



But, will they use it?

Examining Microbicide Use in the Context
of the HPTN 059 Tenofovir Gel Safety Trial

Betsy Tolley, Ph.D.
Family Health International

Why examine use without a proven product?

- Reasons to believe self reported use data are inaccurate

But...

- Data on use behavior essential to interpreting trial results, including:
 - determination of effectiveness
 - generalizability to other populations

What do we know about use behavior?

Taking stock of the field...

Within clinical trials:

- Perfect adherence not achieved
- Acceptability generally high
- Influence of trial context on use not examined

Acceptability Research:

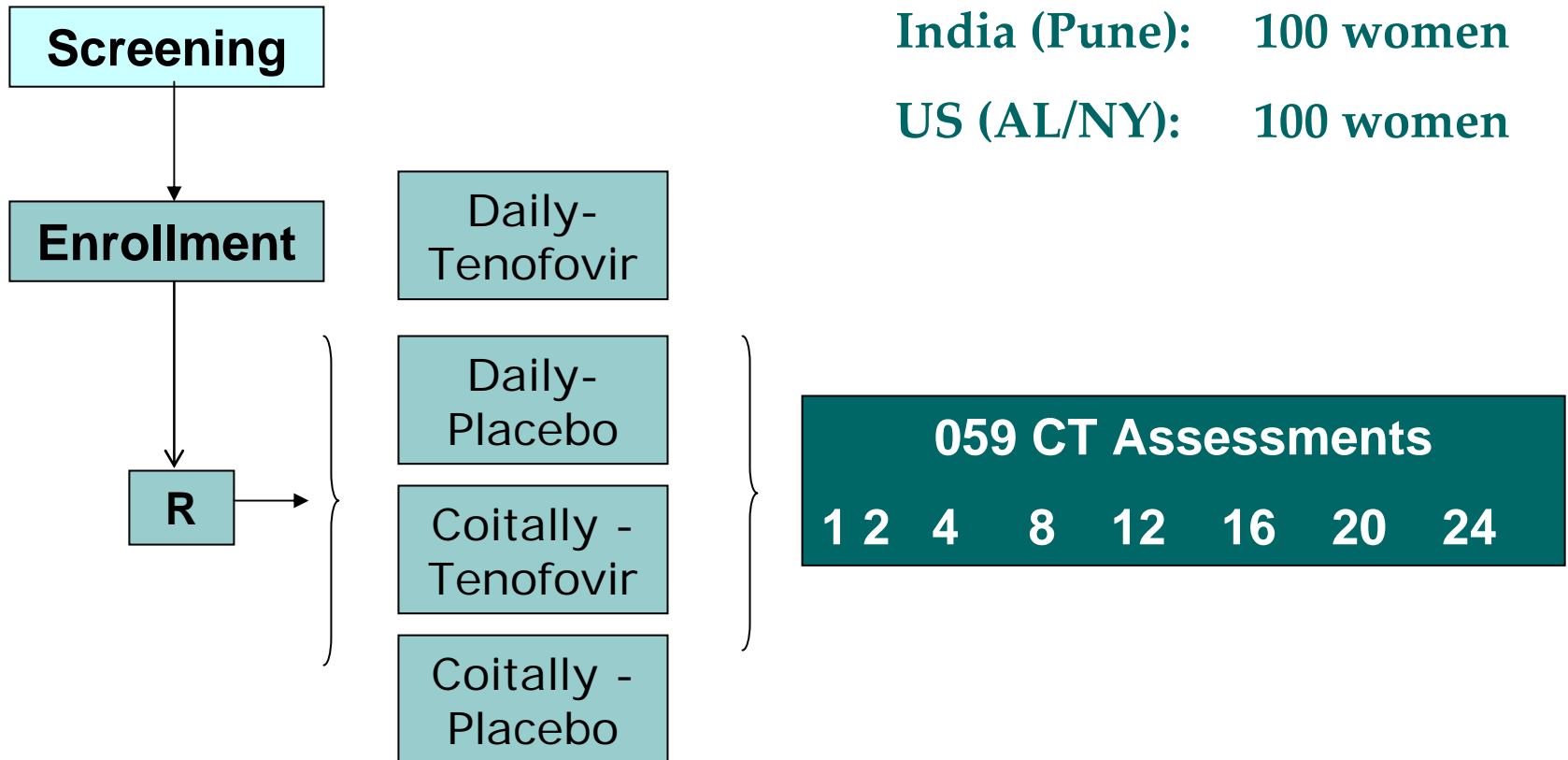
- Product attributes
- Perception of Risk
- Partners
- Power
- Privacy



