Accomplishments of CAT

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CAT Meeting

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The MTN

- First funded in 2006- now in its 10th year of funding (competitively renewed in 2013; funded through November 30, 2020)
- Have enrolled about 10,000 female participants into phase 1-3 clinical trials

VOICE
VAGINAL + ORAL INTERVENTIONS TO CONTROL THE EPIDEMIC

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

HOPE
HIV Open-label Prevention Extension
Out of ASPIRE, there is HOPE

MTN
microbicide trials network

The Requirement for Contraception in MTN Studies

- Why? All of the products we evaluate are "investigational products"
  - This means that they have not been approved for use for the prevention of HIV
  - Most have had little or no safety testing in pregnant women
  - We do not know whether the products will be safe for women and their babies
- Outcome: all women are **required** to be on active contraception when they enroll

How is This Different from "Normal" Provision of Family Planning?

- Women who have joined the studies have been required to be on effective contraception at study entry.
  - About half of these women were not on effective contraception at the time of screening
- Many women are initiating the use of the investigational product and contraception at the same time.
- Women were provided with whatever was available at the clinic, usually DMPA or pills

CAPRISA Contraception Use

Contraception	Rural (n=611)	Urban (n=278)	p-value	Tenofovir (n=445)	Placebo (n=444)	p-value
Injectable	83.1	79.9	0.606*	80.7%	83.6%	0.288*
Oral	14.6	17.6		16.4%	14.6%	
Tubal Ligation	2.1	2.5		2.9%	1.6%	
Hysterectomy	0.2	0.0		0	0.2%	

*** p-value applicable to comparison for all forms of contraception**

TDF2 Study Group
Botswana Contraception Use

Contraception	TDF-FTC (N=611)	Placebo
Oral	56.4%	61.7%
Injection or Implant	37.5%	32.5%
No Contraception	5.4%	4.7%
Other Method	0.7%	1.1%

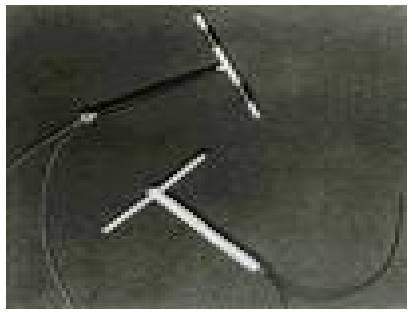
FEM-PrEP Study Group
Kenya, South Africa and Tanzania Contraception Use

Contraception	TDF-FTC (N=1062)	Placebo (N=1058)	All Participants (N=2120)
Oral pills	32.0%	28.2%	30.1%
Injectable	63.6%	68.6%	66.1%
Implant, IUD, or female sterilization	4.4%	3.2%	3.8%

Washington
WASHINGTON·UNIVERSITY·IN·ST·LOUIS

Contraceptive Cohort Study

- Remove financial barriers to most effective long-term reversible methods
- Recruit 10,000 participants over 4 years
  - No-cost contraception
  - Participant choice
    - 2-3 years follow-up
    - Assess continuation, satisfaction
  - Population outcomes:
    - Unintended/teen pregnancy



