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**Treatment as Prevention (TasP) studies: the challenge
of CD4 count treatment eligibility changes in Africa.
Perspectives from the TasP ANRS 12249 trial**

Joseph Larmarange

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TasP

Antiretroviral Treatment as Prevention • ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)



Treatment as Prevention (TasP) studies: the challenge of CD4 count treatment eligibility changes in Africa. Perspectives from the TasP ANRS 12249 trial

Joseph LARMARANGE

Ceped (UMR 196 - Paris Descartes - IRD), IRD, France
hosted by Africa Centre, UKZN, South Africa



Agence autonome de l'Inserm

INTEREST Workshop – Harare – 7th May 2015



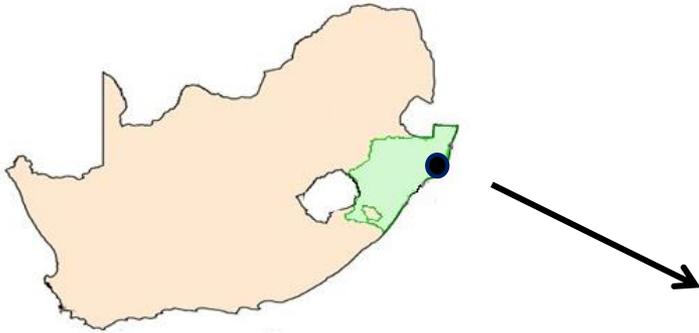
Main hypothesis (formulated in 2010)

HIV testing of all adult members of a community,
followed by immediate ART initiation
of all, or nearly all, HIV-infected participants
regardless of immunological or clinical staging

i.e. Universal Test and Treat

will prevent onward transmission
and **reduce HIV incidence** in this population

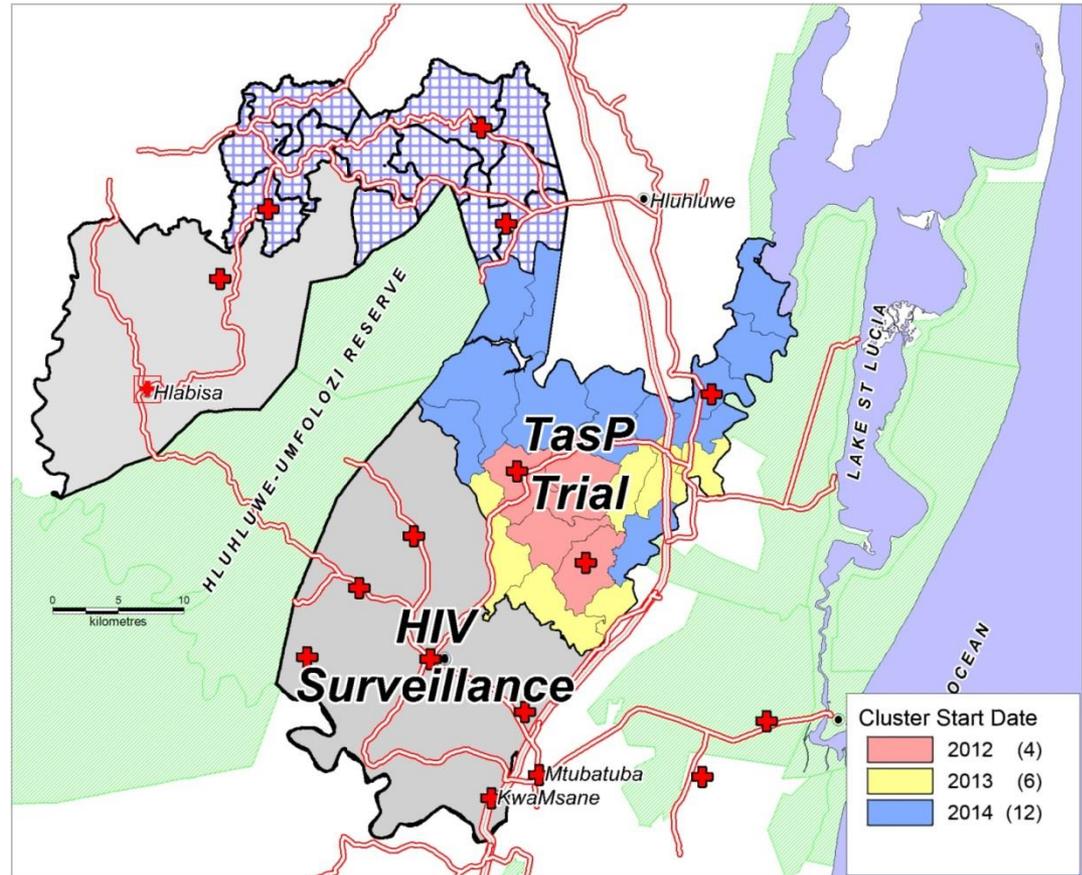
TasP trial area



Sub-district : Hlabisa

Region : KwaZulu-Natal

- Zulu speaking people
- HIV prevalence is ~30%
- Unemployment is ~80%
- 3 DoH clinics located in the trial area



