Evaluating sex behaviors and substance use in pregnant and breastfeeding women in South Africa to inform HIV prevention interventions

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December 13, 2017

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Outline

- Background
  - Risk of HIV acquisition and transmission in pregnant & postpartum women
  - How STIs moderate those risks
- Research to date from South Africa on understanding behavioral risk factors for HIV/STI acquisition and transmission
  1. **STIP: STI study in pregnancy:** Tshwane & Cape Town
  2. **SexPP:** Sex behaviour mixed method study in pregnant/postpartum women
  3. **PrEP-PP:** Pre-exposure prophylaxis (PrEP) study in pregnant/postpartum women
- Discussion and next steps

Background

- Risk of HIV acquisition during pregnancy and post-partum periods is high
  - Hormonal changes that alter genital mucosal surfaces result in distribution of target cells at these surfaces and increase susceptibility to HIV acquisition during pregnancy and breastfeeding
  - Behavioral factors may also contribute to high HIV incidence
- Highest HIV incidence in pregnant women in South African urban health facilities (12.4 infections per 100 woman years)
- High risk time for mother and child – mother to child HIV transmission is highest if a mother seroconvert during pregnancy
  - Approximately 34% of HIV transmission from mother to child happens when a mother seroconverts in pregnancy

Dinh, T., Delaney, K. P., Goga, A., et al. (2015). Correction: Impact of Maternal HIV Seroconversion during Pregnancy on Early Mother to Child Transmission of HIV (MTCT) Measured at 4-8 Weeks Postpartum in South Africa 2011-2012: A National Population-Based Evaluation. *Plos One, 10*(6).
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Drake, A. L., Wagner, A., Richardson, B., et al. (2014). Incident HIV during Pregnancy and Postpartum and Risk of Mother-to-Child HIV Transmission: A Systematic Review and Meta-Analysis. *PLoS Medicine*, *11*(2), e1001608.
Mugo, N. R., Heffron, R., Donnell, D., et al.(2011). Increased Risk of HIV-1 Transmission in Pregnancy: A Prospective Study among African HIV-1 Serodiscordant Couples. *AIDS (London, England)*, *25*(15), 1887–1895

Background, cont.

- 6-months after being on antiretroviral therapy (ART), there still may be a high risk of being viremic
  - In a recent Cape Town study, 21% of patients still had detectable HIV RNA after 6-months on ART

Despite this increased risk:

- Limited understanding of sex behaviour and substance use in pregnancy and postpartum periods
- Need to understand behaviors and risk factors to develop interventions to reduce HIV incidence and onward transmission to sex partners and infants

Malaba TR, Phillips T, Le Roux S, Brittain K, Zerbe A, Petro G, Ronan A, McIntyre JA, Abrams EJ, Myer L. Antiretroviral therapy use during pregnancy and adverse birth outcomes in South African women. Int J Epidemiol. 2017 Oct 1;46(5):1678-1689. doi: 10.1093/ije/dyx136. PubMed PMID: 29040569

Background: STIs in pregnancy

- There are an estimated 351 million new cases of Trichomonas vaginalis (TV), Chlamydia trachomatis (CT), and Neisseria gonorrhea (NG), annually.
- **Risk of STIs in pregnancy**: Those STIs are associated with adverse pregnancy, pregnancy and birth outcomes including increased risk of:
    - ectopic pregnancy,
    - pre-term labor,
    - growth retardation, and
    - intrauterine death.
- STIs can be vertically transmitted to newborns during passage through the birth canal.
- STIs **increase the risk of HIV transmission to sex partners** during intercourse due to increased inflammation and lesions that facilitate HIV shedding and acquisition.
- STIs may **increase the risk of mother-to-child-transmission (MTCT)** of HIV.

