

## CONTEXT

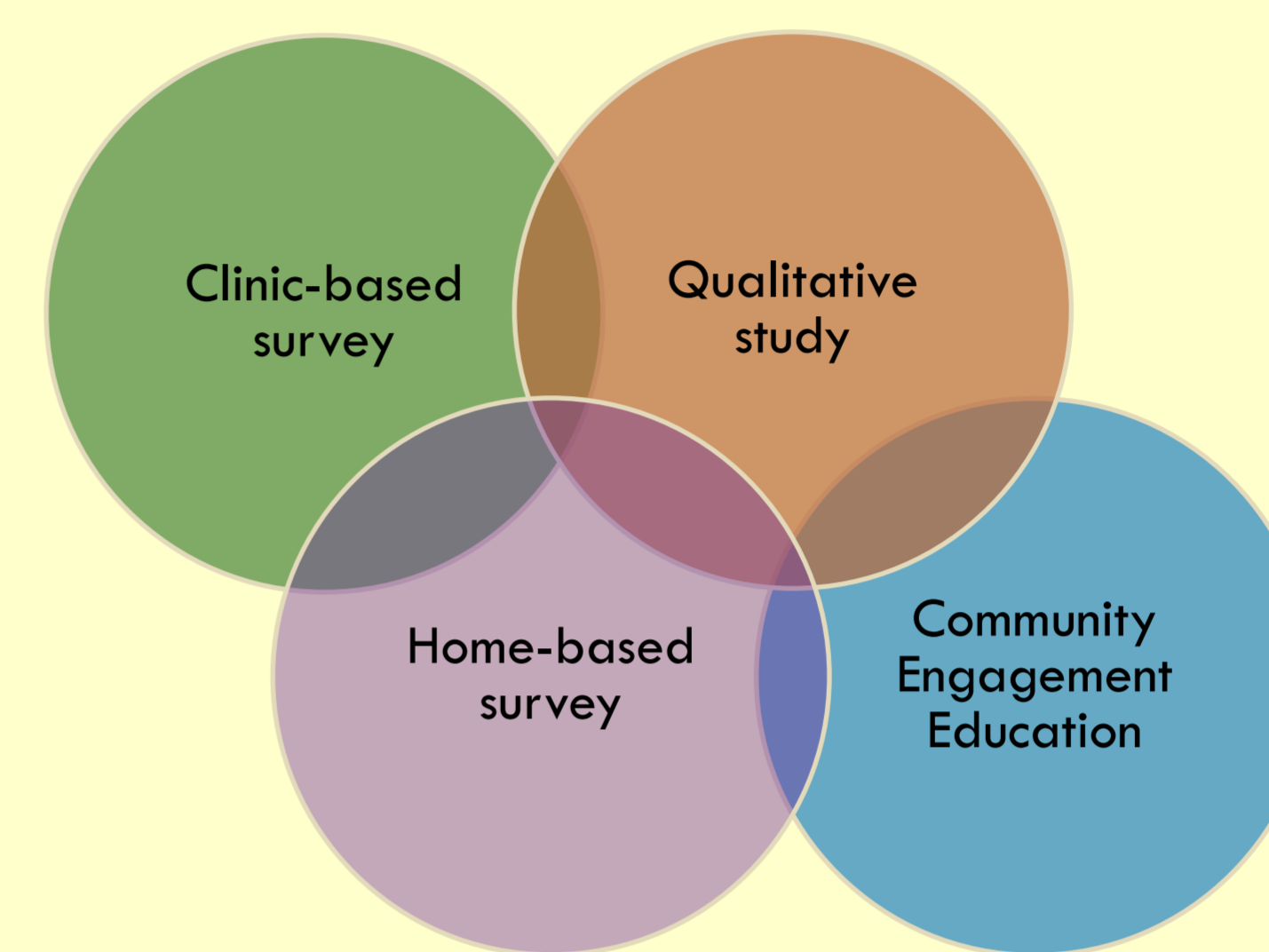
HIV testing of all adult members of a community, followed by immediate antiretroviral treatment (ART) initiation of HIV-infected participants, regardless of immunological or clinical staging, has been suggested as an intervention to prevent onward transmission and reduce HIV incidence. Recently, the question of using *Treatment as Prevention* has become central in the field of HIV.

The first phase of the cluster-randomized ANRS 12249 Treatment as Prevention (TasP) trial aims to test acceptability and feasibility of this strategy in Hlabisa sub-district, KwaZulu-Natal. A full prevention and HIV testing strategy is provided in both the intervention and control arms, consisting of the current range of community and clinic testing options plus the implementation of regular (every 6 months) rounds of home-based HIV testing. HIV-infected patients are referred to a TasP clinic and offered to receive immediate ART if residing in an intervention cluster or ART according to national guidelines if residing in a control cluster (see poster by Iwuji *et al.*).

