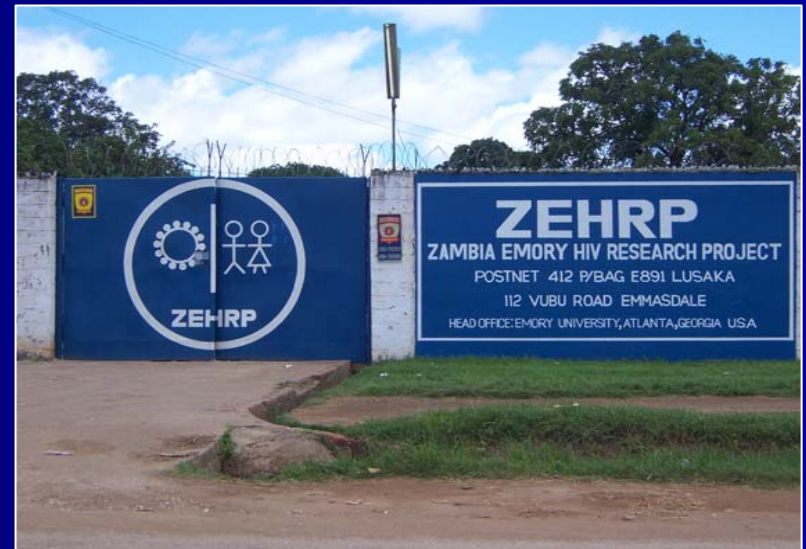


Background

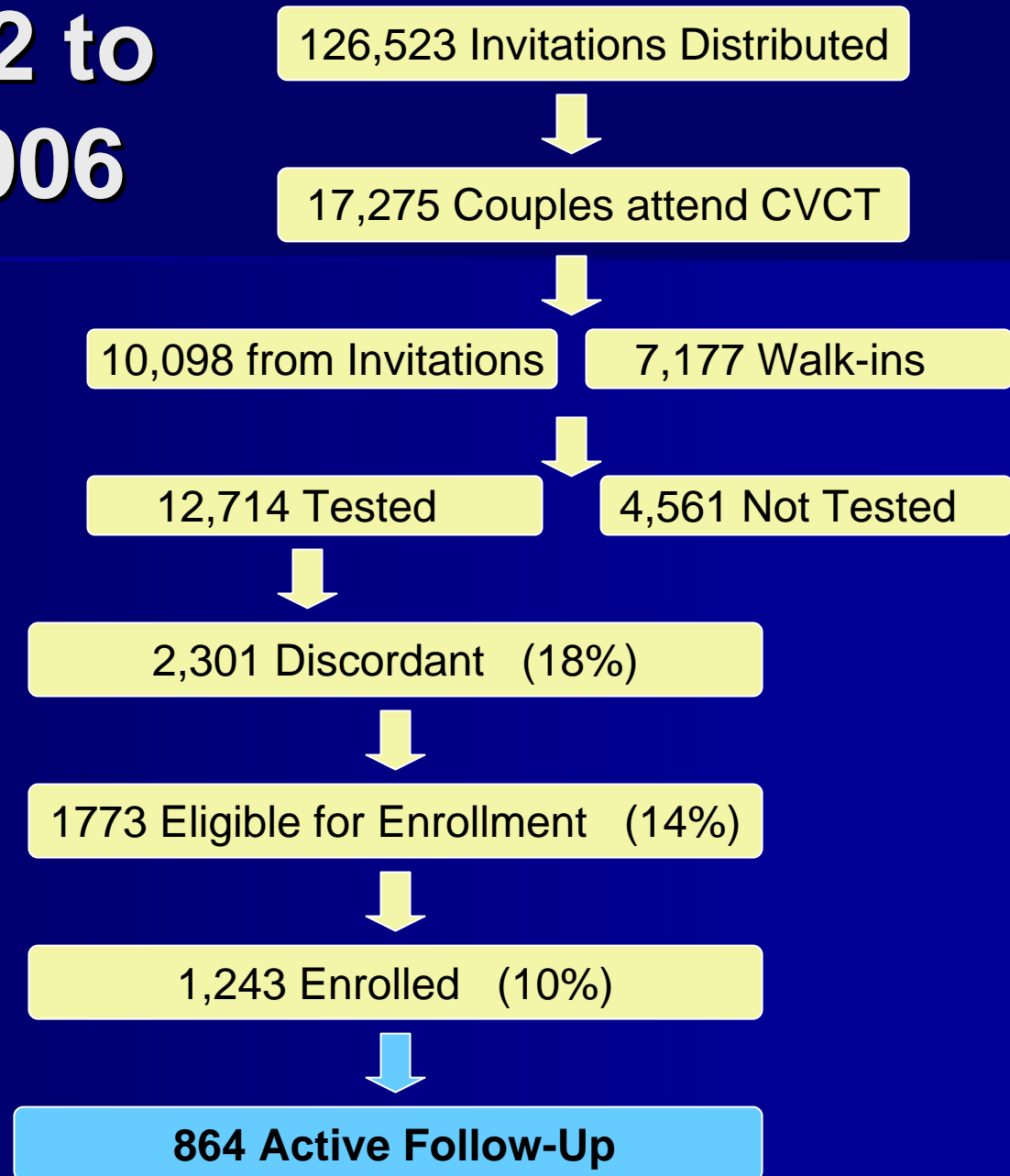
- In African cities, an estimated two-thirds of new HIV infections result from transmission within married or cohabiting couples
- Couples Voluntary Counseling and Testing (CVCT) has been shown to reduce HIV transmission in discordant couples
- Discordant couples remain at risk despite counseling
- Large cohorts of high-risk individuals are needed for HIV vaccine efficacy trials
- A preventive vaccine could reduce incidence in discordant couples