STIP: STI study in pregnancy

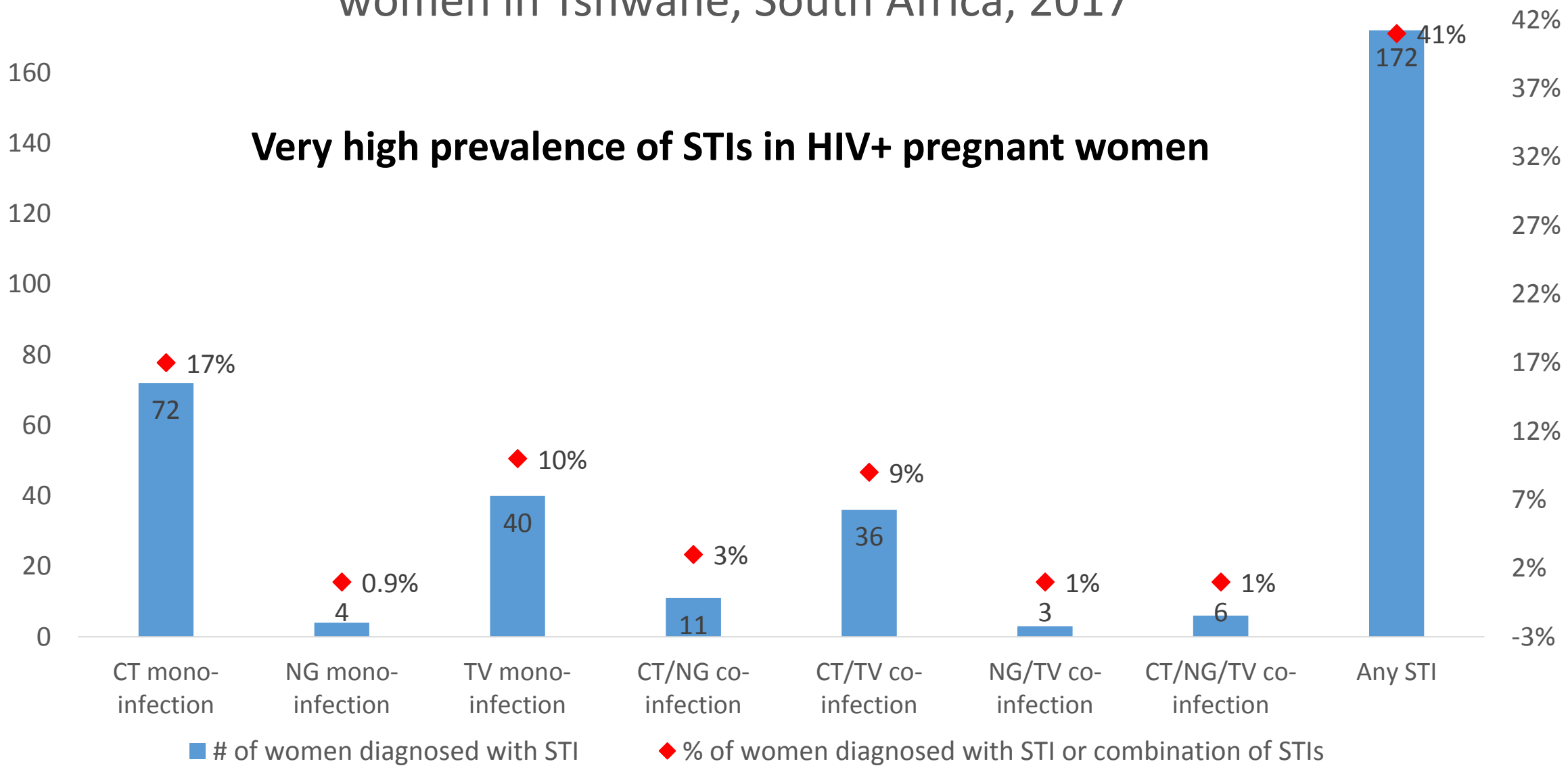
Tswhane & Cape Town

STIP methods

- **Study #1: ongoing in Tshwane (PI: Drs. Klausner & Medina-Marino)**
  - Antenatal care study evaluating the impact of STI screening on MTCT of HIV in 423 HIV-infected pregnant women attending routine antenatal care at three clinics in the public sector in the Tshwane District of South Africa
  - To be eligible, women had to be 18 years or older, HIV-positive, currently pregnant (<34-weeks pregnant), and intend to reside in Tshwane District for the duration of the pregnancy.
- **Study #2: Launched in October 2017 (PI: Drs. Myer and Joseph Davey)**
  - Antenatal care cohort study of 400 HIV-infected (n=200) and HIV-uninfected (n=200) women in antenatal care in Gugulethu Clinic, Cape Town
  - Women recruited at first ANC and tested, then repeated testing at 3rd trimester and within 7-days postpartum
  - Enrollment slow– enrolled 30 women of which 14 had a STI (49%), mostly CT; 50% are treated same-day.
  - Will test for **Mycoplasma Genitalium** (a bacteria that can be caused through sexual contact. Little is known about MG in pregnant women, nor the potential risk of MG on pregnancy outcomes) & **Group B Strep** in amended study in early 2018
- **Specimen Collection and Testing**:
  - During the first postnatal visit, women self-collected vulvovaginal swab specimens (Cepheid, Sunnyvale, CA).
  - Clinic research staff tested specimens immediately for presence of CT, NG, and TV (Xpert® TV, Xpert® CT/NG; Cepheid, Sunnyvale, CA)
  - If women tested positive for any STI they were given their results and appropriate treatment before leaving the clinic.
  - Women are provided with notification letters for partners
  - All women receive condoms and counseling around condom use.

D Joseph Davey, N. Kojima, A Medina-Marino, et al. “Sexual and behavioral risk factors for sexually transmitted infection among HIV-infected pregnant women in South Africa.” Under Review. AIDS & Behavior, December 2017

