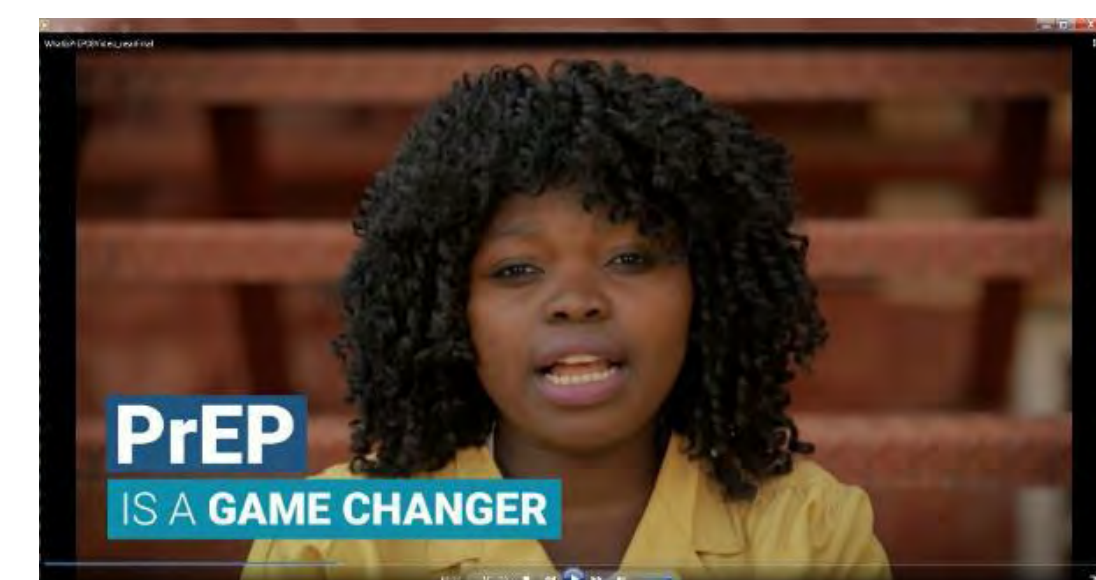


BACKGROUND

- Oral pre-exposure prophylaxis (PrEP) is highly effective when used consistently, and recommended for people at substantial risk of HIV infection.
- Young women in sub-Saharan Africa are an important population who could benefit from PrEP, but may experience barriers to consistent use.
- Strategies are needed to support PrEP uptake and adherence in this population.
- HPTN 082 was designed to address these critical information gaps about effective PrEP delivery and use among young women in southern Africa, among whom HIV incidence is very high (5-10% per year).



HPTN Q82
HERS

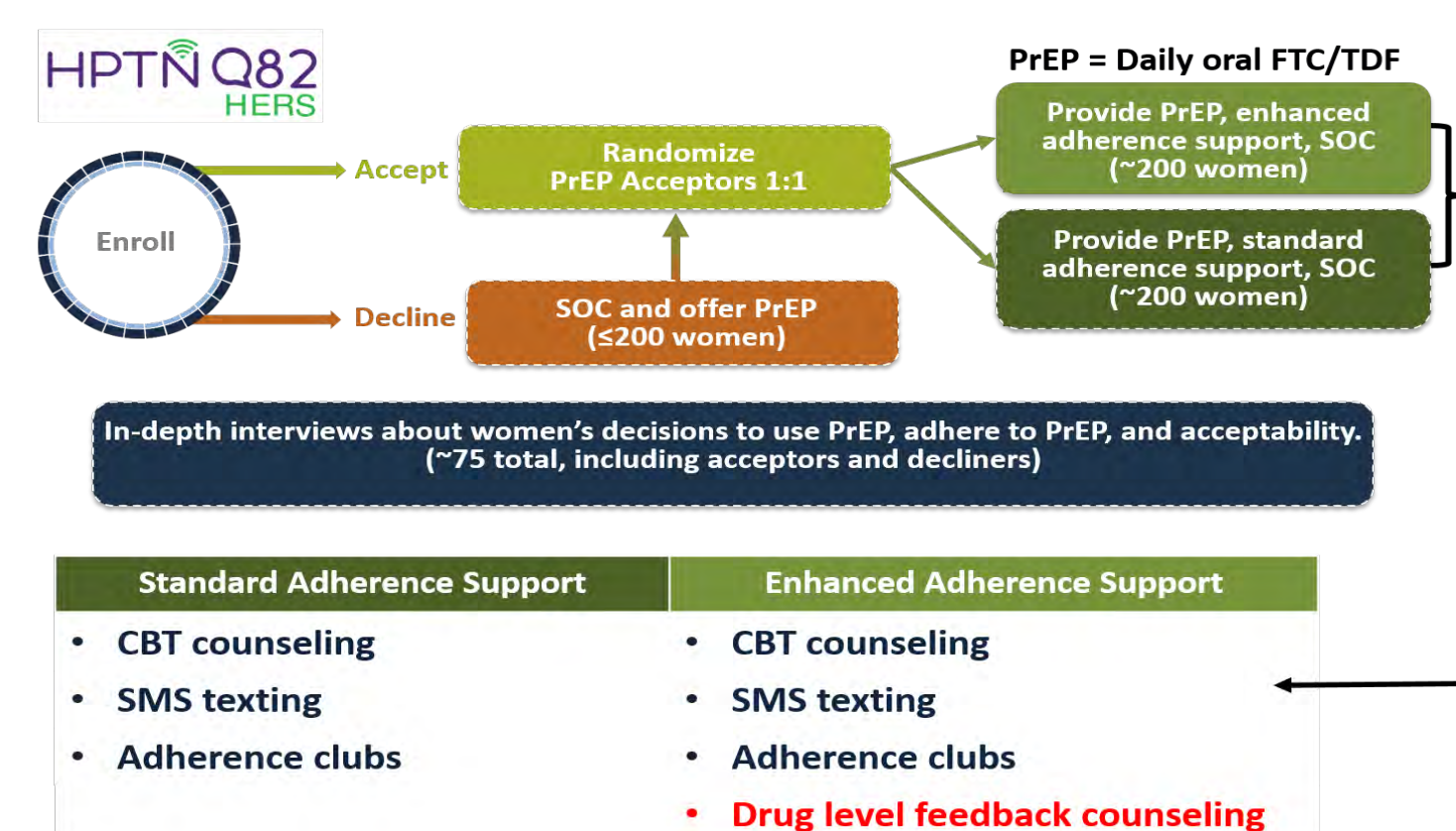
"Get PrEPared: What African women need to know!" (updated June 2017) is a 5-minute film with easy-to-understand information for young African women interested in using oral Pre-exposure prophylaxis (PrEP) as part of an overall HIV prevention package.
www.youtube.com/watch?v=rHkQq--anmo

