Preparations for HIV Vaccine Research at Zambia-Emory HIV Research Project (ZEHRP)

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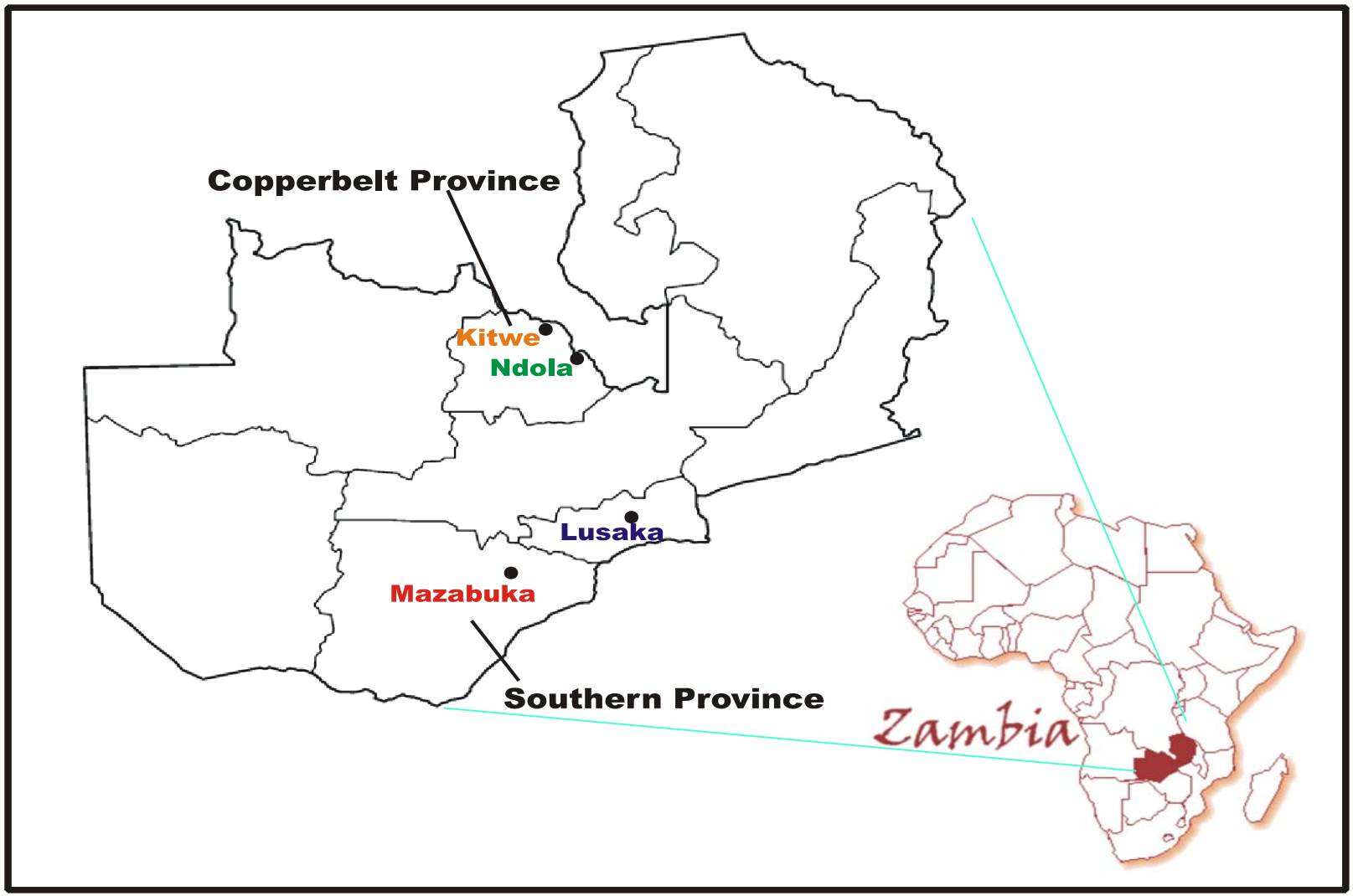
Overview of ZEHRP

- ZEHRP was established in 1994 in Lusaka with the aim of providing Couple VCT.
- 3 Couples VCT sites in Lusaka and other sites on the Copper-belt Province (Kitwe and Ndola) and in Southern Province (Mazabuka).
- HIV Discordant, cohabiting couples who reside in Lusaka and the Copper belt are invited to enroll in ongoing research studies
- Couples are followed at least quarterly and provided with risk reduction counseling and supplied with condoms to prevent HIV transmission to the negative partner.
- determine Virologic and immunologic correlates of HIV transmission if transmission occurs in spite of risk reduction counseling

ZEHRP sites


Copperbelt Province
Kitwe
Ndola
Lusaka
Mazabuka
Southern Province
Zambia

Objectives

Main Objective:

- To carry out research aimed at prevention of HIV infection and development of a safe and efficacious HIV Vaccine.

