs activities	Receptive approach in HIV/AIDS patients
3.2	Interaction between CHWs and ISS	Human resources: Local CHWs 1 expert in communication 1 graphic designer 1 logistic 1 local coordinator	List of CBOs participating in the project List of CBOs activities	Receptive approach in HIV/AIDS patients
4.1	E-learning training (collection, analysis and management of epidemiological data in clinical practice) provided by ISS team to data-managers of MU	Human resources: 1 epidemiologist 1 expert data-managers 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	Data-managers motivated to improve their skills
4.2	On-site training (collection, analysis and management of epidemiological data in clinical practice) provided by ISS team to data-managers and case-managers of MU and HFs	Human resources: 1 epidemiologist 1 expert data-managers 1 administrative coordinator 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	Case-managers and data-managers motivated to improve their skills
4.3	Abroad (Italy) training (collection, analysis and management of	Human resources: 1 epidemiologist	Certificate of attendance for	Data-managers motivated to

	epidemiological data in clinical practice) provided by ISS team to data-managers of MU	1 expert data-managers 1 local coordinator	participating in training sessions	improve their skills
4.4	On-site training (collection and management of epidemiological data in clinical practice) provided by MU team to case-managers of HFs	Human resources: MU trainers 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	HWs motivated to improve their skills and to implement "train the trainer" approach"
4.5	On-site training, in scientific writing, provided by ISS team to MU personnel (physicians, nurses, health-officers, case-managers, data-managers)	Human resources: 1 expert in communication activities 1 logistic 1 local coordinator	Certificate of attendance for participating in training sessions	HWS motivated to improve their skill
4.6	To provide basic equipment, basic hardware, internet access to each HF involved in the project	Human resources: 1 logistic 1 local coordinator	List of furniture acquired	Delivery of furniture by the time foreseen
4.7	Implementation and management of a website dedicated to the project situated at MU	Human resources: 2 IT specialists from ISS 1 IT specialist from MU 1 logistic; 1 local coordinator	Website dedicated to the project situated at MU	MU motivated to participate in the project
4.8	Collection of epidemiological data of HIV/AIDS treated patients in clinical practice at each HF participating in the project	Human resources: MU trainers HWs working at participating HFs 1 logistic; 1 local coordinator.	List of participating HFs Clinical database of enrollment and follow-up visits	HFs motivated to participate in the project and to implement "train the trainer approach"
4.9	Production of periodic reports and scientific publications based on epidemiological data collected	Human resources: research team 1 expert in editorial activities 1 logistic 1 local coordinator	List of reports produced List of scientific publications produced	Communication and sharing among participants in the project

4. BENEFICIARY GROUPS

3.1 Direct beneficiaries

The direct beneficiaries of the project will be the HWs (physicians, nurses, laboratory technicians, health-officers, data-managers, case-managers) participating in this project who will be able to acquire better competency to manage the care of HIV/AIDS patients in a setting of clinical practice.

3.2 Final beneficiaries

The final beneficiaries will be people with HIV/AIDS referring to each participating HFs who will gain medium and long term benefits from the results of the project, in terms of reduced probability of clinical events (mortality and morbidity) and improvement of the quality of life. Particular attention will be provide in all activities of the project at the most vulnerable population, such as women.

5. INTERVENTION STRATEGY

5.1 GENERAL OBJECTIVE

In recent decades, the Ethiopian Government has recognized the close relationship between health improvements and economic development and as a result it has assigned utmost priority to health sector development. This project is in line with the GTP⁽¹⁶⁾, which describes the five year plan (2011-2015) for the economic development of the nation. In particular, the general objective of this project is to contribute to halting and reversing the spread of major CDs such as HIV/AIDS, TB and Malaria.

Indicators of achievement of general objective:

- reduction of mortality related to HIV/AIDS and major co-infections.

5.2 SPECIFIC OBJECTIVE

The specific objective which the project is intended to realize within the three years is to contribute to improve the quality of care of patients with HIV-infection and related co-infections and comorbidities in Tigrai. The achievement of this objective needs a holistic approach including the improvement of the skills of HWs, the strengthening of the laboratory services, the involvement of patients and community based organizations (CBOs) and the optimisation of the use of ARV therapy.