PURPOSE & METHODS

RATIONALE HPTN 082 is an open label PrEP study in Cape Town and Johannesburg, South Africa and Harare, Zimbabwe with the primary objectives to: assess the proportion and characteristics of young HIV-uninfected women who accept versus decline PrEP, and the difference in PrEP adherence in young women randomized to enhanced adherence support (using drug level feedback) versus standard of care adherence support.

STUDY DESIGN

- 400 sexually active HIV-negative women ages 16-25 were enrolled using the VOICE risk score¹ and a PrEP readiness scale.²
- Women interested in PrEP were enrolled regardless of initial decision to initiate PrEP.
- PrEP 'acceptors' were randomized to *standard* adherence support (cognitive behavioral counseling, 2-way SMS, and adherence clubs) or *enhanced* adherence support with drug level feedback at 2 and 3 months plus standard adherence support (see below).



PREP ADHERENCE SUPPORT

- Weekly two-way SMS messages that ask 'Hi girlfriend, how is it going?' to identify those with side effects or other issues for staff to respond to and as a PrEP adherence reminder
- Brief adherence counseling
- Monthly adherence clubs to interact with other young women and for peer support
- Half of women were randomized at enrollment to drug level feedback based on intracellular tenofovir diphosphate levels³ at the 1 and 2 month visit which reflect adherence in the prior month
 - Qualitative drug level feedback was provided at the next monthly visit with 'wireless signals' for the 3 categories of drug levels, as depicted below:

Sample week	Results week	Threshold	Signal	Counseling message
Week 4	Week 8	≥500 fmol/punch	Green signal	Key message: You are doing really well! Keep up the good work and remember that taking one PrEP pill every day is needed for strong protection against HIV.
Week 8	Week 13	≥700 fmol/punch	Yellow signal	Key message: It looks like you are trying to take the PrEP pills, but may have missed some doses. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?
Week 4	Week 8	16.6-499 fmol/punch	Yellow signal	Key message: It looks like you are trying to take the PrEP pills, but may have missed some doses. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?
Week 8	Week 13	16.6-699 fmol/punch	Yellow signal	Key message: It looks like you are trying to take the PrEP pills, but may have missed some doses. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?
Week 4	Week 8	BLQ (<16.6 fmol/punch)	Red signal	Key message: It looks like you haven't been able to take the PrEP pills. Is PrEP something that you are still interested in? If yes, how can we help you?
Week 8	Week 13	BLQ (<16.6 fmol/punch)	Red signal	Key message: It looks like you haven't been able to take the PrEP pills. Is PrEP something that you are still interested in? If yes, how can we help you?

