



# Meeting the challenges of recruiting female participants and avoiding pregnancies during HIV prevention trials

K.Kayitenkore, E.Karita,  
C.Mambo, B.Bekan, C.Schmidt,  
S.Allen and the RZHRG

# Issues

- HIV vaccine trials need to recruit representative samples of the population
- Recruitment of women may be challenging
- Pregnancies often result in discontinuation of study product administration and reduction of study statistical power

# Barriers to female participation



Enrolling women into HIV preventive vaccine trials: An ethical imperative but a logistical challenge  
Mills E, Nixon S, Singh S, Dolma S, Nayyar A, et al. (2006) PLoS Med 3(3): e94.

# Location of PSF site and other IAVI partner sites in Eastern/Southern Africa

Projet San Francisco  
Kigali/Rwanda



# IAVI V001: Phase I trial with VRC vaccine candidates

## Inclusion criteria

- Age 18 to 50 years
- Sexually active female of child bearing potential, using or agree to use effective method of contraception

## Exclusion criteria

- Pregnancy, planning a pregnancy, or lactating

Goal: enroll at least 30% women

# Methods

- Concordant HIV negative couples from Couples Counseling and Testing Centres (CVCT), and an existing cohort invited to information sessions
- On site family-planning and counseling
- Emphasis on long-acting user independent methods (Depo-Provera, IUD, implants)
- Discontinuation of breastfeeding considered for eligible women with children older than 2 years
- Informed consent obtained from both partners
- Childcare provided at site

# Results

274 individuals (134 M, 140F)  
attended information  
sessions

181 individuals (111M, 70F)  
assessed for eligibility

57 individuals enrolled  
(36 M, 21F) into V001

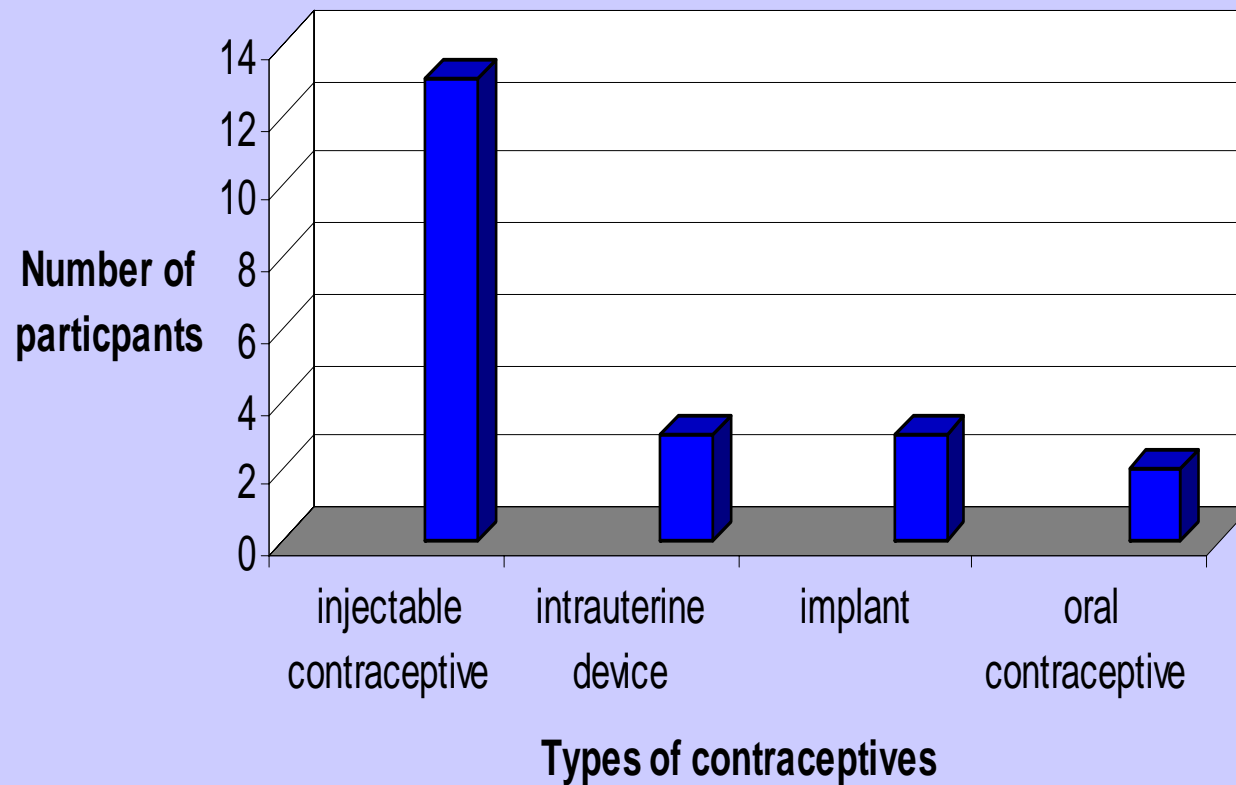
124 individuals (75M, 49F)  
did not meet inclusion criteria  
4 women declined contraception  
5 were pregnant at screening  
2 were breastfeeding  
2 did not return for enrollment

## Results (2)

- Mean age of female participants: 31 yrs
- 4 women started on Depo-Provera 3 wks before enrolment
- 2 women using oral contraceptives for more than a year maintained same method
- 2 females discontinued breastfeeding of children older than 2 years

# Contraceptive methods of choice

Participants contraceptive choices



## Results (3)

- All female participants completed their vaccination schedule
- Retention: 100%
- No pregnancies during the trial
- 5 of 21 women discontinued contraception after study end
- 3 currently pregnant

# Lessons learned

- Involving men in decision-making and family planning education lessens barriers to women participation
- Even where family planning uptake is low, female participants do remain on contraception for the duration of the trial
- Providing on-site family planning allows better follow-up and adherence
- Recruiting, retaining women and avoiding pregnancies is feasible

# Next steps

- Sustain recruitment of couples for future HIV vaccine trials
- Extend Couples HIV Voluntary Counseling and Testing across Rwanda
- Train counselors in the region
- Promote Family Planning and more importantly long-acting user independent methods in all CVCT centers



# International AIDS Vaccine Initiative

iAVI gratefully acknowledges the generous support provided by the following major donors.\*



Alfred P. Sloan Foundation  
 Basque Autonomous Government  
 Becton, Dickinson and Company (BD)  
 Bill & Melinda Gates Foundation  
 Broadway Cares/Equity Fights AIDS  
 Canadian International Development Agency  
 Continental Airlines  
 Crusaïd  
 Deutsche AIDS-Stiftung  
 European Union  
 Google Inc.  
 The Haas Trusts  
 Irish Aid  
 The John D. Evans Foundation  
 Kathy Bole & Paul Klingenstein  
 Merck & Co., Inc.

The Netherlands Ministry of Foreign Affairs  
 The New York Community Trust  
 Norwegian Royal Ministry of Foreign Affairs  
 Pfizer Inc  
 The Rockefeller Foundation  
 Royal Danish Ministry of Foreign Affairs  
 The Starr Foundation  
 Swedish International Development Agency  
 Swedish Ministry of Foreign Affairs  
 U.K. Department for International Development  
 Until There's a Cure Foundation  
 The U.S. President's Emergency Plan for AIDS Relief through the U.S. Agency for International Development  
 The World Bank/Global Forum for Health Research



And many other generous individuals from around the world.

\* As of 11/06