- 4 clusters opened in 2012 
- 6 clusters opened in 2013 
- 12 clusters opened in 2014 



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 ~ 6 months
- All HIV+ identified participants are referred to local TasP clinics (at least one clinic per cluster)

Control clusters	Intervention clusters
ARV treatment according to national guidelines (<350 CD4 or WHO stage 3 or 4) (since Jan. 2015, <500 CD4)	ARV treatment regardless of CD4 or clinical staging



Current package of interventions

- From March 2012
 - ▣ Home-based HIV testing
 - ▣ Clinic-based HIV testing for individuals not wanted to test at home
 - ▣ Clinic-based ART
 - ▣ ART counselling

- In June 2013, added:
 - ▣ Phone call / Home visit if not linked to TasP clinics within 3 months
 - ▣ Phone call by nurse in case of a missed appointment in TasP clinic
 - ▣ A 'tracking team' for patients not reached by the nurse or requiring additional support

Model parameters versus observed estimates

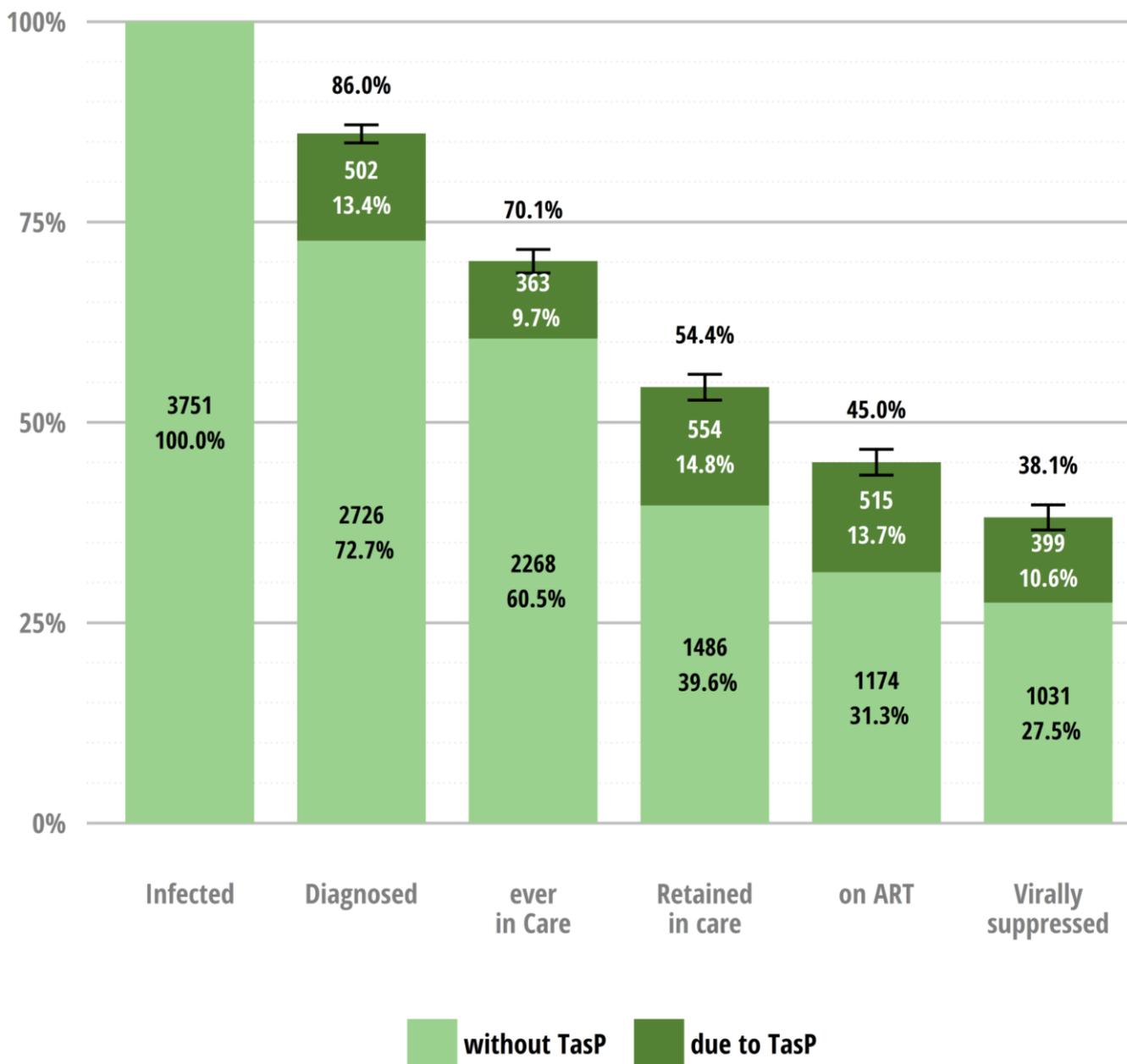


Protocol v2.0		Observation phase 1 (2012-14)	
Parameter	Assumptions	Indicator	Values (%) [95% CI]
HIV test offer among those registered	90%	Contact rate per calendar round (/CR)	67% [63-71]
Test acceptance among those offered	80%	HIV ascertainment rate/CR	77% [74-80]
Linkage to care upon diagnosis among those accepting the test	70%	Entry into care within 6 months among individuals not in care	48% [44-52]
Proportion of all HIV+ on ART in end 2011	39%	ART coverage at the beginning of the trial	39% [36-42]
HIV prevalence in end-2011 (15 years +)	24%	HIV prevalence (first DBS)	30% [29-31]
HIV incidence in end 2011 (15 years +)	2.4 / 100 PY	Observed HIV incidence	2.35 / 100 PY [1.40-3.31]

Presented by Iwuji *et al.* at Melbourne (July 2014)



Estimated Cascade of HIV care at the end of phase 1



Preliminary results

- As of 31st May 2014
- 10 clusters
- Taking into account both TasP and DoH clinics
- Including non-observed HIV+ living in the area



The 90-90-90 target

TasP trial area (end of phase 1)

86.0%

52.3%

84.7%

38.1%
(27.5%
without TasP)

UNAIDS's target

90.0%

90.0%

90.0%

72.9%

diagnosed

on treatment

virally suppressed

Overall

Implementation the 500 CD4 guideline



- Started in January 2015 (as in DoH clinics)
 - ▣ Affects mainly the clusters opened in 2014

- Conditional power estimates done in November 2014 testing several scenarios (taking into account the new guideline):
 - ▣ power to detect an impact on incidence range from 40 to 95% (depends mainly on the baseline incidence in the 12 clusters opened in 2014)