RESULTS: CHARACTERISTICS OF WOMEN WHO STARTED PREP

Table 1: Demographics and sexual behavior for women who started PrEP at enrollment, overall and by site

	Overall	Harare	Cape Town	Johannesburg
Participants screened	647	213	183	251
Participants enrolled	451	148	141	162
PrEP Accepted at Baseline	412	139	136	137
Age (median IQR)	21 (19,22)	21 (20,23)	19 (18, 21)	21 (20, 24)
Education				
Completed secondary school or higher*	404 (98%)	133 (96%)	135 (99%)	136 (99%)
Ever dropped out of school*	122 (30%)	57 (41%)	44 (32%)	21 (15%)
Age difference ≥5 years with primary partner	139 (44%)	73 (65%)	27 (27%)	39 (37%)
HIV status of main partner				
HIV negative	204 (59%)	59 (50%)	63 (58%)	82 (70%)
HIV positive	3 (0.9%)	1 (0.9%)	1 (0.9%)	1 (0.8%)
He doesn't know his status	8 (2%)	2 (2%)	0 (0%)	6 (5%)
She doesn't know his status	58 (17%)	20 (17%)	21 (19%)	17 (14%)
Any transactional sex in past month	95 (23%)	52 (37%)	29 (21%)	14 (10%)
Vaginal sex acts past month (median, IQR)	4 (2,8)	6 (3,16)	4 (3,5)	3 (2, 7)
Condom use with vaginal sex, past month				
Never	65 (20%)	35 (34%)	8 (8%)	22 (20%)
Rarely	48 (15%)	17 (17%)	12 (11%)	19 (17%)
Sometimes	104 (33%)	18 (17%)	49 (46%)	37 (33%)
Often	37 (12%)	10 (10%)	14 (13%)	13 (12%)
Always	65 (20%)	23 (22%)	23 (22%)	19 (17%)
Any anal sex acts past month	63 (23%)	18 (20%)	29 (29%)	16 (17%)
Contraceptive use other than condoms	318 (71%)	123 (83%)	124 (88%)	71 (44%)

*categories not mutually exclusive

RESULTS: PREP UPTAKE: RISK BEHAVIORS AND STI PREVALENCE; DEPRESSION & INTIMATE PARTNER VIOLENCE; PERCEIVED RISK AND PREP MOTIVATIONS