Indicators of achievement of specific objective:

- Increase of 100 CD4 cell (average measure) after the first year of treatment.
- CD4 >200 cell after two years of treatment in all patients.
- CD4 >350 cell after three years of treatment in all patients.
- Clinical non progression of the disease in all patients taking therapy.
- Reduction in mortality in each participating HF.

5.3 EXPECTED RESULTS

The project strategy, in achieving the specific objective, is composed of 4 expected results:

1. To improve clinical skills of HWs (physicians, health-officers, nurses).
2. To strengthen laboratory services for diagnosis and treatment monitoring.
3. To improve retention of patients in care and adherence to the therapy.
4. To improve data collection in clinical practice-

Indicators of achievement of expected result 1:

- 100% of HWs (physicians, health-officers, nurses, laboratory technicians) taking part in training activities pass the assessment test.

Indicators of achievement of expected result 2:

- Each HF involved in the project performs routinely blood chemistry analyses.
- Each HF involved in the project performs routinely CD4 test.

Indicators of achievement of expected result 3:

- *At least 85% of patients return to the routinely clinical visits at HFs involved in the project.*

Indicators of achievement of expected result 4:

- *100% of data-managers and case-managers taking part in training activities pass the assessment test.*
- *Each HF involved in the project utilizes electronic treatment cards and registers to collect the epidemiological data on HIV/AIDS treated patients.*

5.4 ACTIVITIES

The activities planned over a 3-year period can be grouped into 4 main groups:

- A. Training activities
- B. Equipment of HFs
- C. Activities of health communication and therapeutic education for patients
- D. Multi-site epidemiological data collection on HIV/AIDS treated patients

5.4.1 ACTIVITIES FOR EXPECTED RESULTS 1

To achieve the expected **result 1** the following activities are planned:

A. Training activities:

- 1.1 E-learning clinical training provided by ISS team to physicians, nurses and health-officers of MU.
- 1.2 On-site clinical training provided by ISS team to physicians, nurses, health-officers of MU and HFs.
- 1.3 On-site clinical assistance provided by physicians from Italy to the HFs participating in the project.
- 1.4 Participation of HWs (physicians/nurses/health-officers) in international meetings/conferences/congresses.
- 1.5 On-site training, in scientific writing, provided by ISS team to MU personnel (physicians, nurses, health-officers).

5.4.2 ACTIVITIES FOR EXPECTED RESULTS 2

To achieve the expected **result 2** the following activities are planned:

A. Training activities:

- 2.1 On-site laboratory training provided by Partec team to laboratory technicians of MU and HFs.
- 2.2 On-site laboratory training provided by MU (trained *through 2.1 point*) to laboratory technicians of HFs

B. Equipment of HFs

- 2.3 To provide laboratory equipment to each HF involved in the project: laboratory service for blood chemistry analysis; CD4 counting machine.

5.4.3 ACTIVITIES FOR EXPECTED RESULTS 3

To achieve the expected result 3 the following activities are planned:

C. Activities of communication and therapeutic education for patients:

- 3.1 Active involvement of local CBOS.
- 3.2 Interaction between CHWs and ISS team.

5.4.4 ACTIVITIES FOR EXPECTED RESULTS 4

To achieve the expected **result 4** the following activities are planned:

A. Training activities:

- 4.1 E-learning training (collection, analysis and management of epidemiological data in clinical practice) provided by ISS team to data-managers of MU.
- 4.2 On-site training (collection, analysis and management of epidemiological data in clinical practice) provided by ISS team to case-managers and data-managers of MU and HFs.
- 4.3 Abroad (Italy) training (collection, analysis and management of epidemiological data in clinical practice) provided by ISS team to data-managers of MU.
- 4.4 On-site training (collection and management of epidemiological data in clinical practice) provided by MU team (*trained through 4.1 / 4.2 / 4.3 points*) to case-managers of HFs.
- 4.5 On-site training, in scientific writing, provided by ISS team to MU personnel (physicians, nurses, health-officers, case-managers, data-managers).