Number and prevalence of STIs in HIV-infected pregnant women in Tshwane, South Africa, 2017 *



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Factors associated with any STI (CT, NG and/or TV) in pregnant HIV-infected women in South Africa

	Any STI *	OR (95% CI)	Adjusted OR (95% CI)**
Total	174		
Relationship with father of child			
Not cohabiting, casual, no relationship partner	96 (56%)	1.85 (1.25, 2.74)	**1.42 (0.97, 2.03)**
Married or cohabiting	77 (45%)	ref	
Divorced or widowed	0 (0%)	--	
Days since last sex			
0-7 days ago	97 (57%)	0.62 (0.32, 1.20)	0.82 (0.31, 1.21)
8-30 days ago	43 (25%)	0.69 (0.34, 1.44)	0.67 (0.32, 1.40)
31-60 days ago	10 (6%)	0.37 (0.14, 0.95)	**0.35 (0.13, 0.92)**
>60 days ago	21 (12%)	ref	ref
Sex frequency during pregnancy			
>5 times vs. ≤5 times	95 (51%)	1.80 (0.98, 3.30)	**1.88 (1.01, 3.49)**
Frequency of alcohol use since pregnant			
Never	141 (81%)	ref	
Monthly or more frequently	33 (19%)	1.97 (1.07, 3.63)	**1.96 (1.06, 3.64)**

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Findings from STI study in Tshwane

- HIV-infected pregnant women are at high risk for prevalent STIs, and for transmitting both HIV and STIs to their partners and newborns.
  - Most women were asymptomatic, so would not benefit from standard of care syndromic STI management
- Most women reported condomless sex, multiple partners and alcohol use during pregnancy
- Lack of knowledge of HIV status, and/or the father of the child's serostatus actors were associated with condomless sex during pregnancy.
- Factors associated with prevalent STI in pregnancy included:
  - younger age,
  - unemployment,
  - casual or non-cohabiting partner and
  - alcohol use during pregnancy.
- Findings will be used to inform the design of targeted interventions that address the burden of STIs during pregnancy and reduce vertical and horizontal HIV and STI transmission.

