TasP

Antiretroviral Treatment as Prevention • ANRS 12249

*Ukuphila kwami, ukuphila kwethu (my health for our health)*

# ISSUES EMERGING FROM UNIVERSAL TEST AND TREAT (UTT) INTERVENTION TRIALS

John Imrie, Joseph Larmarange,
Joanna Orne-Gliemann, Collins Iwuji, France Lert
for the ANRS 12249 TasP Study Group

ASSHH Conference, Paris, July 2013

# Introduction

- Universal HIV Testing and early initiation of antiretroviral Treatment (UTT) strategy is currently tested in several large-scale studies in Southern Africa

- New WHO guidelines: ART initiation at 500CD4 will constitute in some contexts an hybrid form of UTT

# Introduction

- Several trials on-going as ANRS 12249 TasP trial, MaxART or PopART
- UTT intervention strategies are **major social**, as well as biomedical, interventions
- What additional information, beyond the trial outcomes, will be needed to move any UTT strategy to the next level?

# The complexity of UTT strategies

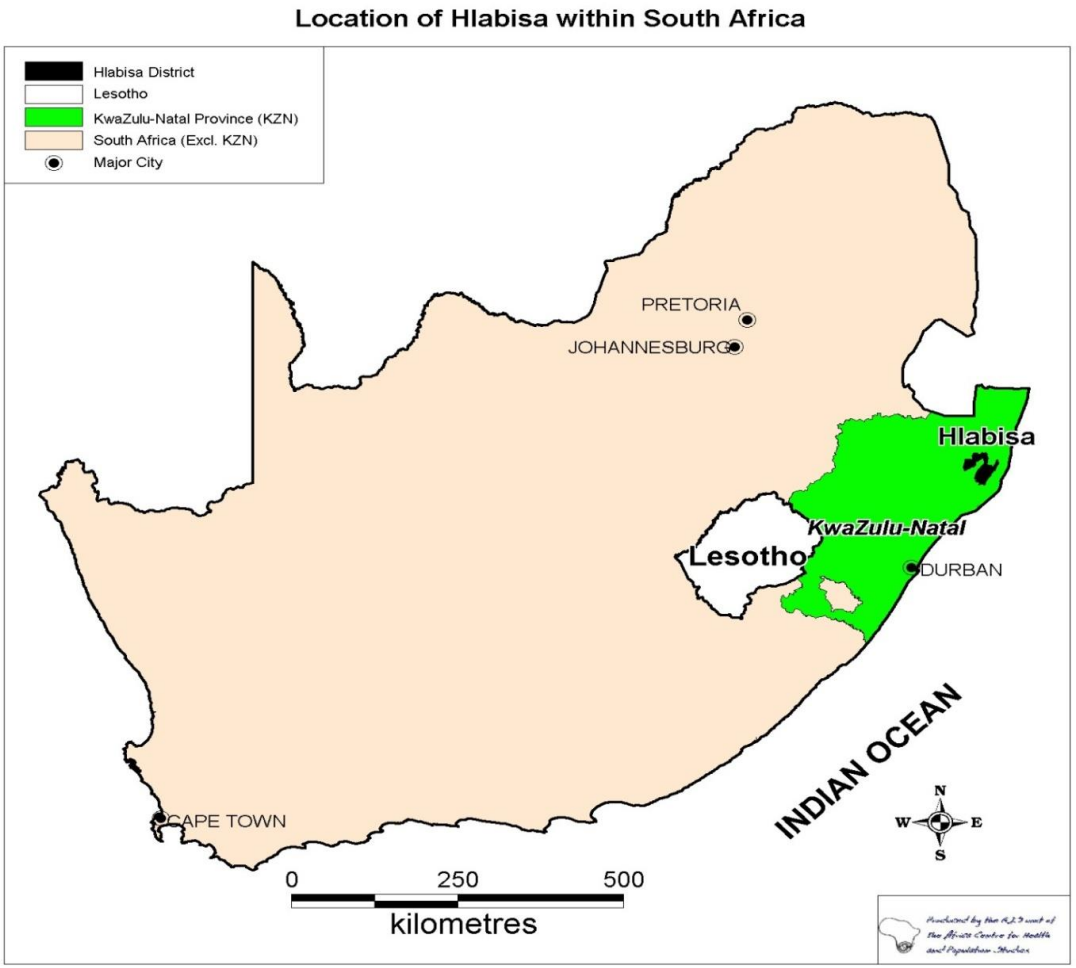
- All UTT interventions comprise 2 components
  - Universal HIV **testing**, repeated regularly for HIV-
  - Life-long ARV **treatment** initiated as soon as possible