B. Equipment of HFs

- 4.6 To provide basic equipment, hardware resources and internet access to each HF involved in the project.

D. Multi-site epidemiological data collection on HIV/AIDS treated patients

- 4.7 Implementation and management of a website dedicated to the project situated at MU.
- 4.8 Collection of epidemiological data of HIV/AIDS treated patients in clinical practice at each HF participating in the project.
- 4.9 Production of periodic reports and scientific publications based on epidemiological data collected.

6. METODOLOGY

6.1 METHODOLOGY FOR EXPECTED RESULT 1

A. Training activities

The training activities will have the objective of reinforcing the clinical skills of the local HWs for improving the care of patients with HIV infection. These training activities fall into three typologies:

1. E-learning training
2. On-site training courses provided by ISS and MU team
3. Participation in international meetings/conferences/congresses

1. E-learning training

A key of the training activities will be the implementation of a E-learning platform. Lessons will be periodically provided by ISS team to MU (about once in a month). The advantages of a E-learning platform compared to traditional training systems are many, in particular time optimization and cost savings. Users will be able to have lessons at any time and in any place where there is an internet connection with the use of a personal computer or mobile device (smartphone and tablet). Lessons on clinical aspect on CDs will be periodically provided by ISS physicians (about once in a month). After each lesson, learners will do an assessment test on the lesson contents. The assessment results will be immediately made available.

2. On-site training courses

1. On-site short courses of two days (four times in a year) aimed to improve the clinical skill of physicians, nurses and health-workers involved in the project will be provided by ISS physicians with solid experience in the field of CDs.
2. On-site short courses of one day (four times in a year) aimed to facilitate active participation of physicians in international contexts through submissions of oral communications or posters will be provided by ISS team expert in communication field.
3. The local HWs will benefit of periodic on-site assistance in their clinical practice by Italian physicians, as per previous agreements stipulated with the School of Specialization in Infectious Diseases and Tropical Medicine, Dept of Health Sciences, University of Genoa. The presence of two infectious diseases specialists is foreseen on site throughout the project. Two physicians are expected to stay for two months two times in a year.

3. Participation in international meetings/conferences/congresses

The project includes short training or refresher periods (from 5 to 7 days) for the local HWs (physicians/nurses/health-officers) through their participation in international meetings or conferences/congresses on CDs. The participation of HWs in international contest will be scheduled at least once in a year. Among these the participation in the AIDS Society (IAS) annual congress of at least two people will be organized.

6.2 METHODOLOGY FOR EXPECTED RESULT 2

A. Training activities

Periodically on-site short courses will be provided by experts in laboratory techniques. The training activities will have the objective of reinforcing the laboratory skills of the local laboratory technicians involved in the project. These courses fall into three typologies:

1. On site short courses of four days (by two to four times in a year) for laboratory technicians will be provided by PARTEC experts (supplier of CD4 machines).
2. On site short courses of one to two days (each six months) for HF's laboratory technicians will be organised by MU laboratory technicians (*previously trained by Partec team: "train the trainer approach"*).

B. Equipment of HF's

Each participating HF will be adequately equipped with standard laboratory services. In addition to blood chemistry analyses, the evaluation of CD4 cell and HIV viral load determination are crucial for the correct diagnosis and treatment of HIV/AIDS patients. The availability of adequate laboratory services will be also necessary to be in line with the strong recommendations of the new WHO guidelines in the laboratory test assessment before and after ART is initiated¹¹. Each HF participating in the project will be equipped with CD4 machine. The equipment will be provided within the first six months of the project.