* D Joseph Davey, N. Kojima, A Medina-Marino, et al. "Sexual and behavioral risk factors for sexually transmitted infection among HIV-infected pregnant women in South Africa." Under Review. AIDS & Behavior, December 2017

SexPP: Sex behaviors and substance use in pregnancy and postpartum women

Cape Town: Gugulethu

SexPP: Methods

- Formative study to inform interventions to prevent HIV acquisition during pregnancy and perinatal HIV transmission
- Cross-sectional study in Cape Town township: Gugulethu
- Survey on sex behaviour among pregnant women (any stage) and postpartum women (up to 6-months post-partum)
- Variables include: demographic factors, sexual risk factors and other risk factors (e.g. alcohol use) for HIV, and knowledge of PrEP
- Developed bivariate and multivariate logistic regression models with sex with >1 partner and condomless sex as outcomes

Gugulethu

- A former township community outside of Cape Town.
- The population of 400,000 is predominantly of low socioeconomic status:
  - 48% unemployment
  - 64% of the adult population lives on <R400 (approximately <$35) per month
- The vast majority of the population uses local public sector health services that are provided free of charge.
- In 2012, the HIV prevalence among women attending the Midwife Obstetric Unit was 27%
- >80% of HIV+ women in this setting elect to breastfeed.
- A lot of previous and current PMTCT research has taken place in other facilities within the same district, affording the team a deep understanding of local health systems and ART programme operations

Demographic composition of study participants in Gugulethu

- 377 women enrolled (N=212 antenatal and 165 postpartum women)
- Intentionally recruited 40% HIV-infected women
- Median age 28
  - 26% of women are <24 years old
- 55% had below secondary level education
- 67% unemployed
- 86% of women reported a household income <$400/month

Demographic and health behaviours among pregnant vs. post-partum women (n= 377)

Socio- Demographics		Pregnant n or mean	Pregnant % or SD	Post-Partum n or mean	Post-Partum % or SD	Total
HIV-infected		78	37%	73	44%	151
HIV-uninfected		134	63%	92	56%	226
Age		28		28		377
Education	*None*	0	0%	1	1%	1
	Below HS	112	53%	96	58%	208
	HS	94	44%	63	38%	157
	Diploma	6	3%	5	3%	11
Relationship with father of child	*None*	18	8%	22	14%	40
	Married/cohabiting	101	48%	65	40%	166
	Casual partner/non-cohabiting	92	43%	76	47%	168
	Widowed	1	1%	0	0%	1
HIV status of father of child (reported)	*Concordant*	105	50%	95	58%	200
	Discordant	14	7%	16	10%	30
	Don't know	93	44%	53	32%	146
Current employment status	*Employed*	80	38%	43	26%	123
	Unemployed	132	62%	121	74%	253
Wanted to get pregnant this time	*Yes*	73	35%	48	30%	121

D Joseph Davey, E Farley, Y Gomba, T Coates, L Myer. "Sexual risk during pregnancy and postpartum periods among HIV-infected and –uninfected South African women: Implications for primary and secondary HIV prevention interventions." PlOS One, In Press, December, 2017

Sex behavior during pregnancy

- 98% of women reported having sex during pregnancy of which:
  - 100% reported vaginal sex
  - 23% reported oral sex (M to F and F to M)
  - 8% reported anal sex (10% of HIV negative women)
- 68% of women did not use a condom at last sex during pregnancy (79% among HIV negative women)
- 16% of women reported >1 sex partner while pregnant
- 75% of women did not know their other partners' status (6% were serodiscordant)
- 35% of women suspected their partner to have other partners as well

Alcohol consumption during pregnancy

- 29% of women reported some alcohol use
  - 2% of women reported drinking >3 times a week during pregnancy
  - 21% of women reported drinking 6+ drinks on one more occasion monthly or more
- Women who reported drinking, reported consuming 4.3 median drinks (IQR=2, 6) when drinking
- 9% of women reported having difficulty stopping drinking when they started

Multivariable models of factors associated with condomless sex in pregnant/postpartum women