- To be effective on reducing incidence, they also require for both components
  - High levels of **uptake** (testing, linkage to care, adherence…)
  - **Sustained** over time

- Complex multi-components strategies
  - With potential needs to evolve overtime
  - Example: providing additional testing opportunities (as self testing)

# The ANRS 12249 TasP trial

Implemented by Africa Centre
in Hlabisa sub-district, KwaZulu Natal (South Africa)




- Rural area of 1430 km²
- 220 000 inhabitants speaking isiZulu
- HIV prevalence: 24% among adults

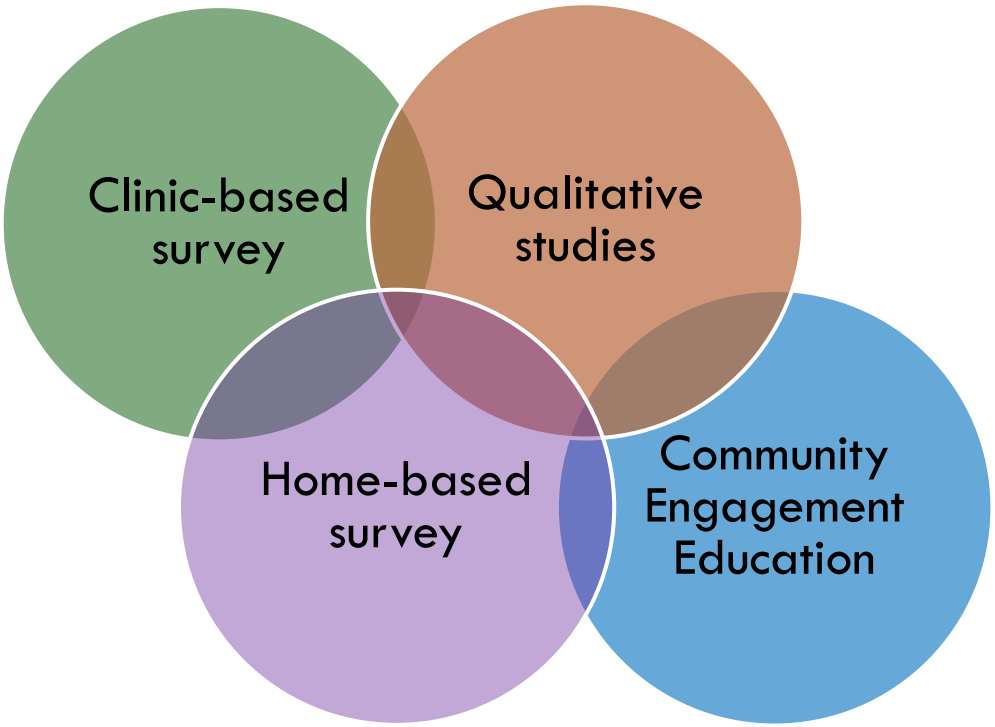
# TasP trial design

- TasP is a cluster randomized trial.
  - Each cluster has a population of approx. 1250 adults (16+ years).
  - The **TasP intervention** has 2 components:
    "universal" repeat testing (all clusters) + early treatment (intervention cluster)