Examining Microbicide Use: an integrated approach

- I. HPTN 059 trial measures
- II. Enhanced acceptability in Pune, India site
- III. Qualitative, in-depth interviews in Pune and US sites

I. HPTN 059: Expanded Safety and Acceptability of Tenofovir 1% Gel



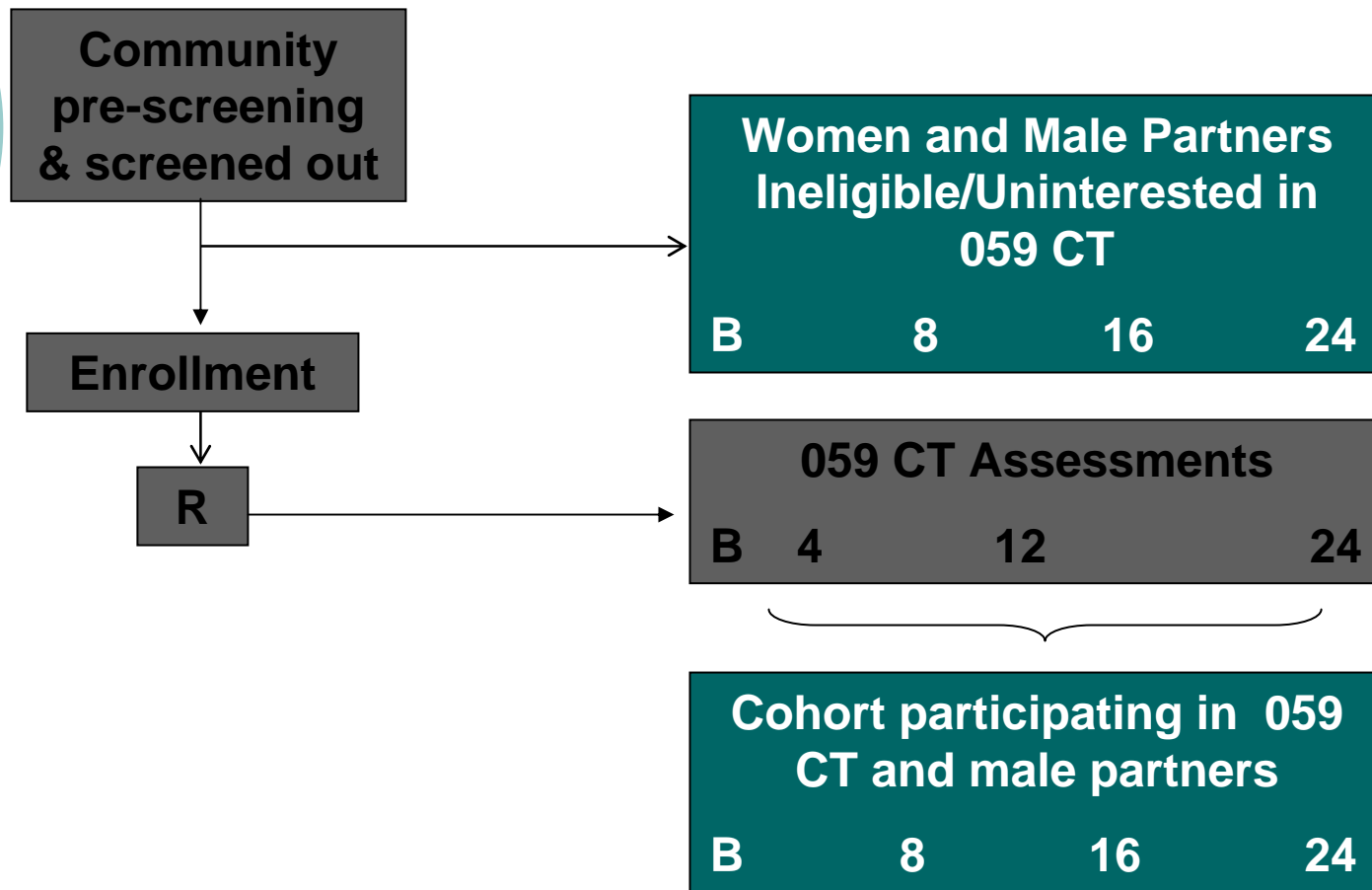
Clinical Trial Acceptability and Use Measures

