

# Phase III Microbicide trial preparation in Kigali- Rwanda A Prospective Cohort HIV-incidence study: Challenges and Lessons learned

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***Site Name: Projet Ubuzima***

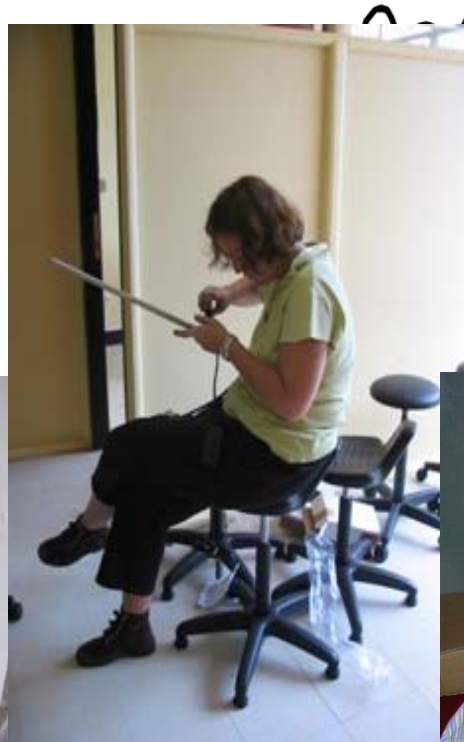
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# Rwanda / Kigali



- Population 9 million
- 90% subsistence farmers
- Life expectancy 47 yrs
- No data on HIV incidence
- Adult HIV prevalence 5%
- ANC prevalence
  - Kigali 13%
  - Other Urban 6%
  - Rural 3%

# ....started from scratch





# Site Profile



- Projet Ubuzima, Kigali, Rwanda
- Established as international NGO in early 2004, as partnership between 3 public Rwandan institutions, a Dutch academic institution and International Partnership for Microbicides (IPM)
- Governed by management team, governing council (consisting of stakeholders from medical and public health community), and community advisory group

# Site Profile

- Participates in two international capacity-building programs for GCP-compliant medical research (EDCTP and INTERACT)
- Participated in IPM003 and is currently conducting HIV incidence study in two populations
- Referral systems
  - Treatment and AIDS Research Center HIV clinic
  - Centre Hospitalier Universitaire de Kigali, Department of Obstetrics and Gynecology

# Site Prof



## ■ Infrastructure

10 clinic & counseling rooms, 3 lab rooms, 4 admin offices, reception, waiting room, conference room, kitchen, regular storage, cold storage, generator

# HIV Incidence study

Objectives

Design

Methods

Results and Challenges

# The need for an HIV incidence study in Rwanda

- Current HIV incidence data are not available for Rwanda
  - We are missing critical information → HIV diagnoses today may include infections that occurred as long as ten years ago!
- Need to characterize the current HIV epidemic in Rwanda so that we can **intervene**
  - focus resources; design new programs; evaluate new preventive interventions, e.g. microbicide trials



# Primary study objectives

- To estimate HIV-1 incidence in high-risk women in Kigali
- To assess Projet Ubuzima's ability to recruit and retain a cohort of 400 high-risk Rwandan women for one year in preparation for a microbicide Phase III trial

