

# THE CASA PROJECT



***Raffaella Bucciardini***

*Istituto Superiore di Sanità  
Rome, Italy*

**Ethiopia and Partners: the Response to HIV/AIDS  
- Workshop -**

Addis Ababa - January 25, 2017



## Ethiopia – HIV/AIDS Therapy Highlights

- Since 2005, a free public ART programme has been introduced with over 362,000 PLWH receiving ART in 2014
- An expansion of HIV treatment programs is expected because of the 2016 change of the (WHO) ART eligibility criteria, from a CD4 cell count below 500 to all HIV patients irrespective of CD4
- The implementation of the new guidelines will result in a significant increase in the number of people who are eligible to begin therapy. Moreover, at the same time, there is now a growing number of patients who have been on treatment for several years
- Long term ART retention still represents one of the major health challenges

**A training and operational research to  
improve retention in care of HIV  
people in Tigray, Ethiopia**

# CASA PROJECT

## Funding

*This work is supported by:*

- Italian Ministry of Health, Rome, Italy



- Italian Agency for Development Cooperation



# CASA PROJECT

## Project Partners



**Tigray Health Bureau (THB)**



**Mekelle University College of Health Sciences (MU)**



**Istituto Superiore di Sanità (ISS)**

# CASA TEAM CORE

## COORDINATION GROUP

## ON SITE PROJECT MANAGEMENT

## IT MANAGEMENT UNIT

**Raffaella Bucciardini**  
Researcher, Project Leader,  
Istituto Superiore di Sanità

**Teame Zegeye**  
Local Project Coordinator,  
Tigray Health Bureau

**Luca Fucili**  
IT professional, Software management,  
Istituto Superiore di Sanità

**Hagos Godefay**  
Head, Tigray Health Bureau,  
Tigray Health Bureau

**Atakilt Halifom**  
Local Supervisor,  
Tigray Health Bureau

**Marco Mirra**  
IT professional, Software management,  
Istituto Superiore di Sanità

**Stefano Vella**  
Director, National Center for Global Health,  
Istituto Superiore di Sanità

**Teshome Abegaz**  
IT professional, Data management support,  
Mekelle University

**Massimiliano Di Gregorio**  
IT professional, Software management,  
Istituto Superiore di Sanità

**Loko Abraham**  
Dean, College of Health Sciences,  
Mekelle University

**Eskedar Tadesse**  
Data Manager,  
Mekelle University

**Vincenzo Fragola**  
Project Coordinator,  
Istituto Superiore di Sanità

**Micheal Berhe**  
Data Manager,  
Mekelle University

**Stefano Lucattini**  
IT professional, Software management,  
Istituto Superiore di Sanità

**Michela Campagnoli**  
ISS, local supervisor,  
Istituto Superiore di Sanità

**Paola De Castro**  
Responsible for Communication Training and  
Dissemination,  
Istituto Superiore di Sanità

**Paola Tatarelli**  
Clinical Trainer,  
Clinica Malattie infettive – Università degli  
Studi di Genova, Italy

**Katherina Pugliese**  
Research Collaborator,  
Istituto Superiore di Sanità

**Roberto Terlizzi**  
Administration Coordinator,  
Istituto Superiore di Sanità



## Health Facilities

### **HFs involved in the project**

1. *Mekelle General Hospital*
2. *Mekelle Health Center*
3. *Ayder Referral Hospital*
4. *Alamata Health Center*
5. *Alamata General Hospital*
6. *Mehoni Primary Hospital*
7. *Lemlem Karl General Hospital (Maichew)*

## Health Facilities





## Project activities

- ☐ Training
- ☐ Active participation of Patients Associations
- ☐ Operational research

## Operational Research

**Systematic analysis and interpretation of collected data may produce evidence-based information for local decision makers to identify appropriate strategies for enhancing long-term effectiveness of therapy**

# CASA PROJECT

## Operational Research

### Study design

Prospective, multi-site study of an open cohort of HIV patients starting antiretroviral therapy

### Data collection

- Baseline data
- Follow-up data (according to standard of care of HFs)

### Main outcomes

- Retention in care
- Disease progression

**Target:** 2000 patients

**Follow-up:** 5 years

## Operational Research

### Retention in care of adult HIV patients initiating antiretroviral therapy in Tigray, Ethiopia: a prospective observational cohort study

Raffaella Bucciardini\*, Vincenzo Fragola\*, Teshome Abegaz§, Stefano Lucattini\*, Atakilt Halefom#, Eskedar Tadesse§, Micheal Berhe§, Katherina Pugliese\*, Andrea Binelli\*, Paola De Castro\*, Roberta Terlizzi\*, Luca Fucili\*, Massimiliano Di Gregorio\*, Marco Mirra\*, Erika Olivieri\*, Tsigemariam Teklu#, Teame Zegeye#, Amanuel Haile, Stefano Vella\*, Loko Abraham§, Hagos Godefay# and the CASA-project Health Facilities. **PLOS-ONE 2015**