6.3 METHODOLOGY OF EXPECTED RESULT 3

C. Activities of communication and therapeutic education for patients

Communication and therapeutic education of HIV/AIDS patients plays an important role for HIV prevention and treatment success. The project will involve local CBOs since the beginning and throughout the study. Specifically CBOs initiatives will provide counselling to the patients, contribute in increasing knowledge of HIV/AIDS and understanding the importance of adherence and retention. CBOs initiatives also will contribute to assist patients in dealing with the social problems of the community where they live, such as stigma, with positive effects on adherence and retention. In addition, a strong interaction throughout the project between CHWs and Italian experts in communications is to be expected. Periodic short sessions (two days, four time in a year) will be organized to discuss how communication on HIV/AIDS can be delivered to the patients. Production of multimedia tools such as videos, posters, cartoons, booklets addressed to PLWH and informal meetings at local level to spread information on HIV will be provided.

6.4 METHODOLOGY OF EXPECTED RESULT 4

A. Training activities

An essential part of the project concerns collection, analysis and management of epidemiological data on HIV/AIDS patients in clinical practice. The ISS multidisciplinary team, composed of physicians, epidemiologists and data-managers will be responsible for conducting training on this topic in the CDs field. These activities fall into two main typologies:

1. E-learning training

2. Training courses.

1. E-learning training

Lessons will be periodically provided by ISS team to data-managers working at MU (about once in a month). After each lesson each learner will do an assessment test on the lesson contents. The assessment results will be immediately made available.

2. Training courses

1. On-site short training sessions of two to four days (four times in a year) will provide by ISS team to case-managers and data-managers of MU and HFs.
2. Abroad training courses seven to ten days (at least once in a year) will be organized in Italy.
3. On site short courses of two to three days each six months will be provided by data-mangers and case managers of MU (*previously trained: train the trainer approach*), to case-managers of HFs participating in the project.
4. Basic skills for health information dissemination will be also faced from the initial stages of the project (two days four time in a year). Tools will be provided to enable HVs to acquire the basic skills to produce quality scientific publications through the application of technical and ethical standards in scientific writing. Different types of scientific publications will be produced at different stages of the project, from activity reports to journal articles, oral communications or posters selected through abstracts submission to national and international conferences, blog postings, and other types of internet communication.

B. Equipment of HFs

Each participating HFs will be equipped with basic equipment (furniture and consumer materials), basic hardware resources (personal computers, scanners, printers, general office supplies) and internet access.

Besides a specific website will be developed for this project. The MU will be the location of the central database, where data will be merged and stored. An Information Technology (IT) expert together with data-managers will have responsibility for managing the central database and will personally update the database with new data collected at HFs. They will periodically visit the HFs for updated data collection. Data will be copied directly at each HF into common USB pen drives. The updated data will periodically be revised at MU, then automatically sent to ISS for additional quality control.

D. Multi-site epidemiological data collection on HIV/AIDS treated patients

In this project is also included the longitudinal collection of epidemiological data (over the entire period of the project) of patients with HIV infection taking ART. The systematic collection of epidemiological data is intended to assess the longitudinal effectiveness of ART as used in Ethiopia in a real-world setting. Data on demographic and clinical characteristics, medical care and clinical and laboratory outcomes will be collected on HIV-infected patients receiving ART at each participating HF. The main objectives of the data collection are:

1. to improve ART delivery by providing information based on a longitudinal multi-site database. First, the analysis of the data will be able to provide suggestions about how to support the successful implementation of ART at each participating HF. First, data on HIV/AIDS treated patients will be studied to investigate predictors of patients adherence and retention. Several factors may cause low retention: distance from HFs, high cost of transports, stigma, premature death, etc. This latter factor is noteworthy, starting treatment at a late stage of HIV disease and the premature death of treated patient may represent a cause of low retention. Additional studies are needed for better

understanding factors that discourage retention. Secondly, data will provide detailed information about care and health status of HIV infected people with major co-infections and comorbidities. Besides, a good monitoring and evaluation is crucial also considering the future adaptation to the new WHO guidelines. Currently, Ethiopia uses the national "guideline for antiretroviral treatment in adults and adolescents"¹⁶. If Ethiopia adopts the new WHO guidelines, on the one side the health system will have to be equipped to conduct more HIV tests, CD4 count and viral-load determinations; on the other side systematic collected data will be necessary to evaluate the impact of the new guides on the health of the HIV/AIDS patients.

