

Challenges of discrepant HIV tests in pregnant women in the PrEP era – to treat or not to treat?

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Background

- Risk of HIV acquisition is high during peripartum period
- Risk of mother-to-child HIV transmission elevated during incident infection
- PrEP recommended during pregnancy in high burden settings as female-controlled HIV prevention option
- HIV retesting – HIV testing after a prior HIV negative test – is a cornerstone in antenatal and PrEP programs
- Discrepant results (i.e. one positive, one negative) can occur, reflecting either true or false positivity (Figure 1)
- **Guidelines lacking for treatment decisions after discrepant rapid results in context of pregnancy and PrEP**

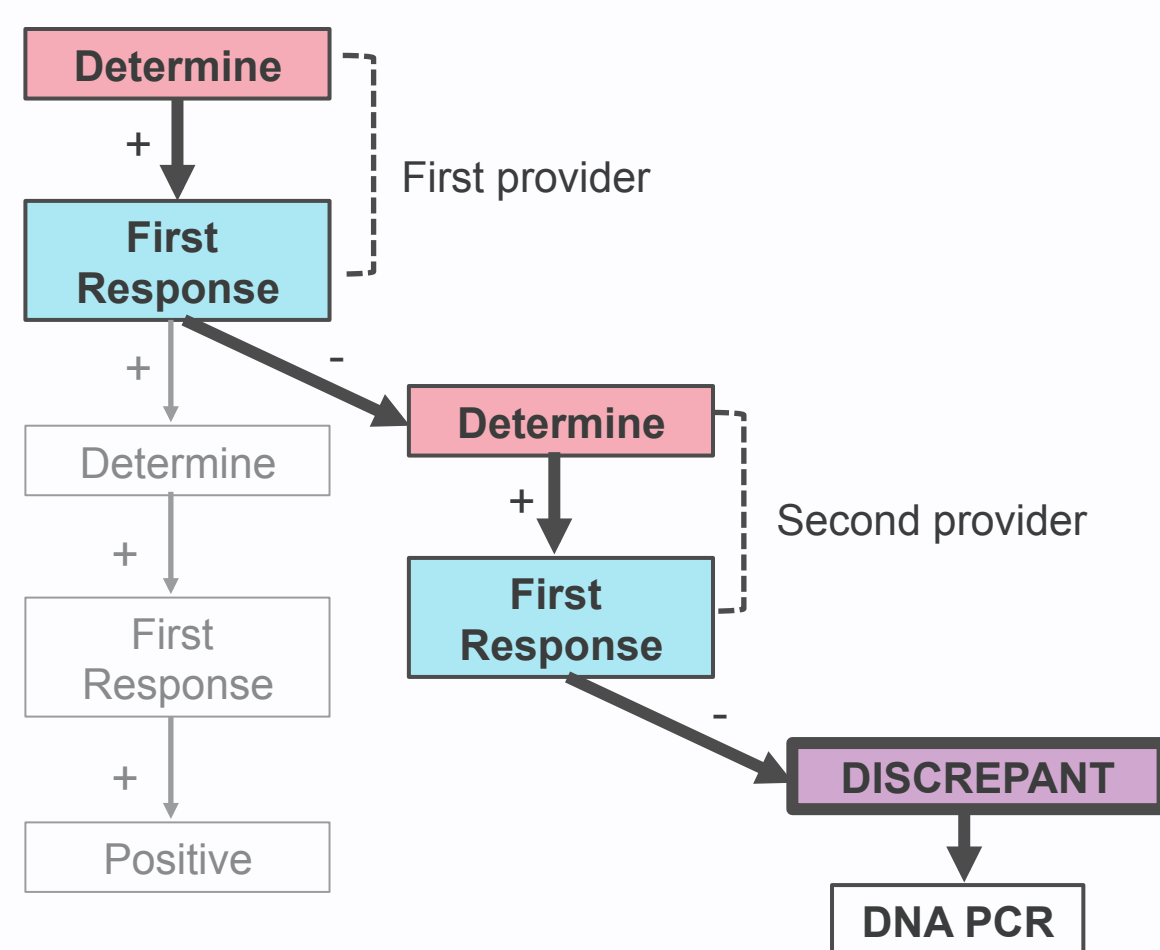


Figure 1: World Health Organization and Kenyan national algorithm for HIV testing

Methods

- PrEP Implementation for Mothers in Antenatal Care (PrIMA) study (NCT03070600) cluster RCT of approaches for integrating PrEP into antenatal care in western Kenya
- Trial ongoing; included data January-November 2018
- HIV-negative pregnant women tested monthly during pregnancy, at 6 & 14 weeks, 6 & 9 months postpartum
- Kenyan national algorithm used for testing (Figure 1); discrepant results tested by DNA PCR
- Women with discrepant results advised to initiate ART while awaiting PCR results

Results

- Among 3,031 women, 6,182 HIV retest sessions conducted, 8 discrepant rapid results (**0.13%, 95% CI: 0.06-0.25%**) among 6 women
- 5 women not using PrEP at time of testing; 1 initiated PrEP, but reported poor adherence and had not taken PrEP within 14 days prior to HIV test
 - Median time to PCR results 21.5 days (range 14-37)
 - **All PCR negative, confirming HIV negative status** (Table 1)
 - While awaiting PCR results, none of the women initiated ART
 - At later visits, 2 women had **recurrent discrepant rapid results with negative PCRs when retested**; one had concordant positive rapid results at delivery; she initiated ART and had two negative PCRs and negative ELISA

