DEFERRING CREATININE CLEARANCE AMONG YOUNG WOMEN TO ENABLE IMMEDIATE PrEP INITIATION

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BACKGROUND

- Oral PrEP is the only self-initiated HIV prevention method currently available to young women (aged 15-24 years)
- Despite their high HIV risk, oral PrEP uptake remains low among young women in eastern and southern Africa
- In most settings, creatinine clearance (CrCl) confirmation is required for oral PrEP initiation
- CrCl assesses kidney function, but renal abnormalities are rare among young people
- The time needed for CrCl confirmation is variable and depends on local resources and infrastructure
- Delays caused by CrCl confirmation can decrease young women's motivation to initiate and use oral PrEP
- To strengthen the argument for immediate oral PrEP initiation, we examined the frequency of renal dysfunction pre- and post-PrEP initiation among young women in South Africa

METHODS

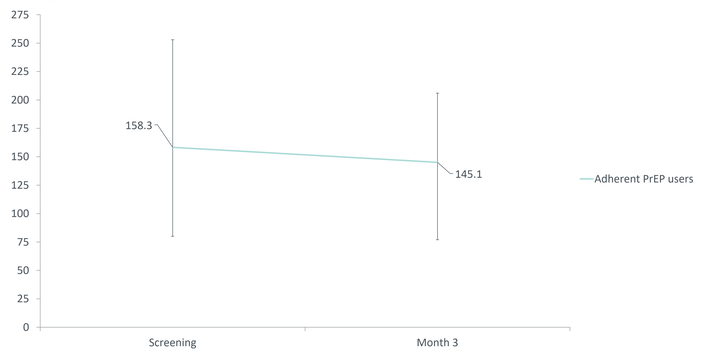
- Data collected from young women enrolled in an oral PrEP demonstration project in KwaZulu-Natal, South Africa
- Collected 5 ml blood specimens and performed laboratory assays to measure CrCl
- Per national guidelines, defined renal dysfunction as <60 mL/min
- Examined reasons for non-enrollment to assess possible lost motivation
- Analyzed differences between non-enrollees and enrollees
- Used dried blood spots to measure concentration of tenofovir-diphosphate on a subset of enrolled participants as indication of adherence
- Assessed CrCl changes among subset with drug concentration data and detectable drug levels at next CrCl measurement (month 3)
- Stratified by age-group (aged 15-17, 18-24); due to enrollment differences, data for those aged 15-17 are exploratory

RESULTS

- Among 319 screened young women, no cases of abnormal renal dysfunction (Table 1); ultimately, 229 enrolled
- 60% (54/90) of non-enrollment due to not returning to the study, a possible indication of lost motivation
- There were no meaningful sociodemographic differences by motivation status
- Most enrollees were not in partnerships that heightened their HIV risk (Table 1)
- Of the drug concentration subset (n=33), 31 young women (aged 18-24) had detectable drug levels at month 3
- Among adherent young women, mean CrCl levels reduced by 7.5% between screening and month 3 (Chart 1)

Renal dysfunction is rare among young women (aged 15-24), and short-term oral PrEP use leads to minimal creatinine reductions. Immediate oral PrEP initiation is a safe option for young women.

Chart 1. Changes in mean creatinine clearance among PrEP-adherent young women (n=31)



The error bars represent the range of creatinine clearance values at each time point

Table 1. Screening CrCl and baseline partnership characteristics of young women

	Aged 15-17 years	Aged 18-24 years	Aged 15-24 years
Mean CrCl levels (SD, Range)	150.4† (42.6, 100.0-258.0)	155.4‡ (43.6, 76.0-362.0)	155.0§ (43.6, 76.0-362.0)
Single or Monogamous	100.0% (16/16)	90.1% (192/213)	90.8% (208/229)
Stable partnership	62.5% (10/16)	89.7% (191/213)	87.8% (201/229)
Mean age difference (SD)	1.9 (1.7)	4.3 (3.9)	4.2 (3.8)
Partner is from the community	81.2% (13/16)	70.0% (149/213)	70.7% (162/229)
Did not know partner's status	43.8% (7/16)	22.5% (48/213)	24.0% (55/229)
Partner is circumcised	87.5% (14/16)	69.0% (147/213)	70.3% (161/229)

SD: Standard Deviation, CrCl: Creatinine Clearance, † 1 individual aged 15-17 years (23/24) did not have CrCl data at screening, ‡ 26 individuals aged 18-24 (269/295) did not have CrCl data, § 27 individuals aged 15-24 (292/319) did not have CrCl data

CONCLUSIONS

- In this context, no young women had renal dysfunction
- Short-term CrCl reductions among adherent users were not clinically significant
- Since most non-enrollees did not return in time for enrollment, harnessing the power of motivation is key
- The risk of renal dysfunction among young women in eastern and southern Africa is disproportional to their HIV risk. Thus, CrCl should not act as a barrier to oral PrEP uptake. Our findings highlight immediate oral PrEP initiation is a safe option for this population.

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