2. to assess the efficacy of health intervention proposed in this project. Periodic evaluations of the data collected will enable to verify that this intervention effectively generate the benefits described in the expected results. The clinical and laboratory outcomes of each participating HF will be routinely compared to those of other HFs not involved in this project and situated in Tigray region. In addition to this, a pre-post intervention assessment intra each participating HF will be also performed.

The MU staff will be responsible for picking up data at the participating HFs (data will be copied on common USB flash drives, then assembled in the centralized database at MU). These actions will be carried out by data-managers on a monthly basis, in the last week of every month. The management of database, monthly updated, will be centralized and carried out at the MU. The analysis of data, scheduled each six months, will be provided by ISS team at early stage of the project then by MU personnel after receiving specific training. A key aspect of this activity will be the discussion of the results and sharing of ideas. Periodic meetings (each six months) will be organized and a strong collaboration between all participating in the project will be encouraged. A large space will be dedicated to development of discussion points, sharing ideas and proposals, and particular attention will be paid to avoid misunderstandings and any barriers related to cultural difference.

7. ACTION PLAN

Activities	1 year												2 year												3 year													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36		
1.1 E-learning clinical training provided by ISS team to physicians, nurses and health-officers of MU (1 lesson per month, 8 times in a year)																																						
1.2 On-site clinical training provided by ISS team to physicians, nurses, health-officers of MU and HFs (2 days per month, each 3 months)																																						
1.3 On-site clinical assistance provided by physicians from Italy at HFs participating in the project (2 consecutive months, 2 times per year)																																						
1.4 Participation of HWs (physicians/nurses/ health-officers) in international meetings / conferences / congresses (In this action plan has been only scheduled participation to the IAS congress)																																						
1.5 On-site training, in scientific writing, provided by ISS team to MU data-managers (1 days, each 3 months)																																						
2.1 On-site laboratory training provided by Partec team to laboratory technicians of MU and HFs (4 days, 2 to 4 times per year)																																						
2.2 On-site laboratory training provided by MU trainers to laboratory technicians of HFs (1 to 2 days, each 6 months)																																						
2.3 To provide laboratory equipment at each HF involved in the project: laboratory service for blood chemistry analysis; CD4 counting machine																																						
3.1 Active involvement of local CBOs																																						
3.2 Interaction between CHWs and ISS (2 days, each 3 months)																																						

8. BUDGET

EXPENDITURE ITEMS	Year I	ISS Contribution	Italian Cooperation Contribution	Year II	ISS Contribution	Italian Cooperation Contribution
1. HUMAN RESOURCES						
1.1 ISS personnel (Tab.1)	282.900,00	186.900,00	96.000,00	282.900,00	186.900,00	96.000,00
Subtotal	282.900,00	186.900,00	96.000,00	282.900,00	186.900,00	96.000,00
2. TRAINING						
2.1 On-site short courses	60.000,00		60.000,00	60.000,00		60.000,00
2.2. On-site long permanence	30.000,00		30.000,00	30.000,00		30.000,00
2.3 Participation to international meetings/conferences	13.750,00		13.750,00	13.750,00		13.750,00
2.4 Local transportation	3.200,00		3.200,00	3.200,00		3.200,00
2.5 THB-training expenses	32.256,00	32.256,00		32.256,00	32.256,00	
2.6 MU-training expenses	60.327,00	60.327,00		60.327,00	60.327,00	
Subtotal	199.533,00	92.583,00	106.950,00	199.533,00	92.583,00	106.950,00
3. EQUIPMENT						
3.1 Basic furniture (desks, chairs, lockers, etc)	1.200,00		1.200,00	-		-
3.2 Hardware (laptops, printers)	6.200,00		6.200,00	3.000,00		3.000,00
3.3 Stationery (paper, pens, pencils, staplers, etc)	960,00		960,00	960,00		960,00
3.4 CD4 machine	10.000,00		10.000,00	-		
3.5 KITs for CD4 machine	55.000,00		55.000,00	55.000,00		55.000,00
3.6 Centralized data-management	60.000,00	60.000,00		60.000,00	60.000,00	
Subtotal	133.360,00	60.000,00	73.360,00	118.960,00	60.000,00	58.960,00
4. OTHER COSTS						
4.1 MU – General expenses	10.000,00		10.000,00	10.000,00		10.000,00
4.2 THB – General expenses	10.000,00		10.000,00	10.000,00		10.000,00
4.3 CBO involvement	20.000,00		20.000,00	20.000,00		20.000,00
4.4 HF's Internet access	6.000,00		6.000,00	6.000,00		6.000,00
Subtotal	46.000,00		46.000,00	46.000,00		46.000,00
TOTAL		339.483,00	322.310,00		339.493,00	307.910,00