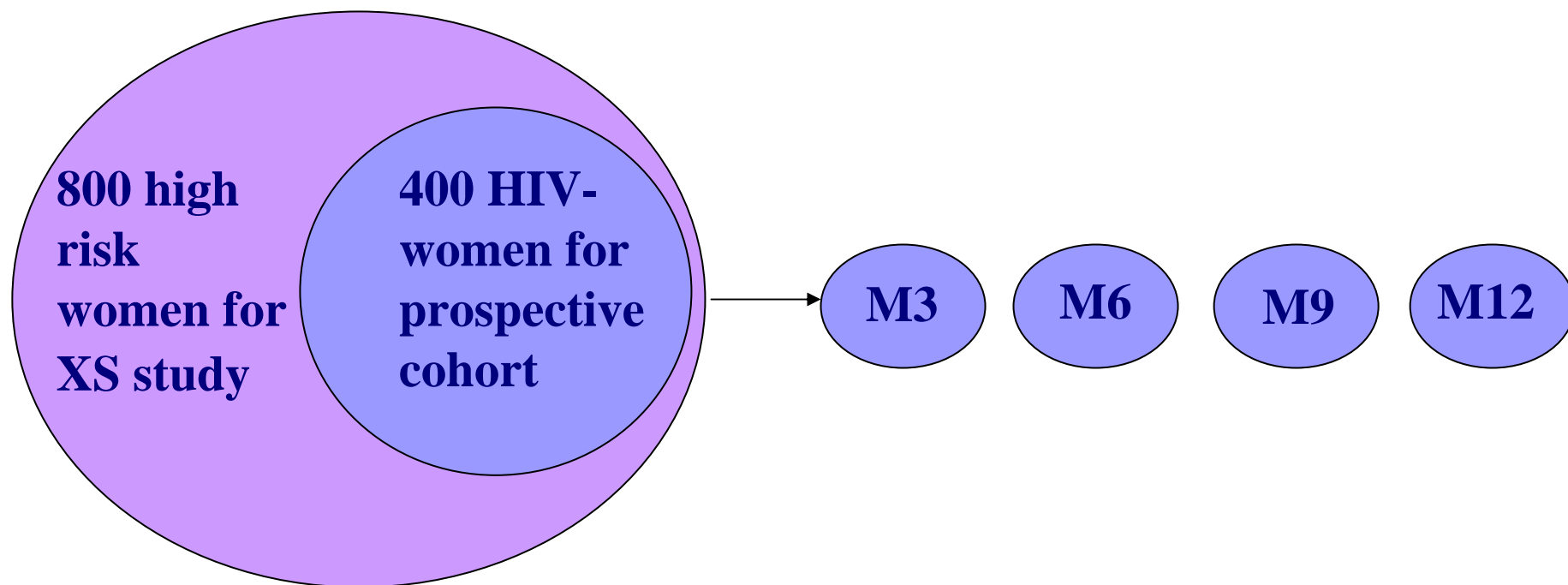
# Secondary study objectives

- To estimate HIV incidence in sub-groups
- To compare three incidence assays/methods, assess their validity in the Rwandan context
- To estimate prevalence and incidence of reproductive tract infections among high-risk women in Kigali

# Study design

- Cross sectional survey: **800 high-risk women**; eligible if:
  - $\geq 18$  years old
  - Willing and able to give written informed consent
  - Never before received a positive HIV test result
  - High-risk for HIV infection (defined as recent transactional sex and/or sexually active with multiple partners)
  - Not participating in another HIV intervention study
- Cohort: of 800 women in XS survey, **follow 400** women for 1 year; eligible for cohort if:
  - HIV-negative on rapid test at cross-sectional survey
  - Currently not pregnant
  - Not planning a pregnancy within the next year
- and 1,250 female VCT clients

# Study design:



- and 1,250 female VCT clients

# Strategies of recruitment

- Recruitment of HRW
  - via community mobilizers,
  - identified by community advisory group,
  - and in collaboration with local authorities.
  - Recruitment sessions in the community by Projet Ubuzima staff and community mobilizers.
- Recruitment since October 2006
- Cross-sectional survey of 1,250 female VCT clients initiated in August 2007

# Study procedures

- Eligibility screening
- Informed consent
- Counseling
- Free condoms
- HIV and HSV-2 testing
- Interview about sexual and other risk behavior.
  
- HIV-negative women who are enrolled in the cohort are also tested for other STIs.

# Preparedness for Cohort Study

## Lessons learnt:

- Recruitment and retention through community mobilizers was very successful



# Results-Current status:

- Cross-sectional survey of 800 HRW completed
- Cohort of 400 HRW ongoing
- Cross-sectional survey of 1,250 female VCT clients initiated in August 2007



# Prevalence and incidence

- HRW preliminary data (per end Sep 2007):
  - Majority identified as sex worker with 1-35 clients per week.
  - Majority said they used condoms with clients “often but not all the time”. Condom use with steady partners was low.
  - HIV prevalence in XS survey: 24.0%
  - HIV incidence in cohort: around **4 per 100 woman-years** of follow-up

# Prevalence and incidence(2)

- Prevalence of other infections at cohort baseline:
  - HSV2: 59.9%,
  - *T. vaginalis*: 17.2%,
  - Syphilis: 7.3% (testing for other infections ongoing)
- Pregnancy prevalence in XS survey: 7.4%

# Preparedness for Cohort Study

## Challenges:

Usual challenges of implementing these types of studies; no unusual challenges encountered.