In addition to epidemiological, clinical and operational challenges, **TasP raises unprecedented social challenges** at individual and population level.

## IMPLEMENTATION / RESEARCH TOOLS

The first phase of the trial began in March 2012 in four clusters, with six added in January 2013. Quantitative and qualitative research tools are implemented at each stage of the TasP intervention: repeat home-based questionnaires with household heads and individual household members; specific questionnaires for the HIV-infected individuals attending trial clinics and for those who do not enter HIV care; combined with in-depth semi-structured individual qualitative interviews, repeat focus groups discussions (consumer panels) using participatory methods.



### Among all participants

- The home-based questionnaires (repeated every 6 months) document knowledge/beliefs about HIV infection, knowledge/expectations about treatment, lifetime HIV testing history, HIV testing attitudes/beliefs, sexual partnerships, condom use, circumcision status, risk behaviors, quality of life, community stigma, health care use and expenditure.
- Focus groups and in-depth interviews focus on mapping health services on the community, community understanding of HIV and the TasP intervention, local culture to support regular and repeated HIV testing.

### Among HIV infected participants

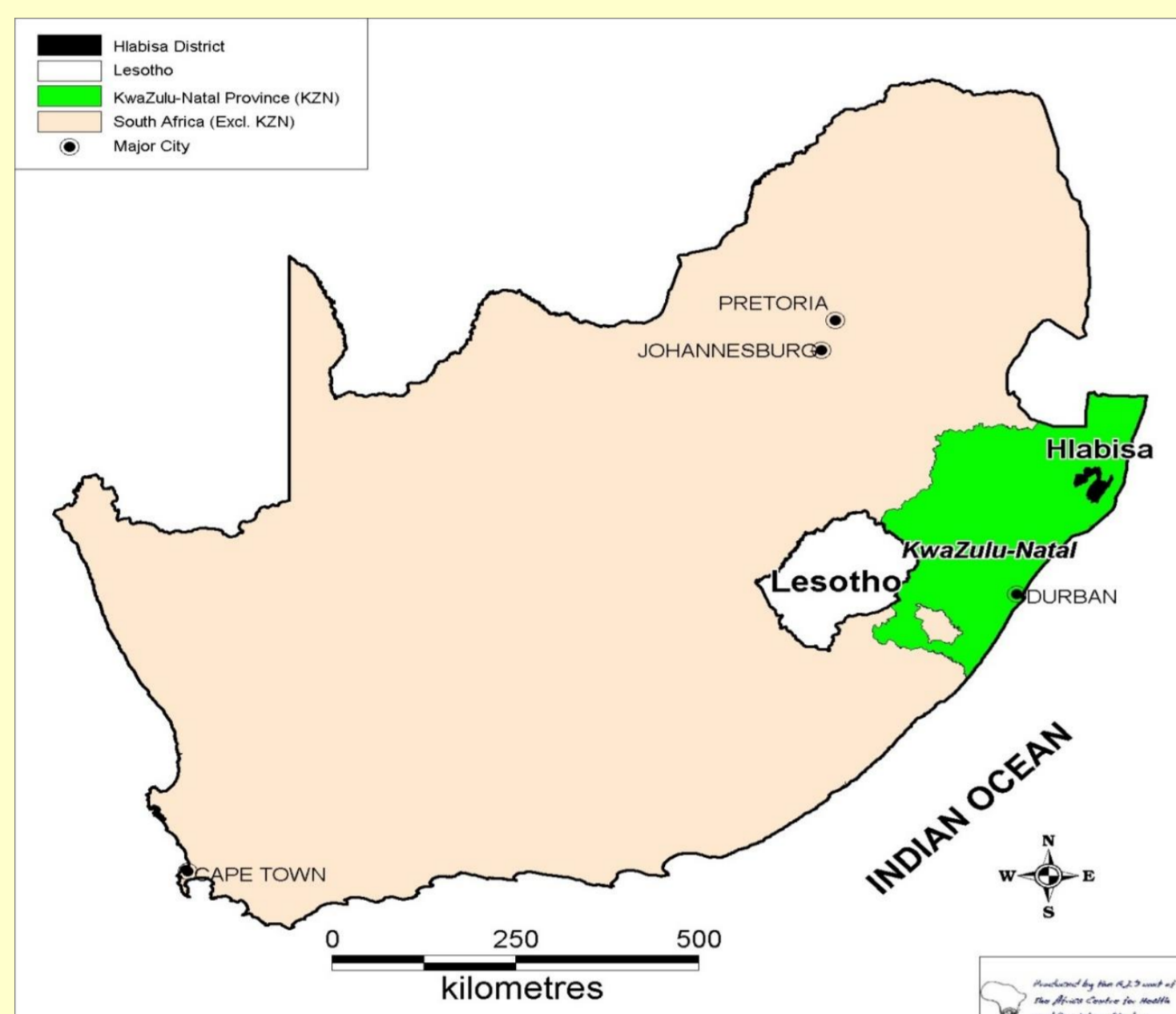
- Questionnaires conducted in TasP clinics both by ART counsellors and independent interviewers provide information regarding ART perception and decision, disclosure, relationships, social and community support, ART knowledge, adherence, quality of life, perceived stigma, satisfaction with care, economic situation.
- A socio-psychological sub-study among HIV-infected participants diagnosed HIV-positive but not seen in clinics will explore obstacles and barriers of linkage and entry into care.