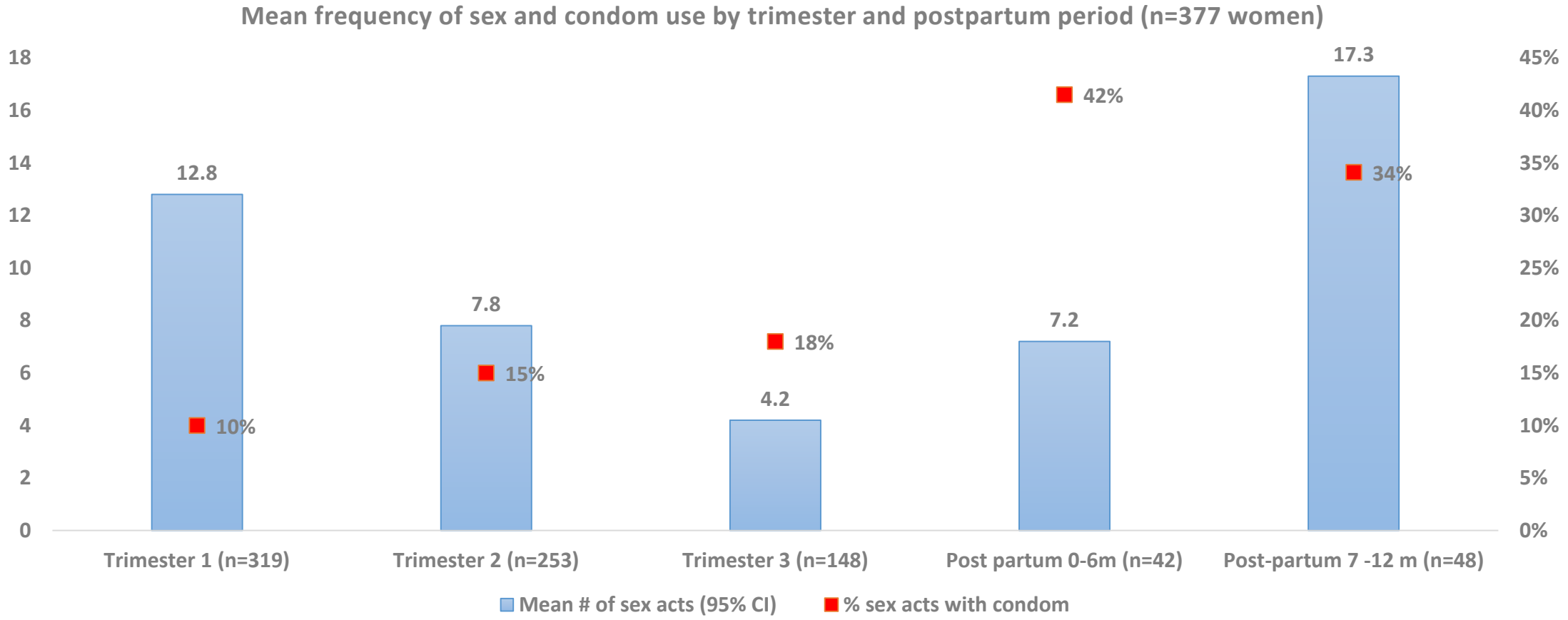
69% of women reported condomless sex at last sex.

Adjusted odds of condomless sex were 3-times higher in **pregnant and HIV-uninfected** women

Adjusted and unadjusted odds ratio for factors of HIV acquisition and transmission in pregnant and postpartum women		
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Model 1: Condomless sex at last sex		
HIV-uninfected	3.21 (2.03, 508)	3.33 (2.04, 5.44)
Pregnant (ref: Postpartum)	3.23 (2.03, 5.12)	2.96 (1.84, 4.78)
Age (per year increase)	1.10 (0.98, 1.05)	1.03 (0.99, 1.08)
In relationship with father of child	1.28 (0.82, 2.02)	1.17 (0.92, 1.98)
Mother's education high school or above(ref. below high school)	1.00 (0.64, 1.56)	1.03 (0.98, 1.36)
Model 2: Ever reported condomless sex during pregnancy or postpartum period		
HIV-uninfected	0.33 (0.21, 0.51)	0.30 (0.19, 0.48)
Pregnant (ref: Postpartum)	2.29 (1.86, 2.97)	2.65 (1.30, 5.44)

Sex behaviour over time of pregnancy/postpartum period

- Sex frequency was highest during the first 2 trimesters of pregnancy and lowest in the 3rd trimester and the first 6-months post-birth, but increased again after 6-months postpartum.
- Condomless sex was highest during pregnancy and lower during postpartum sex
- 39% of women did not know their partner's status and 15% reported more than one partner.