- Sexual Risk Behavior
 - Vaginal sex (last week, last time)
 - Anal sex (ever, last week)
 - Number of sexual partners (last month)
- Adherence
 - % sex acts with gel and/or condom use
 - Correct use: timing of insertion, douching, other vaginal product use
- Acceptability
 - Product attributes
 - Sexual pleasure
- Study Burden
 - Problems: wait time, reimbursement, following instructions, other

Research Questions:

1. How consistently/correctly do participants report using their study gel?
 - Does adherence vary by gel use arm?
 - Does it vary by sexual risk behavior?
 - (How) does gel adherence change over time?
2. Overall, how much do participants like using their study gel?
 - Does acceptability vary by gel use arm?
 - Which product attributes best predict acceptability?
 - Are participants in the daily use arm more likely than those in the coitally-dependent arm to report increased sexual pleasure for themselves? For their partners?
3. What proportion of participants identified problems with trial participation?

II. Enhanced Acceptability Study: Pune, India



Enhanced Acceptability Measures

- Outcome variables:
 - % of sex acts with gel and/or condoms (last week)
 - Perceived consistency of gel/condom use (5 point scale)
 - Interest in gel use outside trial setting (6 point scale)
- Predictors
 - Couple Harmony
 - AIDS Fatalism (HIV risk perception / sexual power)
 - Protection Efficacy
 - Motivation to comply with trial
- Socio-demographic characteristics
 - privacy



Research Questions:

1. What factors best predict women's reports of consistent gel use during the clinical trial? Their partner's reports?
2. Are these factors similar or different to factors predicting consistent condom use outside a trial setting?
3. What predicts interest in using a microbicide gel outside of a clinical trial for women? For their partners?

Participant Characteristics

Socio-demographic Variables	CT Women (N = 81)		Non-CT Women (N = 61)	
	%, mean	N, range	%, mean	N, range
Mean Age (years)	33.2	24-43	32.9	18-46
Current Marital Status				
Not married	0	0	0	0
Married	100	81	100	61
Average # of Children	2.4	1-5	2.3	0-5
Educational Level				
No schooling	6	5	5	3
Some primary (1-4)	30	24	25	15
Some secondary (5-10)	47	38	55	34
> 10 years	17	14	15	9
Earn Income				
No	44	36	44	27
Yes	56	45	56	34
Average Income/Month (Rs.)	1,561	500-3,500	1,131	300-3,000

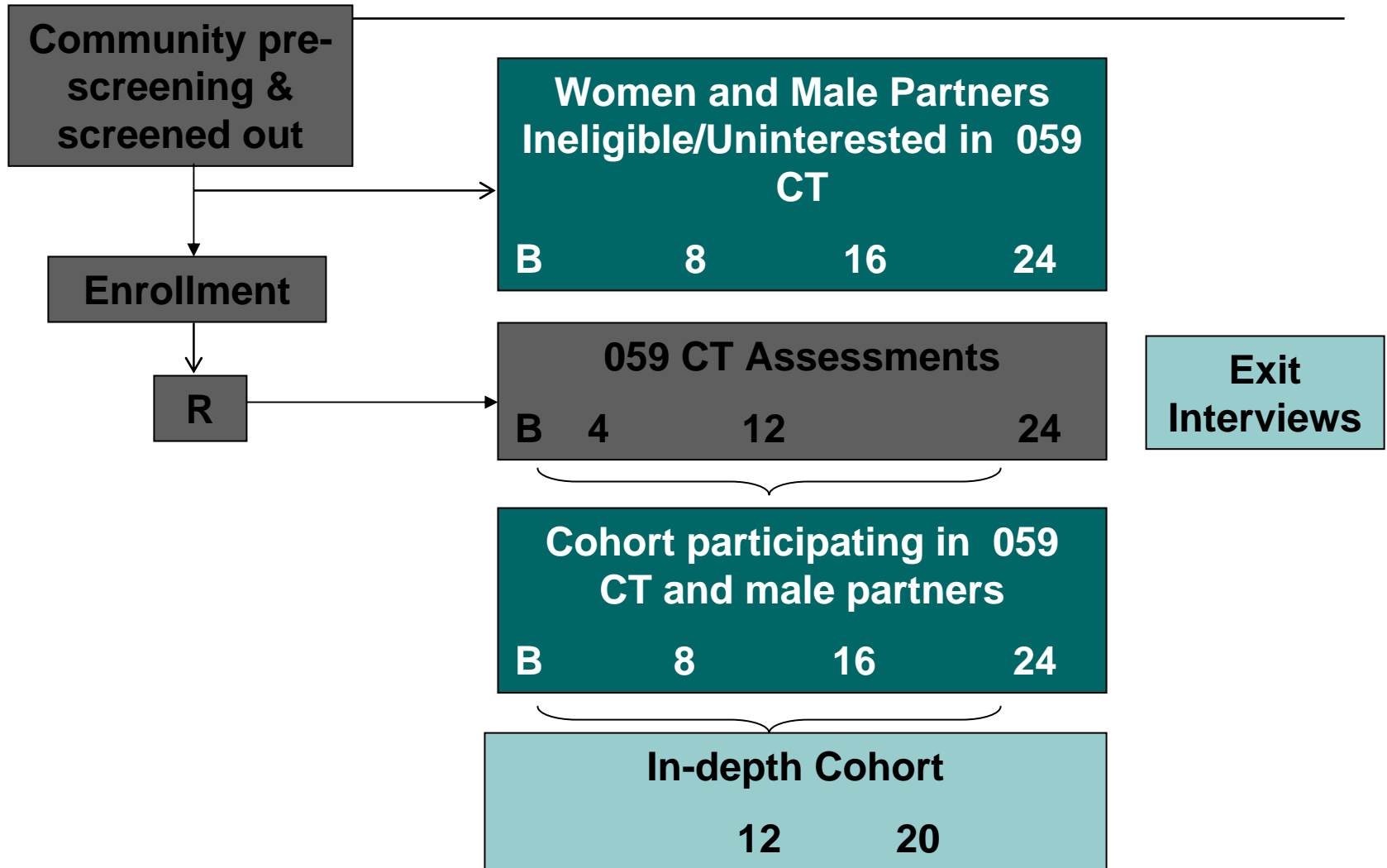
Baseline Data on Condom Attitudes and Use

