ENGLISH VERSION



Volume 26 - Numero 10 Ottobre 2013 ISSN 0394-9303

# Notiziario

dell'Istituto Superiore di Sanità

C.A.S.A.: an operational research project to improve the quality of care for HIV infected people in Ethiopia

R. Bucciardini, V. Fragola, S. Lucattini, R. Terlizzi, M.G. Mancini, P. De Castro, M. Mirra, M. Di Gregorio, L. Fucili, S. Donnini, F. Innocenti, C.M. Curianò, K. Pugliese, E. Longo, M. Lauriola, F. Magnani, E. Olivieri, S. Vella













aliane S.p.A. – Spedizione in abbonamento postale - 70% - DCB Roma

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



Raffaella Bucciardini<sup>1</sup>, Vincenzo Fragola<sup>1</sup>, Stefano Lucattini<sup>1</sup>, Roberta Terlizzi<sup>1</sup>, Maria Grazia Mancini<sup>1</sup>, Paola De Castro<sup>2</sup>, Marco Mirra<sup>1</sup>, Massimiliano Di Gregorio<sup>1</sup>, Luca Fucili<sup>1</sup>, Stefania Donnini<sup>1</sup>, Federica Innocenti<sup>1</sup>, Cosimo Marino Curianò<sup>2</sup>, Katherina Pugliese<sup>1</sup>, Eloïse Longo<sup>3</sup>, Marco Lauriola<sup>4</sup>, Federica Magnani<sup>1</sup>, Erika Olivieri<sup>1</sup> and Stefano Vella<sup>1</sup>

<sup>1</sup>Dipartimento del Farmaco, ISS

<sup>2</sup>Servizio Informatico, Documentazione, Biblioteca ed Attività Editoriali, ISS

<sup>3</sup>Dipartimento di Ambiente e Connessa Prevenzione Primaria, ISS

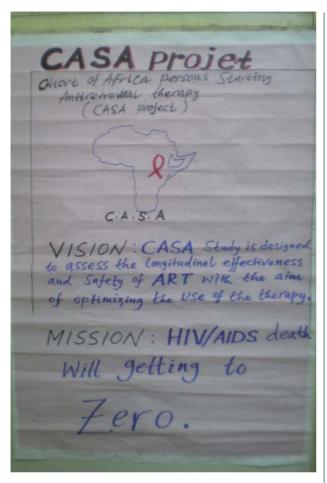
<sup>3</sup>Dipartimento di Ambiente e Connessa Prevenzione Primaria, ISS <sup>4</sup>Facoltà di Medicina e Psicologia, Università Sapienza, Roma

**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 CASA 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

RIASSUNTO (C.A.S.A.: un progetto di ricerca operazionale per migliorare la qualità della cura delle persone con infezione da HIV in Ethiopia) - 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 operazionale, il cui obiettivo è l'ottimale utilizzo delle risorse disponibili per una maggiore efficacia degli interventi. Il Progetto di ricerca operazionale denominato CASA (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.

fter 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. Subsaharan 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 Nation 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), ie "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 - CDs) 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 (coinfection 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 subsaharan 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.

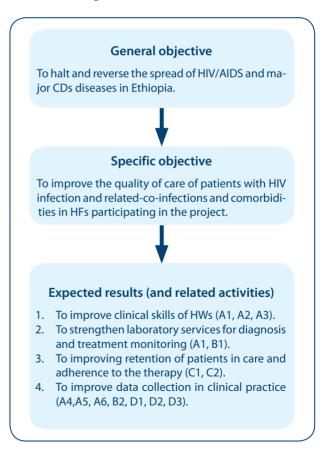
## The CASA project

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 us 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

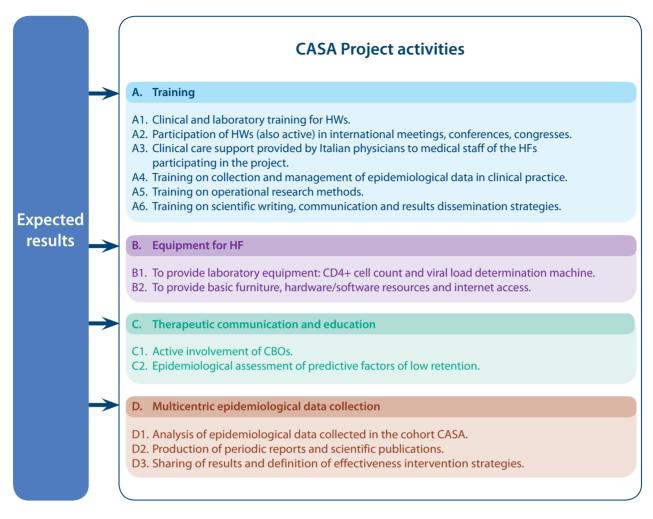


Figure 2 - CASA Project activity related to expected results

#### **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 allows 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 HFs. 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 Alamata 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.

#### References

- World Health Organization (www.who.int/hiv/data/en/index.html).
- 2. UNAIDS. Global report: UNAIDS report on the global AIDS epidemic 2010;2010.
- **3.** Cohen MS, Che YQ, McCauley M, et al. Prevention of HIV-1 infection with Early Antiretroviral Therapy. N Engl J Med 2011;365:493-505.
- **4.** World Health Organization (www.who.int/healthsystems/task shifting\_booklet.pdf).
- 5. WHO, UNAIDS, UNICEF. Towards Universal Access. Scaling up priority HIV/AIDS interventions in the health sector. Progress Report 2009 (www.who.int/hiv/pub/2010progressreport/en/index.html).
- **6.** World Health Organization. *Global tuberculosis report 2012*. Geneva; 2012 (http://apps.who.int/iris/bitstre am/10665/75938/1/9789241564502\_eng.pdf).
- International Human Development Indicators (http:// hdrstats.undp.org/en/countries/profiles/ETH.html).
- **8.** World Health Organization (www.who.int/gho/countries/eth.pdf).
- World Health Organization (www.who.int/research/en/).
- The World Bank Group (http://data.worldbank.org/indicator/SE.ADT.LITR.ZS).
- **11.** The Federal Democratic Republic of Ethiopia. *Country Progress Report on HIV/AIDS Response*; 2012.
- **12.** UNAIDS. Getting to zero: 2011–2015 strategy. Joint United Nations Programme on HIV/AIDS;2010.
- **13.** The Federal Democratic Republic of Ethiopia. *Guidelines* for clinical and programmatic management of TB, TB/HIV and leprosy In Ethiopia; March 2013.
- **14.** The Federal Democratic Republic of Ethiopia. *Growth and Transformation Plan (GTP) 2010/2001-2014/2015*;2010 (www.ethiopians.com/Ethiopia\_GTP\_2015.pdf).