1. Human resources

The project will fully be supported by a team consisting of personnel already working at the ISS. Two further units will have to be added to them: 1 IT manager (responsible for the informatic activity) and 1 administrative assistant for managing technical and scientific activities.

The IT Manager will be responsible for the management of epidemiological data in electronic format, through the use of a software specifically developed for the project. The program, installed and activated in ISS, will allow to communicate via web with similar software located at the MU. The software has been designed for assemblage and management of epidemiological data collected and stored (in databases installed locally) at decentralized structures without internet connection. The software will also contain the material necessary to the formative activities and an e-learning platform for distance learning. The administrative assistant will provide administrative and technical support to all project activities.

The project team will carry out its functions both in Italy and in Ethiopia (Table 1). The transfer of the know-how is the key activity of the project. Training activities by ISS, will be address to MU personnel as well as the HWs working at the HF's involved in the project. Such activities will aim to strengthen specific skills in the clinical, laboratory and epidemiological fields. Training will be also addressed to improve management of data in the clinical practice.

Tab. 1. ISS personnel: project activities costs

Human resources	Person-month	Month-Cost (€)	Year-Cost (€)
General manager	2	6.700,00	13.400,00
Project leader and responsible for training activities	10	4.300,00	43.000,00
1 Responsible for training activities (collection, management and control of epidemiological data in clinical practice)	8	4.300,00	34.400,00
1 Administrative assistant	12	4.000,00	48.000,00
1 IT Responsible	12	4.000,00	48.000,00
1 Bioinformatics	4	4.000,00	16.000,00
1 Responsible for training activities (communication tools for the dissemination of information)	5	6.300,00	31.500,00
1 Responsible for training activities (educational training for CHWs working at the local CBOs)	2	4.300,00	8.600,00
1 Technical assistant (educational training for CHWs working at the local CBOs)	4	4.000,00	16.000,00
1 Graphic designer (support training activities at the local CBOs)	2	4.000,00	8.000,00
1 Administrative Responsible	4	4.000,00	16.000,00
Total			282.900,00

2 . Training

A) On-site short course

To ensure the sustainability of the project, four ISS-team missions per year are planned, with short-term on-site permanence (average 10 days). ISS personnel (5 people per mission) will carry-out the following activities:

- Monitoring of all project activities;
- Organization/participation in meetings with the local partners of the project (THB, MU);
- Coordination of local coordinator;
- Training of local HWs operating at MU and HFs involved in the project;
- Training of CHWs operating at the local CBOs;
- Meetings in Addis Ababa with representatives of the Ministry of Health of Ethiopia.

Travel costs will include the flight (Rome-Mekelle-Rome), the accommodation, food and local transport. The average cost per person is estimated to be about 3.000,00 euro. Four missions will be organized each year, with 5 people, for an estimated total cost of € 60,000. While staying on-site, ISS personnel will benefit of a car with driver in order to reach the participating HFs. The transfer costs, also including fuel expenses, should approximately amount to € 80 per day. The expected annual total cost is € 3,200.00, for 4 missions with an average duration of 10 days.

B) On-site long permanence

On-site long permanence carried out by physicians coming from Italy for providing clinical training to local HWs have been planned. 4 physicians will stay on site, alternately (in pairs) for two consecutive months each year. They will carry out their activities both at MU that and HFs involved in the project. The expected costs are those related to flight (Genoa-Mekelle-Genoa), accommodation, foods, local transport, insurance and vaccinations. The estimated total annual cost is € 30,000.00 .