CHOICE: Inclusion Criteria

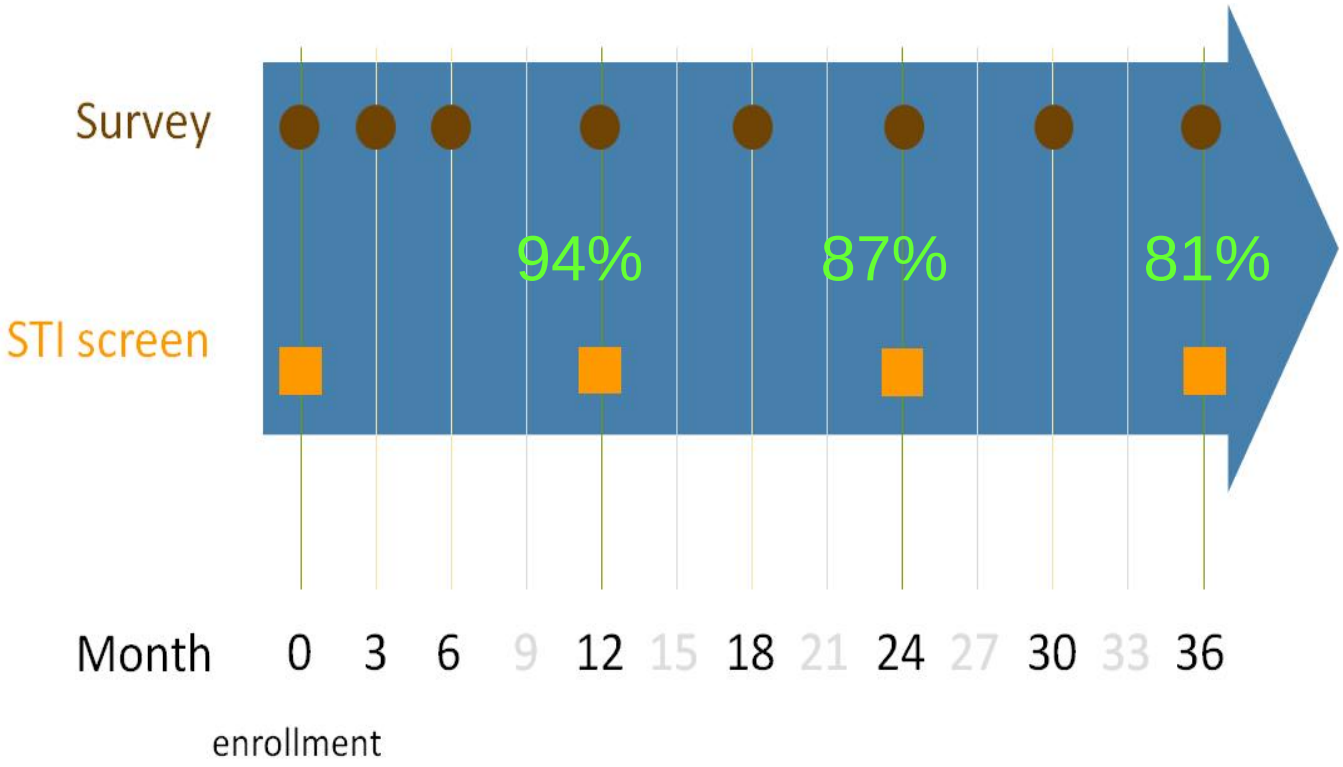
- 14-45 years
- Primary residency in St Louis City or County
- Sexually active with male partner (or soon to be)
- Does not desire pregnancy during next 12 months
  - Desires reversible contraception
- Willing to try a new contraceptive method

Contraceptive CHOICE Project: Study Details

ELIGIBLE

Tiered Contraceptive Counseling

LNG-IUS
Cu-IUD
Implant
DMPA
Pills
Patch
Ring
Other



Secura G, Am J Obstet & Gynecol 2010
Madden T, Contraception 2012

Baseline Characteristics

Age (years)	N	%
14-17	485	5.2
18-20	1548	16.7
21-25	3559	38.5
26-35	3029	32.7
36-45	635	6.9

Race	n	%
Black	4660	50.6
White	3861	41.9
Other	693	7.5

Baseline Characteristics (N=9,256)

SES	n	%
Public assistance	3442	37.2
Trouble meeting basic needs	3639	39.3

Insurance	n	%
None	3782	41.1
Private	3957	43.1
Public	1455	15.8

12- & 24-Month Continuation: Overall Cohort

Method	12-Month (%)	24-Month (%)
LNG-IUS	87.5	78.9
Copper IUD	84.1	77.3
Implant	83.3	68.5
Any LARC	**86.2**	**76.6**
DMPA	56.2	38.0
OCPs	55.0	43.5
Ring	54.2	41.1
Patch	49.5	39.9
Non-LARC	**54.7**	**40.9**

Peipert, et al. Obstet Gynecol 2011; O' Neil , et al. Obstet Gynecol

CAT Lessons

- When offered a broader range of contraceptive choices in ASPIRE, many women chose LARCs: implants and IUCDs.
  - Oral contraceptive use decreased
- Site staff can safely insert IUCDs
- Discontinuation rates appear to be similar to published data
  - Is discontinuation “bad”?
  - How can we increase honesty about pregnancy intentions?
  - Should we develop “tiered” counseling?