### Predictors of retention in care at two years in a prospective cohort of HIV-infected adults in Tigray, Ethiopia

Raffaella Bucciardini1, Vincenzo Fragola1, Teshome Abegaz2, Stefano Lucattini1, Atakilt Halifom3, Eskedar Tadesse2, Micheal Berhe2, Katherina Pugliese1, Luca Fucili1, Massimiliano Di Gregorio1, Marco Mirra1, Paola De Castro1, Roberta Terlizzi1, Paola Tatarelli4, Andrea Binelli1, Teame Zegeye3, Michela Campagnoli1, Stefano Vella1, Loko Abraham 2, Hagos Godefay3 and the CASA-project Health Facilities

***Under review***

# CASA PROJECT

**Operational Research - Data updated up to December 2016**

## **Primary outcome measure:**

Retention in care between January 2013 and December 2016

### ***Operational definitions***

Retain in care: patients who were alive and receiving ART at the same HF after ART initiation

It does not include patients who were recorded as:

- Lost to follow-up (LTFU)
- Dead patients
- Discontinued ART for any reasons
- Transferred out

# CASA PROJECT

## Operational Research

### Health facilities and enrolled patients

Health Facilities	n (%)
Mehoni primary hospital	338 (18.8)
Mekelle general hospital	263 (14.6)
Mekelle health center	329 (18.3)
Alamata health center	225 (12.5)
Alamata general hospital	223 (12.4)
Michew L.K. general hospital	210 (11.7)
Ayder referral hospital	210 (11.7)
Total	1798 (100.0)

# CASA PROJECT

## Operational Research

### Baseline characteristics (1)

Sex, n (%)	Value at baseline
Female	1102 (61.3)
Male	696 (38.7)

Age, n (%)	Value at baseline
At start of ART (years), mean $\pm$ SD (n, range), median	35 $\pm$ 9.9 (1796,16-82),33
14-25 n (%)	270 (15.0)
26-50	1388 (77.3)
>50	138 (7.7)

# CASA PROJECT

## Operational Research

### Baseline characteristics (2)

Religion, n (%)	Value at baseline
Orthodox Christian	1596 (88.8)
Muslim	193 (10.7)
Protestant	6 (0.3)

Educational status, n (%)	Value at baseline
No education	777(43.2)
Primary	533 (29.6)
Secondary	320 (17.8)
Tertiary	168 (9.3)



## Operational Research

### Baseline characteristics (3)

CD4+ count (cells/ $\mu$ L)	Value at baseline
Mean $\pm$ SD (n, range), median	236 $\pm$ 170 (1734, 2-1777), 214
<200 n (%)	804 (46.4)
$\geq$ 200 n (%)	930 (53.4)
<i>Missing data: 64 (3.6)</i>	

BMI (kg/m <sup>2</sup> ), n (%)	Value at baseline
Underweight	740 (41.3)
Normal	978 (54.6)
Overweight	74 (4.1)

## Operational Research

### Baseline characteristics (4)

Hemoglobin (g/dL), n (%)	Value at baseline
<b>&lt;=10</b>	<b>161 (9.3)</b>
<b>&gt;10</b>	<b>1570 (90.7)</b>
<i>Missing data: 67(3.7)</i>	

Active TB, n (%)	Value at baseline
<b>Yes</b>	<b>151 (8.6)</b>
<b>No</b>	<b>1609 (91.4)</b>
<i>Missing data: 38 (2.1)</i>	