Condom Attitudes and Use	CT Cohort %		Non-CT Cohort %	
	Women (N=81)	Partners (N=50)	Women (N=61)	Partners (N=27)
Consistent Condom Use/ 2 months				
Never/Rarely	50	52	79	78
Sometimes/Frequently	{ 28	{ 24	{ 8	{ 15
Always	{ 22	{ 24	{ 13	{ 7
Attitudes towards Condoms				
Like somewhat/a lot	38	70	25	44
Neutral	50	18	36	11
Dislike somewhat/a lot	12	12	39	45

Mean Scale Scores, by Cohort and Gender

Predictors of Microbicide Acceptability	CT Women (n=81)	Male Partners/CT (n=50)	Non-CT Women (n=61)	Male Partners/Non-CT (n=27)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Couple Harmony	5.14 (0.81)	5.28 (0.42)	5.10 (0.68)	5.30 (0.31)
Partner Abuse	2.78 (1.18)	1.95 (0.62)	2.90 (1.31)	1.92 (0.41)
Perception of Partner Infidelity	1.54 (1.02)	1.30 (0.69)	1.70 (1.00)	1.29 (0.67)
AIDS Fatalism	3.30 (0.92)	3.14 (0.84)	3.38 (0.90)	3.49 (0.88)
Protection Efficacy	5.65 (0.56)	5.77 (0.33)	5.34 (0.73)	5.13 (1.22)

III. Qualitative In-Depth Interviews (repeated or at exit)



Qualitative Research Questions:

- How adherent are participants to gel and condom use?
- How do individual and couple factors influence adherence to protocol and product?
 - Women's perceptions of HIV risk
 - Her control of decisions affecting trial participation and gel use
 - Her control over sex
 - Her own and her partner's attitudes towards product attributes
- How does the clinical trial context influence gel use?
 - Women's and their partners understanding of clinical research and their expectations about trial participation
 - Motivations to comply with the clinical trial protocol
- (How) do experiences with trial participation and product use vary by gel administration arm (coital or once-daily)?
- In what ways do sexual partners influence trial participation and adherence to gel or condom use?

Summary:

- Mix of qual/quant data collection increases reliability of self reported use behavior
- Increased attention on how partner, power and privacy influence adherence
- Context of clinical trial (including motivation to comply) actively examined
- Addition of non-trial cohort increases generalizability
- Male partner perspective included



Thanks!

For further information, contact:

Betsy Tolley

Scientist

Behavioral and Social Science Research Unit

Family Health International

btolley@fhi.org