Specific Objectives:

- To adequately train staff and prepare site for clinical trials
- To establish baseline characteristics of study population
- To provide accurate information to potential trial participants
- To recruit and retain vaccine trial participants
- To expand cohort of HIV discordant couples for future vaccine trials in at risk individuals

Training of staff

- Local requirements- attend Good Clinical Practice (GCP) and Good Clinical and Lab Practice (GCLP)
- All of the staff also completed Collaboration IRB Training Initiative (CITI) course for human rights protection and are expected to renew every two years
- DAIDS policy training e.g. Expedited Adverse Event (EAE) training.
- Clinic staff trained on Basic Life Support

Staff training on Basic Life Support

GCP and GCLP training

Infrastructure development:

Development of an additional site where vaccine trials are co-ordinated

- Internationally accepted laboratory standards
- Pharmacy for vaccine storage and preparation has been put in place

Protocol D

- Protocol D was a cross sectional observational study to establish Clinical Laboratory reference values
- 400 healthy HIV negative individuals (200 males and 200 females) between 18 and 60 years of age were recruited from Couples VCT and discordant couple cohort and enrolled into the study.
- Study close out for all participating sites was March 2007.

Present and Future HIV Vaccine Trials

A002

Preparation for future vaccine trials

Couples Voluntary Counseling and Testing (CVCT) Centers

Mobile CVCT

400 enrolled in Protocol D

HIV negative partners

Discordant Couples Cohort

Information Sessions including
- basic clinical research concepts
- information on HIV vaccines
- effective contraception and circumcision

A002

A Phase II Placebo-controlled double-blind trial to evaluate safety and immunogenicity of tgAAC09, an HIV Vaccine containing Clade C gag-PR-ΔRT DNA In An Adeno-Associated Virus (AAV) Capsid, Administered twice, at Three Dosage Levels and Two Dosing Intervals.

Enrolled = **16**

V002

A Phase II, Randomized, Placebo-Controlled Double blind trial to evaluate the Safety and immunogenicity of a Multi-clade HIV- 1 DNA Plasmid Vaccine followed by Recombinant, Multi-clade HIV-1 Adenoviral vector Vaccine in Healthy adults volunteers at Risk for HIV Infection

PAVE 100

A Phase IIB Randomized, Placebo-Controlled, International Clinical Trial to Evaluate the Efficacy, Safety and Immunogenictiy of a Multi-clade HIV-1 DNA Plasmid vaccine, RC-HIVDNA016-VP, Followed by a Multi-clade Recombinant Adenoviral Vector Vaccine VRC-HIVADV014-00-VP, in participants at Risk for HIV-1 infection

Lessons Learnt

- Enrolling participants from existing cohorts into vaccine trial is a good strategy to improve retention and follow up rates.
- Collection and update of locator information (i.e. Address and telephone numbers of participants) has assisted greatly in follow up of participants.
- Experience gained and lessons learnt from the previous smaller vaccine trial will help with upcoming larger trials.
- Information sessions given in form of focus group discussion have facilitated the informed consent process at screening visits

Lessons Learnt(2)

- Information sessions have allowed enough time for potential participants to decide about their choice to participate or not
- Information sessions have also helped the study site staff to identify which concepts of HIV vaccine clinical trials need emphasis to aid understanding
- Involvement of the Community Advisory Board has helped a great deal in ensuring cooperation from participants

Future perspectives

- **Expansion to involve 2 new clinical trial sites in the Copper-belt for the upcoming vaccine trials to be conducted in Lusaka and the Copper-belt.**
- **Ramp up of Couples VCT activities to increase cohort of discordant couples:**
  - **Mobile Units to provide CVCT**
  - **Expansion of CVCT to district clinics in Lusaka**
  - **Revert to old system of providing CVCT at sites 6 days a week instead of the current 3 days (once maximum capacity is reached during the current 3 days)**
  - **Training and enrolling new Influential Network Agents (INAs)**

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International AIDS Vaccine Initiative

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