### Community engagement

- Community engagement meetings are organised in each cluster. They facilitate education about what TasP means and involves and allows additional clarification of what project implementation involves

**Triangulation of Social Science Studies will provide comprehensive insights, complementary to clinic and epidemiological outcomes on the acceptability and effectiveness of TasP at individual, community, patient and health system level.**

## LOCATION OF HLABISA SUB-DISTRICT



## RESEARCH QUESTIONS

TasP is often perceived as a "biomedical intervention" as opposed to a "behavioural change intervention". Yet the **implementation and effectiveness of TasP requires important behaviour changes at the individual level**. To be effective, a TasP strategy requires that HIV-infected individuals:

- are tested regularly;
- initiate ART immediately after HIV diagnosis and remain on ART for life.

The impact of TasP on HIV incidence requires a high and sustained uptake of repeat HIV testing and a high ART coverage. We need not only to measure precisely the "cascade" of TasP uptake but also to have a comprehensive understanding of **factors and determinants at each step of this cascade**. If some of them (linkage and entry into care...) have already been documented in different contexts, the question of **acceptability and feasibility of repeated (six-monthly) generalized home-based testing is new**.

Will the overall effect of ART be sufficiently important not to be counterbalanced, at the community level, by other potential effects of TasP (increased HIV prevalence; increased sexual activity of HIV+; sexual and preventive behaviour changes in the community)?

Furthermore, if effective, the **cost-effectiveness of the TasP intervention** needs to be demonstrated in the context of scarce resources.

Finally, TasP raises unprecedented challenges at population and individual level. How **TasP impacts on people's lives** in terms of quality of life; HIV disclosure; stigmatisation, relationships; sexual behaviour; perceptions; social support; treatment experience and adherence? Economic impact for households and health care systems? What are the **changes at the community level during TasP implementation** and influences on individual behaviours?

## EXPECTED OUTCOMES

Outcome	Indicators
HIV testing experience	• HIV testing history and attitudes
Repeat HIV testing	• Acceptability and determinants of repeat testing
Sexual behaviours	• Sexual partnerships over time, Condom use
Partnership / Gender relations / Violence	• Partners / relationships (disclosure, communication) • Gender attitudes & IPV
Quality of life	• Quality of life at baseline and over time (in general population and among HIV infected on treatment)
Economic impact of HIV infection and ART on the household welfare	• Cost analysis / Budget impact • Health care use and health care expenditures • Activity and employment
Community awareness	• Stigma, disclosure patterns, social support • Perception & awareness of ART
Acceptability / Uptake of entry into care	• Entry into care • Expectations and perceptions of early treatment • Knowledge of HIV care and ART
Programme retention	• Adherence to ART • Patterns of retention over time and their determinants
Satisfaction with care	• Perception of quality of care received
Societal response	• Changes in attitudes regarding testing, treatment and stigma • Changes in individuals community, economic and social • Social impact of the programme participation
Cost-effectiveness performance	• Life years gained • Quality Adjusted Life Years (QALYs) saved (including both direct and indirect costs)

**TASP STUDY GROUP:** Marie-Louise Newell (Co-PI), Francois Dabis (Co-PI), Collins Iwuji (South Trial Coordinator/Trial Physician), Joanna Orne-Gliemann (North Trial Coordinator), Nonhlanhla Okesola, John Imrie, Till Barnighausen, Ruth Bland, Richard Lessells, Frank Tanser, Tulio de Oliveira, Johannes Viljoen, Colin Newell, Kevi Naidu, France Lert, Rosemary Dray-Spira, Joseph Larmarange, Bruno Spire, Sylvie Boyer, Alexandra Calmy, Marie-Laure Chaix, Sophie Karcher, Rodolphe Thiebaut, Ken Freedberg

**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 für 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.