First test	Second test	Third test	Fourth test	Fifth test	Days to PCR results	PrEP user	Weeks pregnant / postpartum	Initiated ART	Final HIV Status
R (D)	NR (FR)	R (D)	NR (FR)	Negative DNA PCR (FP)	28	No	20 wk pregnant	Yes	Negative*
R (D)	NR (FR)	R (D)	NR (FR)	Negative DNA PCR (FP)	37	No	38 wk pregnant	No	Negative
R (D)	NR (FR)	R (D)	NR (FR)	Negative DNA PCR (FP)	21	No	37 wk pregnant	No	Negative
R (D)	NR (FR)	R (D)	NR (FR)	Negative DNA PCR (FP)	22	No	26 wk pregnant	No	Negative**
R (D)	NR (FR)	R (D)	NR (FR)	Negative DNA PCR (FP)	14	Yes	34 wk pregnant	No	Negative
NR (D)	R (HIV & Syphilis dual test) ^{&}	R (FR)	Negative DNA PCR (FP)		16	No	26 wk pregnant	No	Negative

R: Reactive; NR: Non-reactive; (D) Determine; (FR) First Response; (FP) Filter paper

* Recurrent discrepant at next visit (36 weeks pregnant) but PCR negative; concordant rapid positive at delivery, PCR negative; follow up PCR and ELISA negative

** Recurrent discrepant at next visit (30 weeks pregnant), no PCR taken

& SD Biorline HIV/Syphilis Duo tests used for initial tests in the event of stock outs of Determine kits or missing ANC syphilis results

Conclusions

- As true HIV incidence decreases with PrEP and retesting, discrepant results will be observed in program settings
- Clinically, false positive results occur during pregnancy due to cross-reactivity with autoantibodies & alloantibodies
- Clinical, emotional, interpersonal, logistical reasons in favor and against treatment while awaiting PCR results (Figure 2)
- Point-of-care viral testing may be helpful, tailored strategy to confirm diagnosis in such limited cases
- **Need for guidelines to clarify public health approaches for programs providing PrEP in pregnancy**



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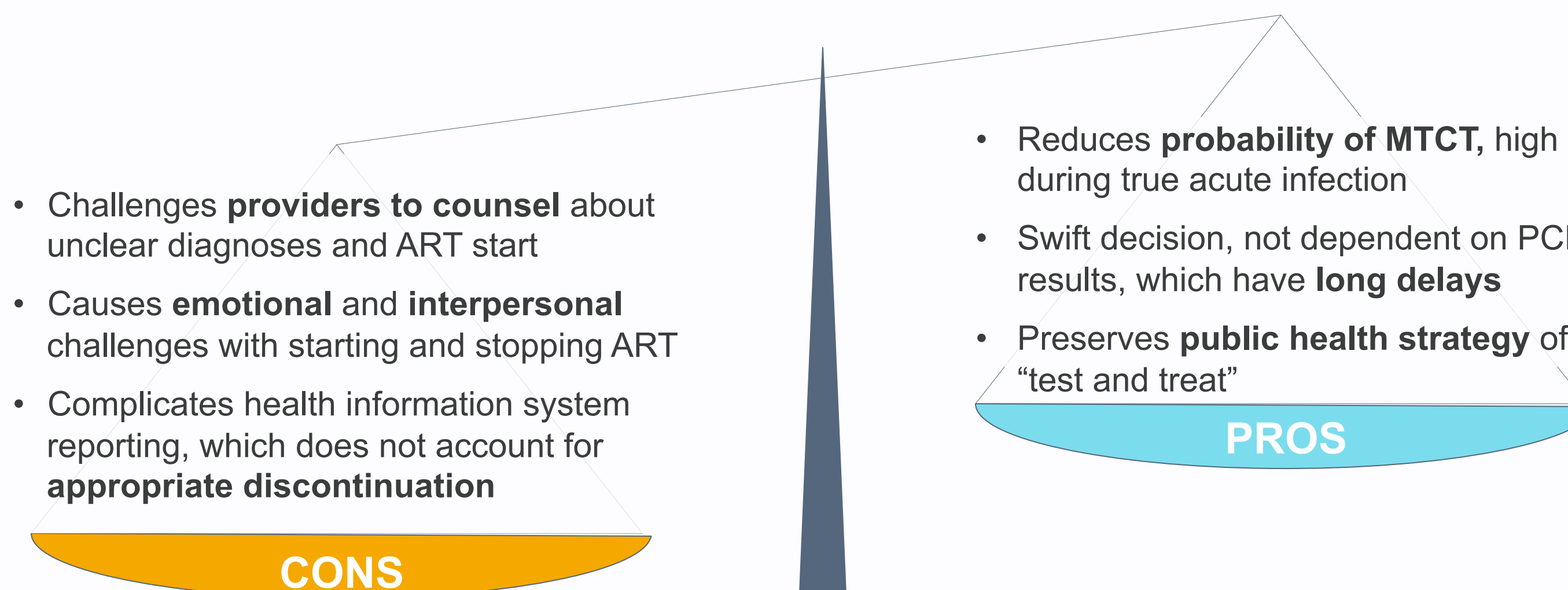


Figure 2: Pros and cons of immediate treatment of women with discrepant results while awaiting PCR

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