Figure 1: PrEP uptake overall and by site

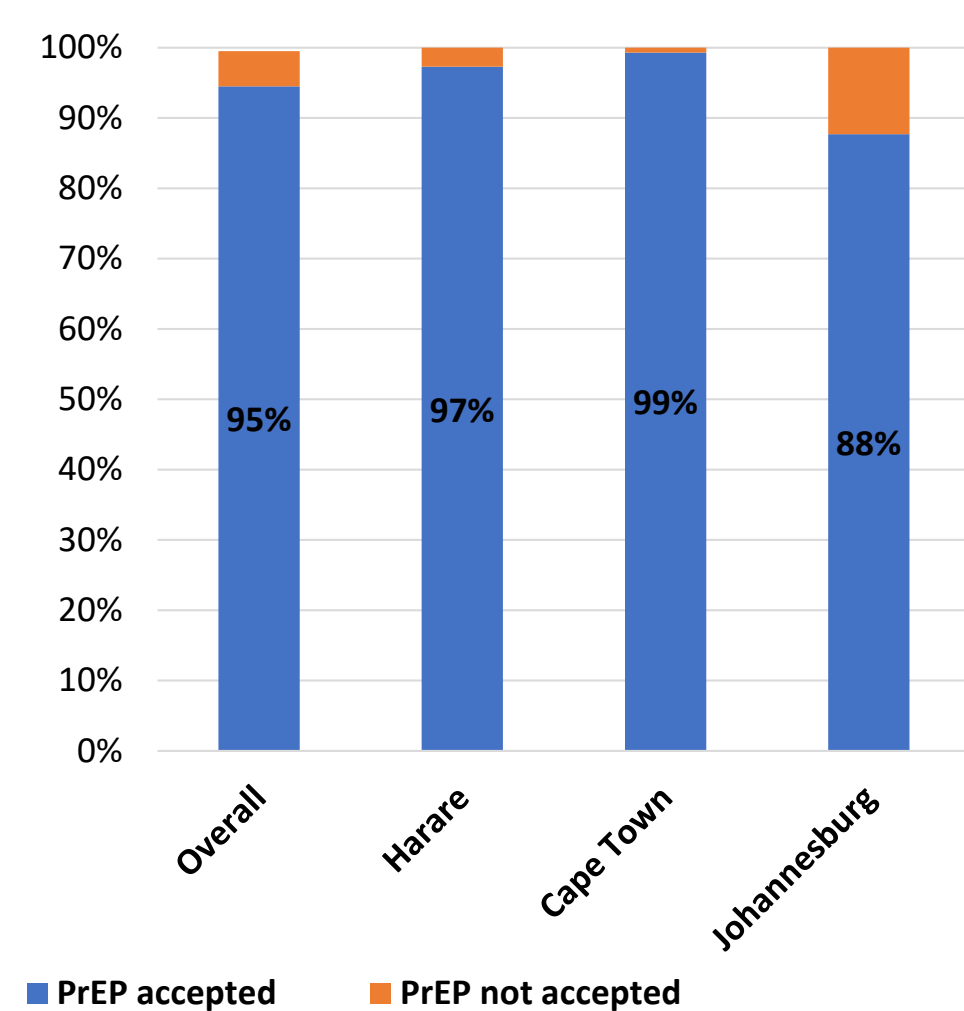


Table 2: VOICE risk score and STD prevalence among PrEP acceptors at baseline

	Overall	Harare	Cape Town	Johannesburg
Married or lives with primary partner	81 (20%)	64 (46%)	3 (2%)	14 (10%)
Husband or primary partner provides material support	237 (58%)	89 (64%)	81 (60%)	67 (49%)
Believes husband or primary partner has other sex partners				
Yes	102 (25%)	82 (59%)	14 (10%)	6 (4%)
Don't know	246 (60%)	57 (41%)	85 (63%)	104 (76%)
2 or more alcoholic drinks past 3 months	187 (45%)	53 (38%)	100 (74%)	34 (25%)
Curable STI				
Gonorrhea	161 (39%)	40 (29%)	69 (51%)	52 (38%)
Chlamydia	33 (8%)	8 (6%)	20 (15%)	5 (4%)
Syphilis seropositivity	120 (29%)	28 (20%)	52 (38%)	40 (29%)
Trichomonas vaginalis	9 (2%)	3 (2%)	3 (2%)	3 (2%)
Trichomonas vaginalis	27 (7%)	10 (7%)	7 (5%)	10 (7%)
VOICE risk score (median, IQR) Range 5-10	7 (6,8)	7 (5,7)	8 (7,9)	7 (6,8)

Table 3: Depression and intimate partner violence among PrEP acceptors at baseline

	Overall	Harare	Cape Town	Johannesburg
Depression CES-D score > =11	171 (42%)	56 (40%)	50 (37%)	65 (47%)
≥ 1 episode of intimate partner violence, past year	200 (49%)	68 (49%)	68 (50%)	64 (47%)
Any physical violence, past year	81 (20%)	23 (17%)	32 (24%)	26 (19%)
Partner insulted, ignored or humiliated her, past year	149 (36%)	48 (35%)	44 (33%)	57 (42%)
Sexual coercion, past year (Partner forced her to have sex or touched her sexually in way she did not want)	35 (9%)	16 (12%)	10 (7%)	9 (7%)
Partner made her feel afraid, unsafe, or in danger, past year	75 (18%)	41 (29%)	20 (15%)	14 (10%)

Table 4: Perceived HIV risk, and PrEP readiness

	Overall	Harare	Cape Town	Johannesburg
Chances of getting HIV in next year				
No risk at all	193 (47%)	70 (50%)	57 (42%)	66 (49%)
Small chance	127 (31%)	21 (15%)	55 (41%)	51 (38%)
Moderate chance	33 (8%)	16 (12%)	8 (6%)	9 (7%)
Great chance	33 (8%)	27 (19%)	5 (4%)	1(1%)
Chances of getting pregnant in the next year				
No risk at all	174 (42%)	60 (43%)	59 (44%)	55 (40%)
Small chance	132 (32%)	31 (22%)	51 (37%)	50 (37%)
Moderate chance	42 (10%)	13 (9%)	10 (7%)	19 (14%)
Great chance	35 (9%)	24 (17%)	6 (4%)	5 (4%)
PrEP would give me side effects				
Strongly disagree	57 (14%)	49 (35%)	4 (3%)	4 (3%)
Disagree	97 (24%)	68 (49%)	12 (9%)	17 (13%)
Neutral	85 (21%)	6 (4%)	29 (21%)	50 (37%)
Agree	111 (27%)	11 (8%)	62 (46%)	38 (28%)
Strongly agree	46 (11%)	3 (2%)	23 (17%)	20 (15%)
Taking PrEP would keep me from getting HIV				
Strongly disagree	10 (2%)	1 (1%)	5 (4%)	4 (3%)
Disagree	12 (3%)	3 (2%)	6 (4%)	3 (2%)
Neutral	9 (2%)	1 (1%)	3 (2%)	5 (4%)
Agree	192 (47%)	68 (49%)	63 (47%)	61 (45%)
Strongly agree	182 (44%)	63 (45%)	57 (42%)	62 (46%)
Friend encouraged PrEP use	258 (63%)	106 (76%)	94 (70%)	58 (43%)

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