C) Formative travels for local partners: participation in international meetings/conferences/congresses

The formative program includes the integration of the on-site training activities with further initiatives to be implemented through HWs participation in meetings, conferences or congress at international level. Transfers in and outside Europe with a minimum duration of 7 days and a maximum of 10 days have been planned. This training will be ensured to a maximum of 5 persons each year. The total estimated cost, which includes air transfer, accommodation, food, per-diem and possible registration for the conference/congress, is between € 2,000.00 and € 3,500.00, depending on the purpose of the journey. Considering the average of the above possibilities, it is expected a average cost of € 2,750.00 per person (5 people), for a total annual amount of € 13,750.00 .

THB- Training expenses

We will involve in the project, as a starting point, a total of 8 health facilities (4 Health Centers, twinned with 4 Hospitals). The HFs personnel who will receive the training will be refunded for travel, accommodation, food, plus a per diem during their training days. The THB will guarantee the realization of the project and the

execution of all activities. For all support activities performed by THB, a lump sum for general expenses has been planned.

MU- Training expenses

The University, as an essential support to the project, will ensure the availability of personnel to be trained by ISS team. They will be able, in turn, to train the HWs working at the HFs participants (Train-the-trainer approach). The MU team will also be responsible for picking up data at the participating HFs and managing of centralized database. MU personnel will receive a financial reward for its training activities, in addition to a per diem and a reimbursement for travel, food and accommodation during their missions at the HFs.

3. Equipment and Supplies

The eight HFs participating in the project will be adequately equipped with basic furniture, hardware and software necessary for collection and management of HIV/AIDS patients data in clinical practice. Four out of the eight HFs have previously been equipped by ISS. Below, a detailed list of equipment:

- Furniture (1 desk, 2 chairs, 2 lockers for each HF). Average cost per structure: € 300,00. Average overall cost for 4 structures: € 1.200,00.
- 8 laptops (2 computers for each HF: one to be used for the clinical data collection, the second to be used for internet connection. Average cost per computer approximately € 700,00. Average overall cost for 8 computers: € 5.600,00.
- 4 printers (1 for each HF). Average unit cost: € 150,00. Average overall cost for 4 printers: € 600,00.
- Stationery (paper, pens, pencils, staplers, binders, etc.). Annual average unit cost: € 120,00. Annual average overall cost for 8 structures: € 960,00.

Strengthening of laboratory services was also planned in this study. Each HF (if it's lacking) will be provided with an instrument for CD4 cell count. Seven out of eight HFs already have CD4 machine (four CD4 machine have previously been purchased and delivered by ISS). Project funds will be utilized to buy one CD4 machine for 1 additional HC. It will be purchased at PARTEC (a specialized company internationally recognized) and will have a unit cost of approximately € 10,000,00. In addition to the CD4 instruments, HFs will also be provided with consumables necessary for their use (KITs and reagents) and technical assistance for any malfunctions. The total cost of the KITs, annually needed for CD4 detection in the area of the 8 HFs, amounts to € 55.000,00.

The University will provide the material necessary to carry out training activities and make available a room to be used as an office for the project local coordination, meeting place for the MU team responsible for the project, and also meeting place for the ISS team during the missions.

A specific software for centralized management of epidemiological data and distance learning activity (E-learning platform) will be used all through the project. Expected annual average cost for the software management is € 60.000,00.

4. Other costs

General expenses for THB and MU

They will consist in local transportation, communication, internet connection, meeting organization, printing of educational material etc.

Involvement of local CBOs

Involvement of local CBOs will be essential to carry out communication activities and therapeutic education of patients through seminars, events (coffee ceremonies, theatrical performances) and dissemination initiatives (posters, brochures). Annual cost: € 20,000.00.

HFs Internet connection

Installation and use of internet in all the HFs participating in the project. Annual cost: € 6.000,00.

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