- Access to study populations – gaining trust
- Proof of identification for each participant
- Effect of HIV prevention package on risk behavior (will be fully characterized in data analysis phase of the study)
- Ensuring and maintaining high quality laboratory testing

# The Way Forward

## Plans for the next 12 months:

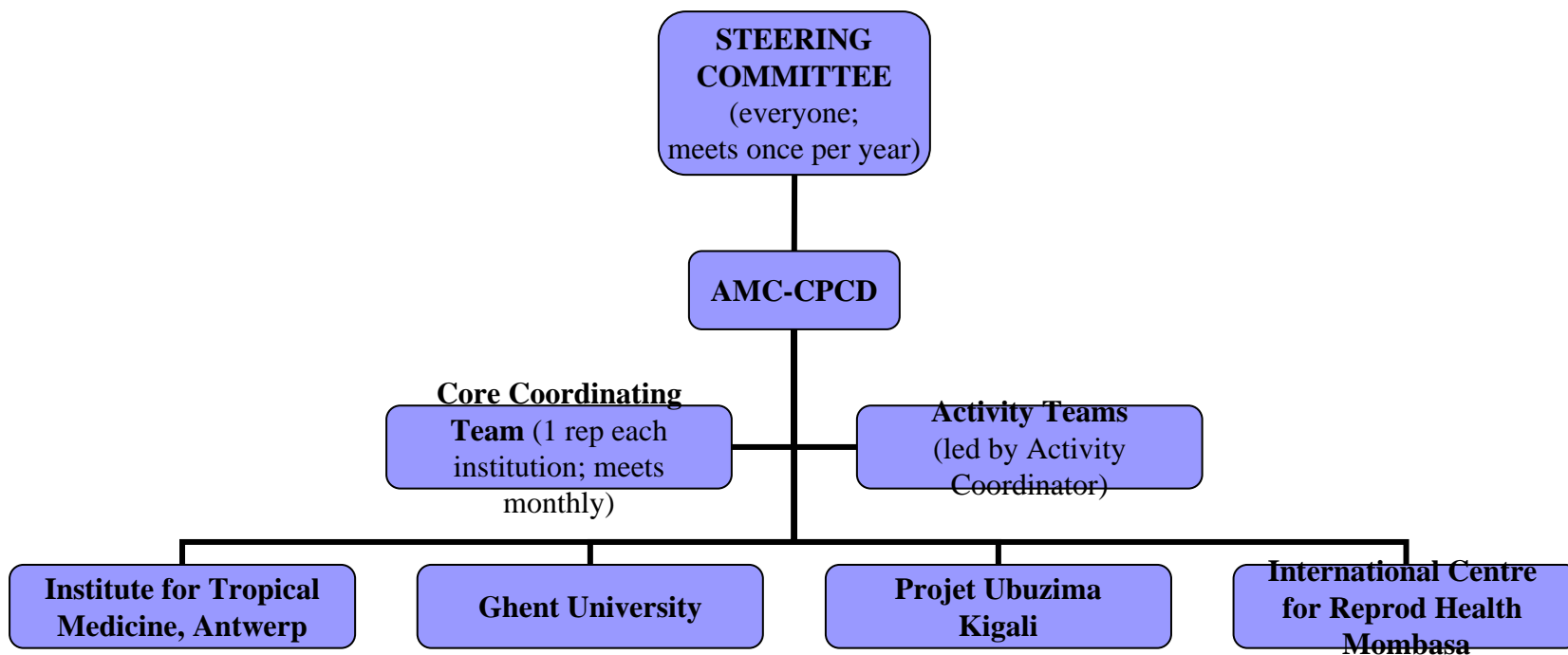
- Complete and analyze HIV incidence study
- Continue capacity-building activities within EDCTP and INTERACT programs
  - Strengthening of reproductive health services at referral sites (cervical cancer screening and treatment, management of reproductive tract infections, and family planning)
  - Clinical training in Colposcopy and cervical cancer screening and its management to Staff of Kigali Teaching Hospital has starting in November 2007

# Continue Capacity building(cont)

- Strengthening quality assurance systems for laboratory testing at the Projet Ubuzima and national reference laboratories
- Training of Rwanda National Ethics Committee (especially in microbicides area)
- Academic training of Projet Ubuzima collaborators in medical research

# Networking Activities

## EDCTP Grant Organizational Structure



# Conclusions

- After three years of preparations related to networking, capacity-building, and infrastructure development, Projet Ubuzima successfully completed its first Phase I microbicide trial and initiated a Phase III preparedness study.
- It is possible to recruit HRW in Kigali but close collaboration with local authorities and communities is needed.
- HIV prevalence in HRW in Kigali is at least three times as high as in the general female population of Kigali (DHS+ 2005, 8%).
- EDCTP grant collaboration with other European partners and the International Centre for Reproductive Health in Mombasa, Kenya, was successfully initiated.

# Acknowledgements







**We are ready**  
**for questions**  
**and**  
**collaboration**  
*Thank you*  
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