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Discussion:

- Many pregnant women did not know their partners' HIV status (39%), and no HIV-uninfected women reported having HIV-infected partners
- Over 10% of women reported that they did not have a relationship with the father of the child, or the father was a casual sex partner
- HIV-negative pregnant women reported high levels of risky sex during pregnancy including:
  - (1) >1 sex partners (16% of women)
  - (2) condomless sex with partners of unknown status partners (30% of women)
  - (3) condomless anal sex (12% of women)
- Alcohol use was also commonly reported among pregnant women
  - 9% of HIV-negative women reported heavy drinking ($\geq$2 alcoholic drinks/day while pregnant)
- After pregnancy many women go home and live with their mother for up to 2 months
  - <2% of women reporting sex in the first 6 weeks post-birth
- Alcohol use and binge drinking was prevalent during pregnancy

Next steps from our research:

- Our studies have demonstrated:
  - High STI prevalence (evaluating STI incidence)
  - Multiple partners, high frequency of condomless sex, insecure relationship status
  - Lack of knowledge of partner's serostatus
  - Reported heavy alcohol use in pregnancy (drugs TBD)
- Those high risk behaviors and relationship statuses have implications on the effectiveness of PMTCT programs, including regular HIV testing and condom promotion.
- Need for female-controlled methods of HIV prevention

PrEP for pregnant and breastfeeding women

PrEP in pregnancy – what we know

- PrEP is one of the only female controlled methods that is effective for preventing HIV acquisition.
- PrEP trials excluded pregnant women from enrolment, and those who fell pregnant during these studies were discontinued from PrEP.
- Systematic reviews have demonstrated that PrEP was not associated with increased pregnancy-related adverse events, and no studies have found adverse effects among infants exposed to tenofovir disoproxil fumarate (TDF) as part of treatment for HIV-infected women during pregnancy or breastfeeding.
- Risk of HIV acquisition combined with multiple partners, condomless sex, transactional sex, substance use, gender based violence and rape, all compound the challenges of addressing the need for effective female-controlled interventions to prevent HIV
- PrEP is a public health priority in settings of high HIV incidence, especially in peri-conception, pregnancy and breastfeeding in South Africa where HIV incidence is high and the probability of vertical transmission is highest when women seroconvert and are viremic.

Joseph Davey D, Bekker LG, Gorbach P, Coates T, Myer L. "Delivering PrEP to pregnant and breastfeeding women in sub-Saharan Africa: The Implementation Science Frontier. AIDS. July, 2017

PrEP-PP– PrEP in pregnancy and postpartum period: Methods

- Interviews were recorded, following which they were translated into English and transcribed by one of the study interviewers.
- All of the translation and transcription were quality controlled by the study coordinator.
- We used inductive coding derived from the surveys and interviews and a thematic approach to our analysis, identifying key themes that were identified during the interviews, which helped support findings from our prior analysis of our quantitative survey of the same population
- We used this technique to capture the meaning of their answers to their responses to the semi-structured interview questions.
- Analysis was conducted using Nvivo software.

