

ARV Therapies and Therapeutic Strategies

REPORTING ON IAS 2015

Comprehensive Expert Review and Discussion of Key Presentations

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HPTN 067 ADAPT – Daily vs Intermittent PrEP in:

Cape Town

R. Grant, Gladstone Institutes, United States (Abstract MOSY0103)

Harlem

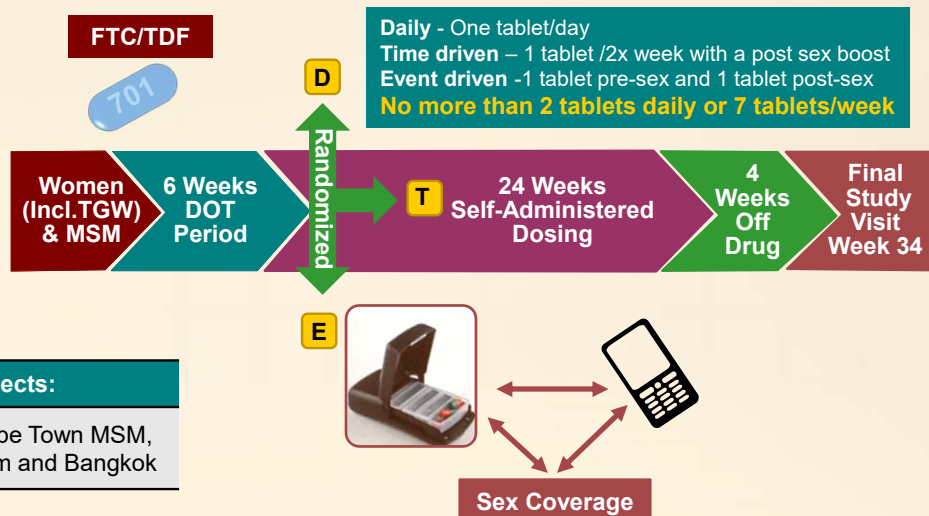
S. Mannheimer, Columbia University, United States (Abstract MOAC0305LB)

Thailand

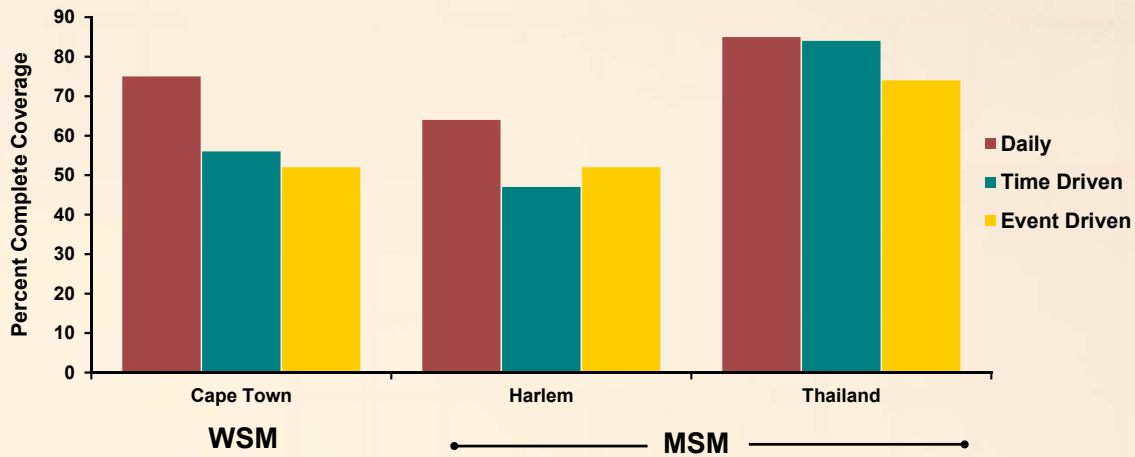
T. Holtz, Thailand Ministry of Public Health, US CDC, Thailand (Abstract MOAC0306LB)

HPTN 067: Daily vs Intermittent PrEP Trial Design

- ❖ **Primary Outcome: Sex Coverage with Drug:**
≥1 dose within 4 days of sex and ≥1 dose within 24 hours after sex



HPTN 067: Primary Outcome



- ❖ 1^o Outcome: Percent Complete Coverage by PrEP Strategy
- ❖ Post Sex Dose Most Frequently Missed

Grant R, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0103; Holtz T, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0104; Mannheimer S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0104.

HPTN 067: Daily vs Intermittent PrEP Waning Adherence Over Time in Cape Town Cohort

Percent with TFV-DP >9.1 fmol/M PBMC*

Cape Town Site	Time Period	Daily	Event Driven	Time Driven
	Week 10 (with sex in the past 7 days)	81% (33/41)	52% (12/23)	54% (20/37)
Week 30 (with sex in the past 7 days)	66% (19/29)	46% (11/24)	32% (10/31)	
Thailand Site	Time Period	Daily	Event Driven	Time Driven
	Week 10 (with sex in the past 7 days)	100% (33/33)	97% (28/29)	93% (28/30)
Week 30 (with sex in the past 7 days)	91% (21/23)	95% (18/19)	86% (12/14)	

*Indicative of two doses per week

Grant R, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0103; Holtz T, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0104;

HPTN 067: Daily vs Intermittent PrEP Infections During the Study

Site	Period of Treatment Phase			Total	
	DOT	Randomization Arm			
		Daily	Time		Event
Cape Town	2	2	2	1	7
DOT phase – no drug detected (2); Randomization - negligible levels (3), low detectable (2)					
Harlem	1	1	-	-	2
DOT phase – no drug level; Randomization – no drug level seroconversion, very low TDF in DBS, none in plasma					
Thailand	2	-	-	-	2
DOT phase – low FTC, no TFV in plasma; low detectable FTC and TFV in DBS					

Grant R, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0103; Mannheimer S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0104.