 - ▣ DSMB concluded that there is no reason to stop this study for futility at this point
 - ▣ Recommendation of implementing new interventions to improve the cascade of HIV care and treatment

- May 2015:
 - ▣ Interim analysis among the ten first clusters
 - ▣ DSMB will look at it next week



Ongoing discussion

- Implementation of a new interventions package?
 - ▣ **Community level:** improving community engagement and mobilization package
 - ▣ **HIV testing:** combination of repeat home-based testing, mobile testing and clinic testing
 - ▣ **Linkage to care:** SMS reminders, counselling and motivational support (phone calls, face-to-face visits), escort to clinics, health navigators, clinical assessment at home, option between home-based or clinic-based ART initiation
 - ▣ **Retention in care:** SMS reminders, phone calls and home visits in case of missed appointment, simplified ART care for stable patients, additional health services in clinics



Ongoing discussion

- How to implement this new interventions package?
 - ▣ Contingent upon *May 12 DSMB* conclusions
 - ▣ Starting during the 2nd semester of 2015?

- Extending follow-up until mid-2018?



Conclusions

- Real world is complex
- Impact of interventions on the cascade, and therefore on HIV incidence takes time
- Can we reach 90-90-90 at population level in real world?
- Which services/tools to propose in a comprehensive HIV interventions package?
- What would be the impact on HIV incidence?
- At what cost?



Primary objective remains

to demonstrate that
a UTT approach
reduces HIV incidence
at population level

Target date to close the trial:

June 2016



Acknowledgements

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- Africa Centre staff
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ANRS 12249 Study Group: François Dabis (co-PI), Marie-Louise Newell (co-PI), Deenan Pillay (co-PI), Collins Iwuji (South coordinator), Joanna Orne-Gliemann (North coordinator), Till Bärnighausen, Eric Balestre, Sylvie Boyer, Alexandra Calmy, Vincent Calvez, Marie-Laure Chaix, Rosemary Dray-Spira, Kamal El Farouki, Kenneth Freedberg, Kobus Herbst, John Imrie, Sophie Karcher, Joseph Larmarange, France Lert, Richard Lessells, Thembisa Makowa, Anne-Geneviève Marcelin, Laura March, Nuala McGrath, Kevi Naidu, Colin Newell, Nonhlanhla Okesola, Tulio de Oliveira, Melanie Plazy, Tamsen Rochat, Bruno Spire, Frank Tanser, Rodolphe Thiébaud, Johannes Viljoen, Thembelile Zuma.



Registered Individuals (as of 4th May 2014)

PRELIMINARY RESULTS