Demographics

- In-depth interviews conducted in Oct-Dec 2016 in 26 pregnant and postpartum women
- Median age =24 (IQR=21, 31)
- 31% were married or cohabiting relationship and 19% reported no relationship with the father of the index pregnancy/child
- 77% were not employed
- 96% reported sex during pregnancy; 39% reported >1 sex partner in past year

Table : Demographic Characteristics of Participants (n=26)

	n / median	% / IQR
Age	Median 24	IQR 21, 31
Education		
Below high school	14	54%
Graduated high school	11	42%
Degree/diploma	1	4%
Relationship Status		
No relationship	5	19%
Married	3	12%
Steady partner living with me	5	19%
Steady partner not living with me	13	50%
Employment Status		
Employed fulltime	6	23%
Not Employed	20	77%
Household Income Per Month		
None	1	4%
Less than 1000 ZAR per month	11	42%
1001 to 5000 ZAR per month	11	42%
5001 to 10 000 ZAR per month	3	12%
Previous Pregnancies	Median 1	IQR 0, 1
Live Children	Median 1	IQR 0, 1
Vaginal sex during pregnancy		
Yes	25	96%
Multiple partners in past year		
Yes	10	39%

Theme 1: Risk perception in HIV negative pregnant and postpartum women

Risk Perception	
When you are drunk, yeah, when we are drunk and careless (you are highest risk of getting HIV). You just think about what you are going to do right now and don't think of a condom.	Pregnant, 20 yrs
I tell him we need to use a condom because I can't have sex without a condom if I keep on seeing numbers I don't know on his phone. He will bring me AIDS.	Pregnant, 20 yrs
I would say the festive season and it is the riskiest time for HIV transmission, because people drink alcohol, and they take things lightly. They don't see a reason for using a condom because they are drunk. And then you wake up in the morning, you don't even know who you slept with and you didn't use a condom. They want to be happy all time; happiness sometimes has bad results.	Pregnant, 27 yrs
Yes, (my risk fluctuates) right now I am not even concerned (as I am not having sex as I have had my baby). I can't get anything right now. I am not doing anything; how would I get it. It can't put itself in me	Postpartum, 24 yrs

Joseph Davey D, Bekker LG, Gorbach P, Coates T, Myer L. "Risk perception and sex behaviour in pregnancy and breastfeeding in high HIV prevalence settings: Programmatic implications for PrEP delivery." Under review, PlOS One, December 2017

Theme 2: Power differences between men and women with regard to sex and condom use

Power differences	
I don't know what his status (is) and I can't just ask to go test. You have to give it time. Men like changing our minds as if they hypnotize us. You might have told yourself that you will use a condom and he changes your mind.	Pregnant, 22 yrs
If it was up to me, I would want us to use a condom when we have sex.	Pregnant, 34 yrs
I once suggested we use a condom, he got angry and asked why I am saying we should use a condom, he asked if I have a disease.	Postpartum, 21 yrs
I thought I was also infected. So when I tested and found out I don't have it, that when we started using a condom. He did (have a problem using condoms) but I told him I will not infect my baby. I would rather break up with him.	Postpartum, 27 yrs

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Theme 3: Socio-cultural beliefs about sex in pregnancy and postpartum period

Socio-cultural beliefs about sex during pregnancy	
We have that belief that when you are pregnant, you get horny. It might because that's how the baby was conceived and the baby just likes the sex. They say it hardens the baby's fontanelle.	Pregnant, 20 yrs
I know that you need to (have sex) harden the fontanelle.	Pregnant, 22 yrs
He thinks if we have sex, the baby will look like him, the more we have sex, the more the baby will look like him.	Pregnant, 24 yrs
I believe that a male partner opens you up, preparing you for the labour	Pregnant, 24 yrs
Sperm helps the baby grow. When I told him we need to use a condom because I am pregnant. That I am at a high risk of getting diseases and the baby would also be at risk. He said that won't happen because he needs to make the baby develop the way the baby was conceived.	Pregnant, 23 yrs

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PrEP knowledge and potential acceptability in pregnant/postpartum women

PrEP knowledge and potential acceptability	
It's a new drug and I don't know what it will do. You know how sensitive babies are.	Pregnant, 20 yrs
It's suitable because we know HIV is a lot here in South Africa. We should prepare ourselves. We don't know what men will do the next day. I would say we will just have to take up this opportunity because it might change your whole life. I would advise that all the women in South Africa should use it (PrEP).	Pregnant, 20 yrs
I would not be sure how it would affect the baby… because its pills. I think it's those with multiple partners (should take PrEP). Yes I would use it because they say a pregnant woman get infected easily. Even when breastfeeding, it would act as extra protection. They say breast milk has vitamins and nutrients for the baby so it would do the extra job on the side.	Pregnant, 32 yrs
I am not a pill person. Pills make me sick, especially you say it has side effects. But I would like to use it because I don't think there is a person who does not want to protect themselves from HIV. I would be afraid of one thing. Maybe… I don't know how ARVs look like… if I use it someone will think it's ARVs	Pregnant, 22 yrs

