

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

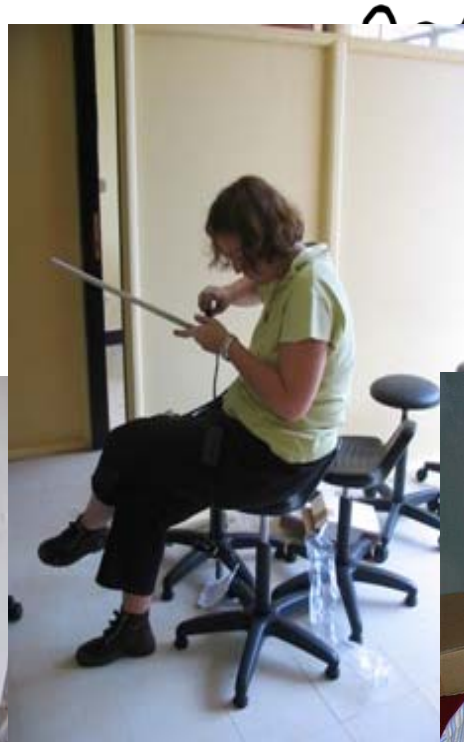
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Rwanda / Kigali



- 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

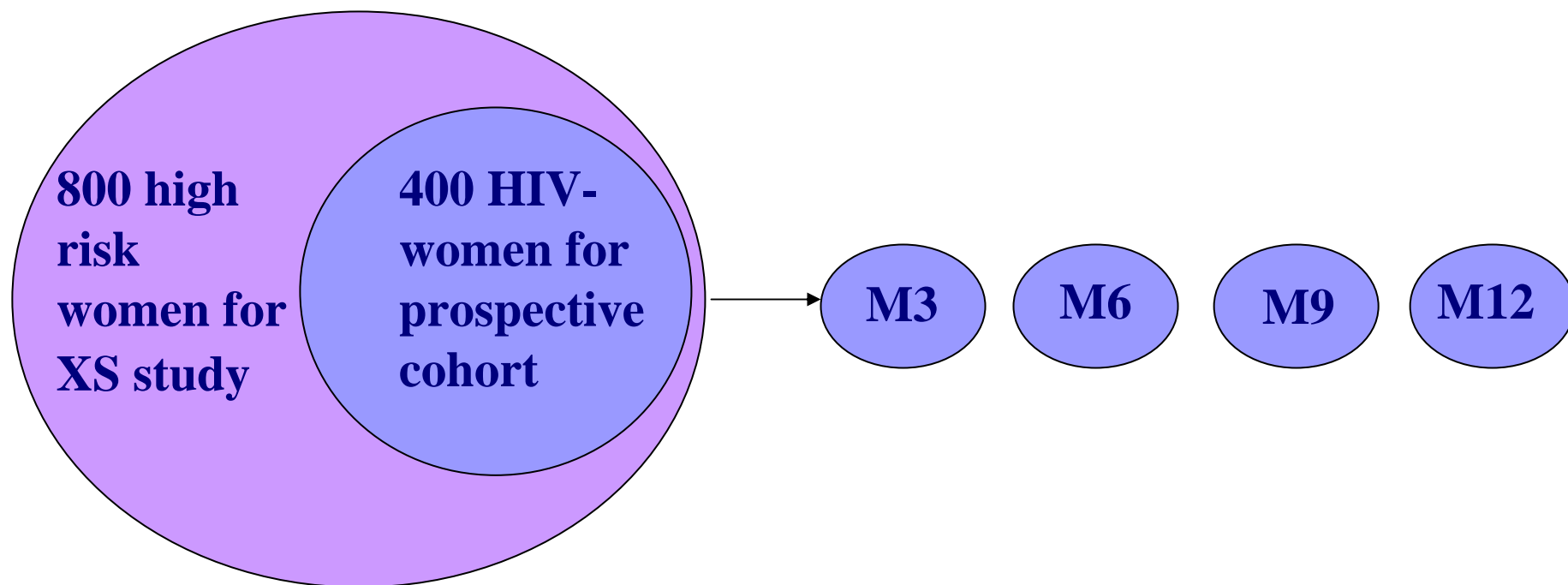
Secondary study objectives

- 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:
 - ≥ 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:

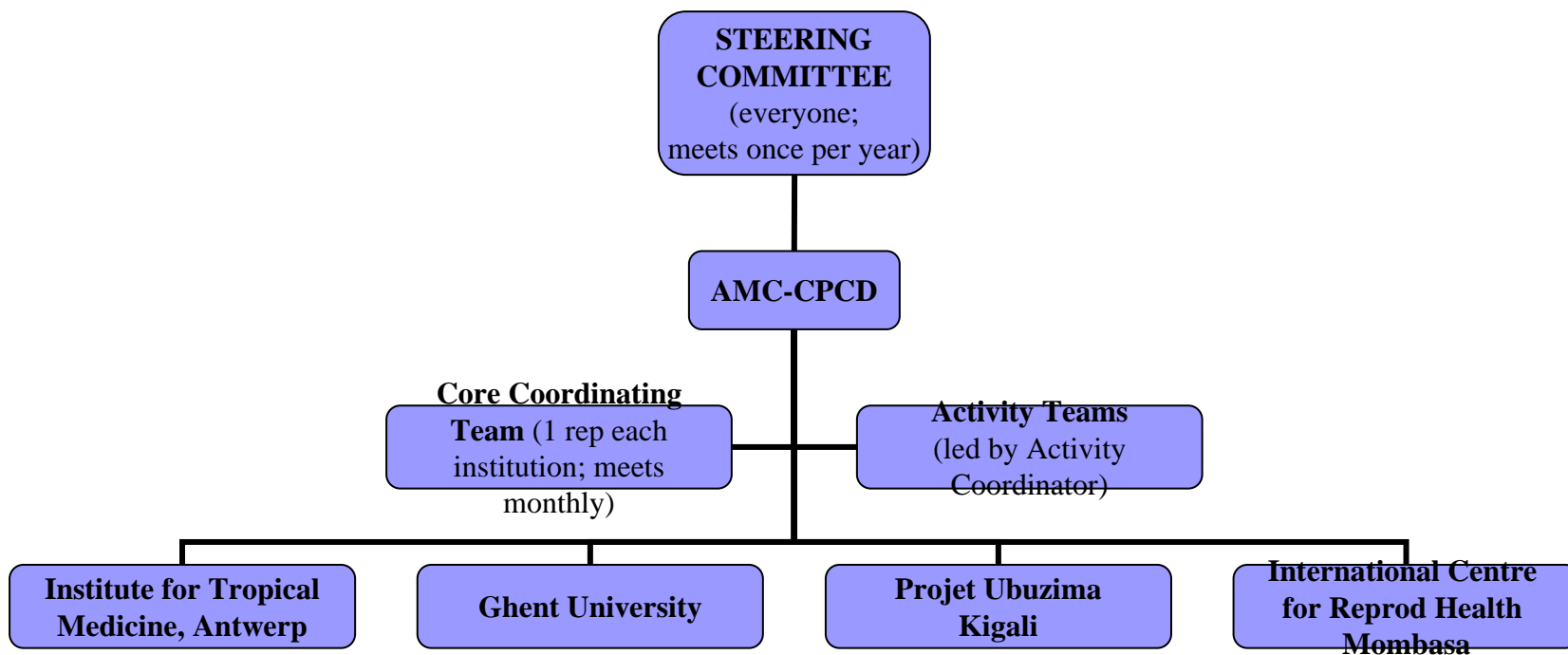
- Complete and analyze HIV incidence study
- Continue capacity-building activities within EDCTP and INTERACT programs
 - Strengthening of reproductive health services at referral sites (cervical cancer screening and treatment, management of reproductive tract infections, and family planning)
 - Clinical 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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