HPTN 035

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On behalf of the HPTN 035 Protocol Team

MTN Annual Meeting

21 April 2008

Primary Objectives

- To evaluate the safety of BufferGel and 0.5% PRO 2000/5 Gel (P) when applied intravaginally by women at risk for sexually-transmitted HIV infection

- To estimate the effectiveness of BufferGel and 0.5% PRO 2000/5 Gel (P) in preventing HIV infection

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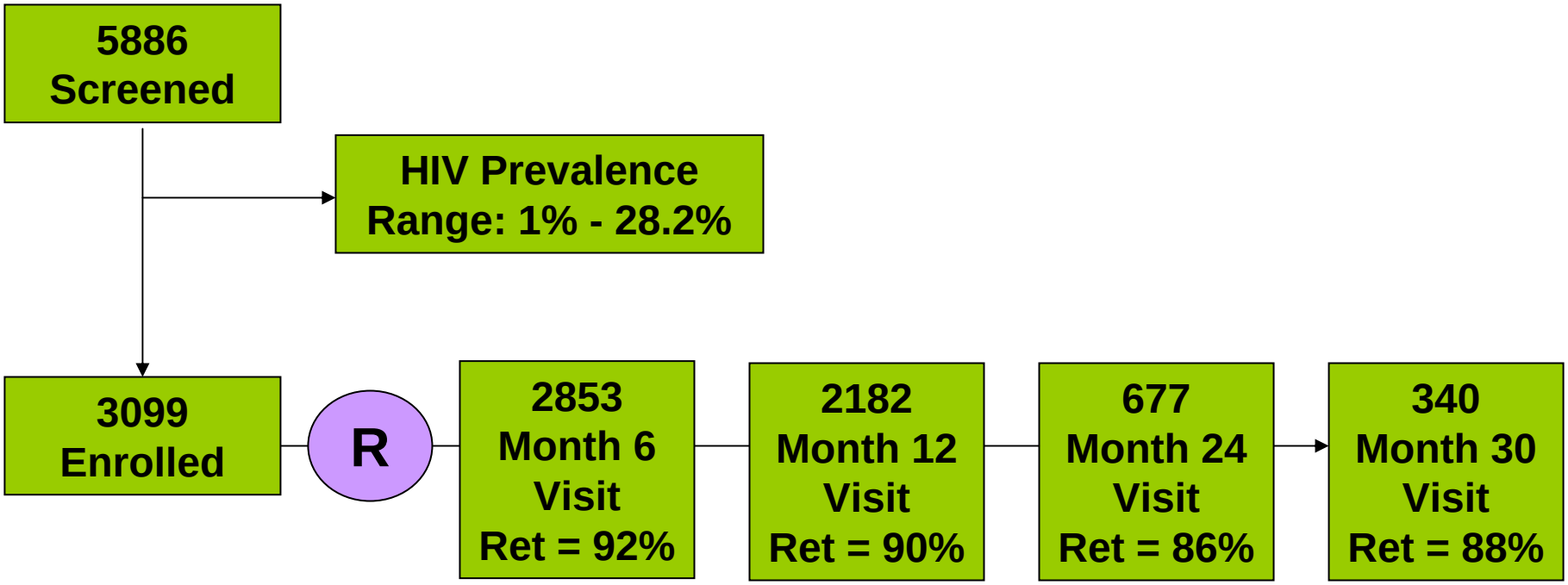
Accrual and Follow-up



20 participants have not returned for any follow-up visits
32 participants terminated from the study prematurely
Most common reasons for early termination are:
participant refusal (n=15), relocation (n=8), & death (n=6)

Baseline Characteristics

	Mean Age	% Some Sec Ed	% Married	% One Partner
Blantyre	25.9	30	95	100
Durban	25.2	93	18	96
Harare-Chitungwiza	26.3	93	96	100
Hlabisa	25.3	78	9	99
Lilongwe	27.3	16	99	100
Lusaka	23.0	44	81	97
Philadelphia	26.3	99	14	73

Mean # vaginal sex acts in past week = 2.9

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Adherence to Gel Use

Vaginal Sex Acts in the Last Week Excluding Visits on Product Hold

	With Gel	Without Gel	Total
With Condom	12,767	1,945	14,712
Without Condom	4,909	1,099	6,008
Total	17,676	3,044	20,720

29% of sex acts did not include condoms
82% of condomless sex acts included gel

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Some HPTN 035 Numbers …

- **419,660: number of gel applicators dispensed**
- **319,023: number of CRF pages received by SCHARP**
- **17,917: number of adverse events reported**

Pregnancies and Outcomes

- 480 pregnancies to date

- Outcomes to date:
  - 187 (54%) full term live births
  - 19 (5%) premature live births
  - 40 (12%) therapeutic/elective abortion
  - 88 (25%) spontaneous abortions
  - 12 (4%) fetal deaths/still births
  - 1 (<1%) ectopic pregnancy
  - 144 pregnancies currently ongoing

Effectiveness and p Values

- **Smallest level of effectiveness with one-sided $p < 0.025$ = 33%**

- **Smallest level of effectiveness with one-sided $p < 0.0025$ = 44%**

Estimated Timeline…

- Initiate close-out visits : 1 June 2008
- Complete close-out visits : mid-Sept 2008
- Complete data cleaning : ~ November 2008
- Deadline for data-lock : 1 December 2008
- Primary results meeting : ~ December 2008
- Release primary results to team : ~Dec 2008
- Release primary results to public : early 2009

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