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Limitations

- Analyses of sex behaviors and alcohol use were from a cross-sectional study
  - We were not able to follow women up over time to evaluate changes in behaviors
- Self-reported data through face to face interview and lack of bio-markers- more prone to bias and under-reporting risk behaviors
  - Next study will include bio-markers and use ACASI to reduce bias
- Reported information about partner was from mother, no data collected from partner

Discussion

HIV prevention in pregnant women

- Our research demonstrates:
  - high risk behaviors during pregnancy (HIV status of partner unknown, condomless sex, alcohol use, multiple partners)
  - However, sexual risks may be highly variable during this period
- Existing behavioral interventions may be ineffective when pregnant women are not in stable relationships, don't know their partners status, are not using condoms, etc.
- PrEP is an essential female controlled prevention intervention for women who continue to engage in risky sexual activity with HIV infected or partners of unknown serostatus during & after pregnancy
- Because of variable risk (e.g. no sex after birth for up to 6-8 weeks) different levels of PrEP adherence may be needed depending on sexual risk

Next steps: **PrEP-PP study** PrEP among pregnant and postpartum women in Cape Town

- Using our formative results thus far, we have submitted and will resubmit a R01 proposal to evaluate PrEP initiation, retention and adherence in pregnant and breastfeeding women in two facilities with different populations in Cape Town through an observational cohort

- Will apply for a Fogarty International K award in March 2018

Implications of formative study on upcoming research

- Majority of HIV-uninfected pregnant women reported condomless sex with a partner of unknown status or HIV-infected partner, continued alcohol use, and multiple sex partners
  - *How will this affect PrEP initiation and adherence?*
  - *How to we retain women in postpartum period when women don't come in for regular care?*
- Need for a **risk score** to identify at-risk pregnant women?
  - Or target PrEP to all HIV uninfected pregnant women?
  - How best to provide PrEP and counselling to postpartum women?

Opinion piece in AIDS to review the importance of implementation science in PrEP delivery

Delivering preexposure prophylaxis to pregnant and breastfeeding women in Sub-Saharan Africa: the implementation science frontier

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AIDS 2017, **31**:000–000

Table 1. Key operations research questions for optimal preexposure prophylaxis efficacy to prevent maternal HIV acquisition.

Issue	Key questions
Clusters of risk factors and their effect on PrEP initiation and adherence	What are the various clusters of risk factors that may affect pregnant and breastfeeding women's HIV risk, and young women in particular? How do such clusters of risk affect PrEP access, initiation and adherence? What are interventions to address these barriers?
Healthcare provision for PrEP in pregnant women	Can midwives, nurse practitioners, or doctors prescribe PrEP? Who can provide PrEP prescription refills? At what frequency? Follow-up labs and clinical monitoring?
Healthcare provision for PrEP in postpartum women	Who is able to prescribe PrEP in postpartum care? What kind of provider is in the best place to do so? What frequency are labs and clinical monitoring needed in the postpartum period? What are the strengths and limitations of PrEP integration into family planning counselling and serve provision versus into postpartum or routine child health care?
Partner or partners involvement in PrEP care	Does the father of the child, or sex partner (s) need to be involved in PrEP decision-making and counselling? If so, when do partners become facilitators to HIV prevention intervention such as PrEP, and when are they barriers? What is the role of the father of the child (and other sex partners) in preventing HIV acquisition and transmission?
Role of peer support	What is the impact of peer counselling from peers, including other mothers on PrEP, on PrEP initiation and adherence?

PrEP, preexposure prophylaxis.

Thank you!

Any Questions?

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