- In each cluster, rounds of **home-based HIV testing** repeated every 4 to 6 months
- All HIV+ identified participants are referred to local TasP clinics (at least one fixed or mobile clinic per cluster)

| Control clusters | Intervention clusters |
|---|---|
| ARV treatment according to national guidelines (<350 CD4 or WHO stage 3 or 4) | ARV treatment regardless of CD4 or clinical staging |

# Social science studies implemented




to ensure a comprehensive understanding of the **social determinants** of intervention uptake and the **impact of the intervention** at individual, household and community level

For more details, cf. communication presented this morning

# What questions the trials will leave unanswered?

- Long-term social and behavioural consequences at individual and community levels
- Social normative changes at individual and community levels
- Operational and ethical implications of transforming research interventions into routine care

# Social and behavioural consequences

- Would continuous provider-initiated regular and repeat HIV-testing remain acceptable?
- Will linking newly diagnosed patients - without any visible symptoms or perceived HIV-risk - into care become easier or more difficult?
- Long-term social and behavioural consequences of large numbers of people in a given community knowing their HIV-status and starting treatment early?

# Social normative changes

- UTT trials, including TasP, are attempting to measure and understand social changes during the trial
- However, it may be difficult to disentangle and disassociate the drivers of the social changes within the trial communities
- Community preparation will be central in the success of any attempt to move UTT interventions to scale under real-life circumstances

# Operational and ethical implications of moving into routine care

- What aspects of the intervention will need greatest attention when moving into routine care?
- Logistics, financing and potential for targeting of a scaled-up UTT
- Ethics of taking UTT to scale as part of a broader public health strategy

# Operational and ethical implications of moving into routine care

- Ethics of taking UTT to scale as part of a broader public health strategy
  - Potential risks of a state institutions 'knowing' and recording individuals' HIV-status, their uptake in testing and care?
  - Special concerns for vulnerable key groups (SW, MSM…)

# Discussion

- How to scale UTT as public health policy?
- Potential problems of seeing UTT as prevention process
- Additional research is one way to ensure adequate evidence

**UTT interventions have potentially great social consequences that need to be explored alongside the actual trials, to guide and inform future decisions and policy**

# TasP Study Group

Marie-Louise Newell (Co-PI, Africa Centre)
Francois Dabis (Co-PI, Inserm ISPED)
Collins Iwuji (Trial Coordinator/Physician, AC)
Joanna Orne-Gliemann (Trial Coordinator, ISPED)
Nonhlanhla Okesola (Africa Centre)
John Imrie (Africa Centre)
Till Barnighausen (Africa Centre)
Ruth Bland (Africa Centre)
Richard Lessells (Africa Centre)
Frank Tanser (Africa Centre)
Tulio de Oliviera (Africa Centre)
Johannes Viljoen (Africa Centre)
Colin Newell (Africa Centre)
Kevi Naidu (Africa Centre)
France Lert (Inserm CESP)
Rosemary Dray-Spira (Inserm CESP)
Joseph Larmarange (IRD CEPED, Africa Centre)
Bruno Spire (Inserm SE4S)
Sylvie Boyer (Inserm SE4S)
Alexandra Calmy (HUG Genève)
Marie-Laure Chaix (Université Paris Descartes)
Sophie Karcher (Inserm ISPED)
Rodolphe Thiebaut (Inserm ISPED)
Ken Freedberg (Massachussets General Hospital)

# Acknowledgements

The French National Agency for Aids and Viral Hepatitis Research (ANRS) is the sponsor of the TasP trial.

The ANRS and the Deutsche Gesellschaft fur Internationale Zusammenarbeit (GIZ) GmbH provided funding for first phase of the trial.

The trial is conducted with the support of MERCK & Co. Inc and Gilead Sciences that provided Atripla® drug supply.

The Africa Centre receives core funding from the Wellcome Trust, which provides the basis for the population- and clinic-based research at the Centre.