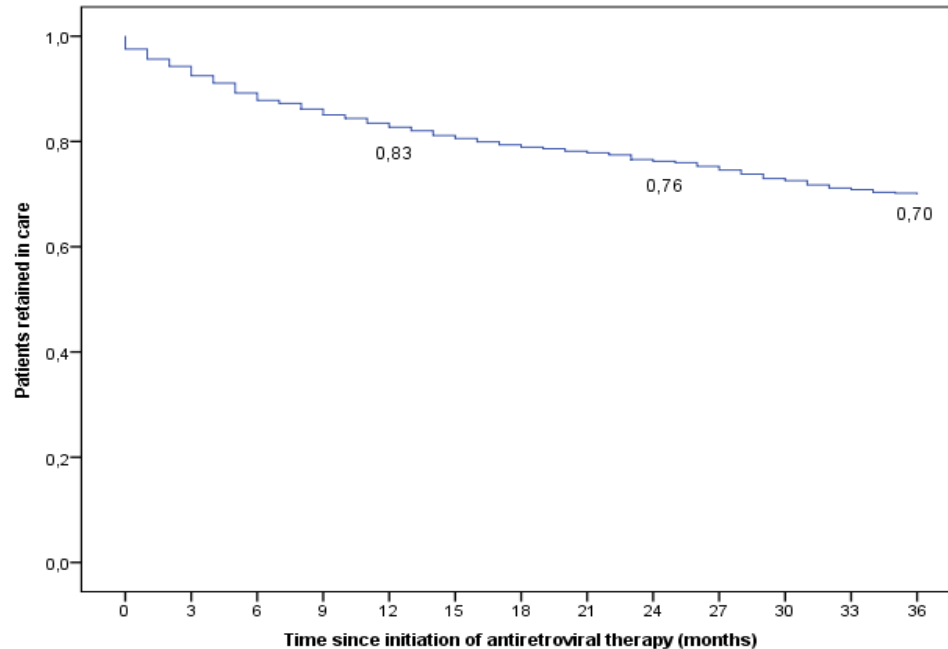
## Operational Research

### Baseline characteristics (5)

Initial treatment regimen, n (%)	Value at baseline
Efavirenz based	1669 (92.8)
Nevirapin based	129 (7.2)

# CASA PROJECT

## Operational Research



Kaplan-Meier estimate of retention in care at different months of follow-up on ART

Kaplan-Meier estimate of mortality, loss to follow-up, transfer out, stop ART medication and retention in care after ART initiation

Months of follow-up	Cumulative Events	Mortality (%)	LFTU (%)	Transfer-out (%)	Stop ART (%)	Retention %
12 months	298	66 (4.0)	85 (5.3)	137 (8.4)	10 (0.6)	82.7%
24 months	386	78 (5.1)	118 (8.1)	180 (11.9)	10 (0.6)	76.2%
36 months	437	83 (5.9)	135 (10.7)	209 (16.1)	10 (0.6)	70.0%

## Operational Research: Take-Home Message (1)

- **Data show that the majority of the LFTU occurred in the first year of treatment:** efforts to improve retention should be mainly focused on the initial 12 months after starting ART.
- **Mortality estimate was lower than findings reported from other studies conducted in Ethiopia and in low-and-middle-income countries:** some of the patients classified as LFTU might have died.
- **High proportion of transfer-out patients:** in this analysis transferred-out patients were not considered as retained in care, because official documentation to certify that they were still on ART was not always available. Interventions aimed at networking clinical centers and developing systems for tracking transfer outs should be necessarily implemented.

# CASA PROJECT

## Operational Research

### Cox proportional hazards model of association between baseline characteristics and retention in care

Health Facility	Multivariate analysis Hazard ratio of attrition (95% CI)
Ayder hospital ( <i>referral hospital</i> )	Reference
Alamata health center ( <i>health center</i> )	1.57 (1.00 – 2.51)
Alamata hospital ( <i>general hospital</i> )	2.58 (1.65 – 4.03)
Mekelle health center ( <i>health center</i> )	1.65 (1.08- 2.51)
Mehoni hospital ( <i>primary hospital</i> )	2.14 (1.43 – 3.20)
Mekelle hospital ( <i>health center</i> )	2.58 (1.66 – 4.00)
Michew hospital ( <i>general hospital</i> )	1.92 (1.19 – 3.09)
<b>Gender</b>	
Female	Reference
Male	1.46 (1.19 – 1.79)
<b>CD4 count (cells/<math>\mu</math>L)</b>	
$\geq 200$	Reference
$< 200$	1.40 (1.14 – 1.73)
<b>Hemoglobin (g/dL)</b>	
$>10$	Reference
$\leq 10$	1.42 (1.05 – 1.93)

## Operational Research: Take-Home Message (2)

- Data show that the retention in care varies across HFs with high, medium and low retention rates (*this data is confirmed by other studies conducted in Ethiopia*): more specific studies to analyze the reasons for a different retention among HFs are needed
- HIV infected males have a higher risk of attrition for care than females (*differences in retention in care between HIV-infected men and women have been observed in many other studies conducted in sub-Saharan countries*): new interventions designed for women and men should be also explored

## Operational Research: Take-Home Message (3)

- **Low CD4+ cell count was another factor associated with a higher attrition rate:** these results suggest that initiatives for expansion of WHO “Treat All” approach and early initiation of therapy should be further supported
- **Low hemoglobin value at baseline:** these findings suggest that initiatives for prevention and treatment of anemia should be intensified (it could just be a measure of severe malnutrition or an opportunistic infection that is or is not diagnosed)





Thank you

*raffaella.bucciardini@iss.it*