Methods

- ZEHRP established in 1994, ZEHRP-IAVI vaccine center established 2004
- 3 CVCT centers
- Influence Network Agents distribute invitations to cohabiting couples
- Couples tested together
- Eligible discordant couples enrolled in prospective cohort follow-up
- Couples recruited from cohort for preparatory activities and clinical trials



**Jan 2002 to
June 2006**

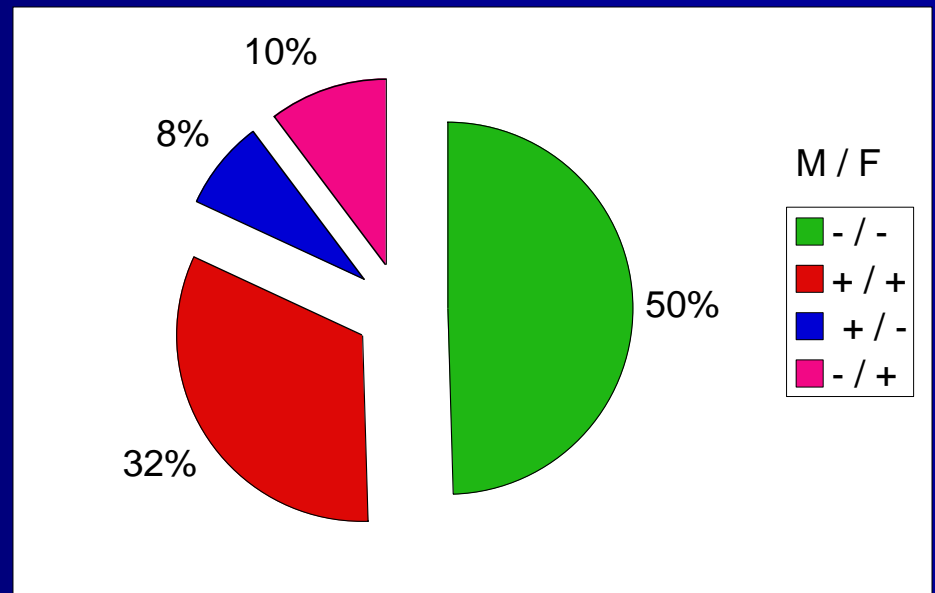


HIV status at CVCT

Tested 12,741 couples

18% couples discordant

- 8% man HIV+
- 10% woman HIV+



Cohort Eligibility Criteria

- Eligibility Criteria for Cohort Enrollment
 - Discordant HIV test results
 - Cohabiting for at least 3 months
 - Woman 16 – 45 years, man 16 – 65 years
 - HIV+ partner not on ARVs/Stage IV
 - Plan to stay in Lusaka for at least 12 months
 - Willing and able to participate
 - Not enrolled in another study

Demographics at enrollment

Demographic Characteristics of CVCT Clients Enrolling in HIV Research (23 July 2002 - 01 October 2005)

Characteristic	Men (N = 947)		Women (N = 947)	
	n	%	n	%
Age (years)				
Range	19-65		16-49	
Median	34.0		28.0	
Mean	35.4		29.0	
Occupation				
Does not work for money	131	14%	483	51%
Work for money	816	86%	464	49%
Years cohab with partner in project				
0-2	240	25%		
3-5	275	29%		
6-9	166	18%		
10+	266	28%		
More than one wife				
Yes	17	2%		
No	928	98%		

Language and Literacy at enrollment

Demographic Characteristics of CVCT Clients Enrolling in HIV Research (23 July 2002 - 01 October 2005)

Characteristic	Men (N = 947)		Women (N = 947)	
	n	%	n	%
Tribal/Linguistic Group				
Nyanja	378	40%	380	40%
Bemba	251	27%	293	31%
Tonga	80	8%	53	6%
Other	238	25%	220	23%
Understand Nyanja				
Easily	830	88%	835	88%
With difficulty	113	12%	107	11%
Not at all	4	0%	5	1%
Read Nyanja				
Easily	395	42%	195	21%
With difficulty	384	41%	238	25%
Not at all	168	18%	514	54%
Understand English				
Easily	574	61%	224	24%
With difficulty	331	35%	400	42%
Not at all	42	4%	323	34%
Read English				
Easily	547	58%	188	20%
With difficulty	303	32%	334	35%
Not at all	97	10%	425	45%

Cohort Follow-up

Study Visit Schedule:

- HIV- partner seen quarterly
- HIV+ partner seen annually

Services offered:

- Repeat HIV testing for negative partner
- STI screening and treatment
- Counseling on HIV risk reduction, condom use, family planning
- Medical Insurance card for district clinics
- Hospital referrals



Cohort Attrition

- Of 1243 enrolled, 864 couples currently active in follow-up
 - 70%-80% follow up after 12 months
- Reasons for attrition:
 - Death, moved or unable to locate, no interest, separation
 - HIV+ partner initiated on ART (n= 176)
 - HIV seroconversion

HIV Seroconversion

Seroconversion rate per 100 couple-years

	N	Rate	95% C.I.
Male	120	6.78	5.62 – 8.11
Female	169	9.86	8.43 – 11.5
<i>Total</i>	<i>289*</i>	8.30	7.37 – 9.31

85% of transmissions are linked to cohabiting partner

* Accumulated in 10 years of follow-up

Conclusion

- It is possible to recruit and retain HIV discordant couples for Phase IIb and III clinical trials
- Identifying discordant couples will require substantial expansion of CVCT promotion and services
- Screening from an existing cohort benefits from 'run in' design and reduces loss to follow-up
- The use of couples may improve the recruitment of female volunteers into vaccine trials

Thank you

