

## Mini-Oral Abstract Presentations 1

# #15 Is the Use of Creatinine Clearance Test at Baseline for PrEP Enrolment Necessary in Resource-Constrained Settings?

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# Is the use of creatinine clearance test at baseline for oral PrEP enrollment necessary in resource-constrained settings?

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# Background

- Malawi has made great strides in addressing the HIV epidemic. Yet, HIV prevalence and annual incidence rates among FSWs is estimated at 62.7% and 2.8 % respectively
- In 2015, WHO recommended that people at substantial risk of HIV infections should be offered oral pre-exposure prophylaxis (PrEP) as an additional prevention option
- In response, the Ministry of Health launched the USAID/PEPFAR-funded PrEP Implementation Science project, with technical support from FHI 360 Malawi



# Study: Design, Aim, Objectives, Site, Duration and Population size

- Prospective cohort study among FSWs aged 18 and above
- To assess the operationalization of oral PrEP in Malawi as an additional HIV prevention method among FSWs at high risk of HIV infection
- To determine PrEP acceptance rate, feasibility of integration of PrEP into public health facilities, adherence and retention rates
- FHI 360 local partner Pakachere at Bangwe, Chirimba & Naperi drop in centres
- 6 months recruitment and 12 months (February 2019 and Sept 2020) follow-up
- Sample size of 560 new PrEP initiations, conducted in-depth interviews with 9-12 clients who declined PrEP and FGD with PrEP providers

# Study: Inclusion and exclusion criteria

## Eligibility

- FSWs 18 years of age or older, HIV negative status, and no evidence of acute HIV infection
- Are at risk of HIV (answers yes to any of the questions on HTS (Risk Assessment Tool))
- Able and willing to provide written informed consent to participate in the study
- Access services at a DIC or mobile clinic in the defined catchment area
- Willing and able to adhere to daily PrEP

## Exclusion

- Under 18 years of age, suspicion of acute HIV infection with using risk score of 2 , evidence of impaired kidney function
- Unwilling/unable to adhere to daily PrEP
- Pregnant or breastfeeding

# Study Participants Flow

Clients sensitized  
on PrEP at  
Zingwangwa  
Chirimba HCWs



Self-referral  
Drop in  
Centre DICs



Targeted  
community  
referral



HIV risk  
assesment done  
by healthcare  
worker



PrEP eligibility  
screening for  
those at risk and  
interested in  
PrEP

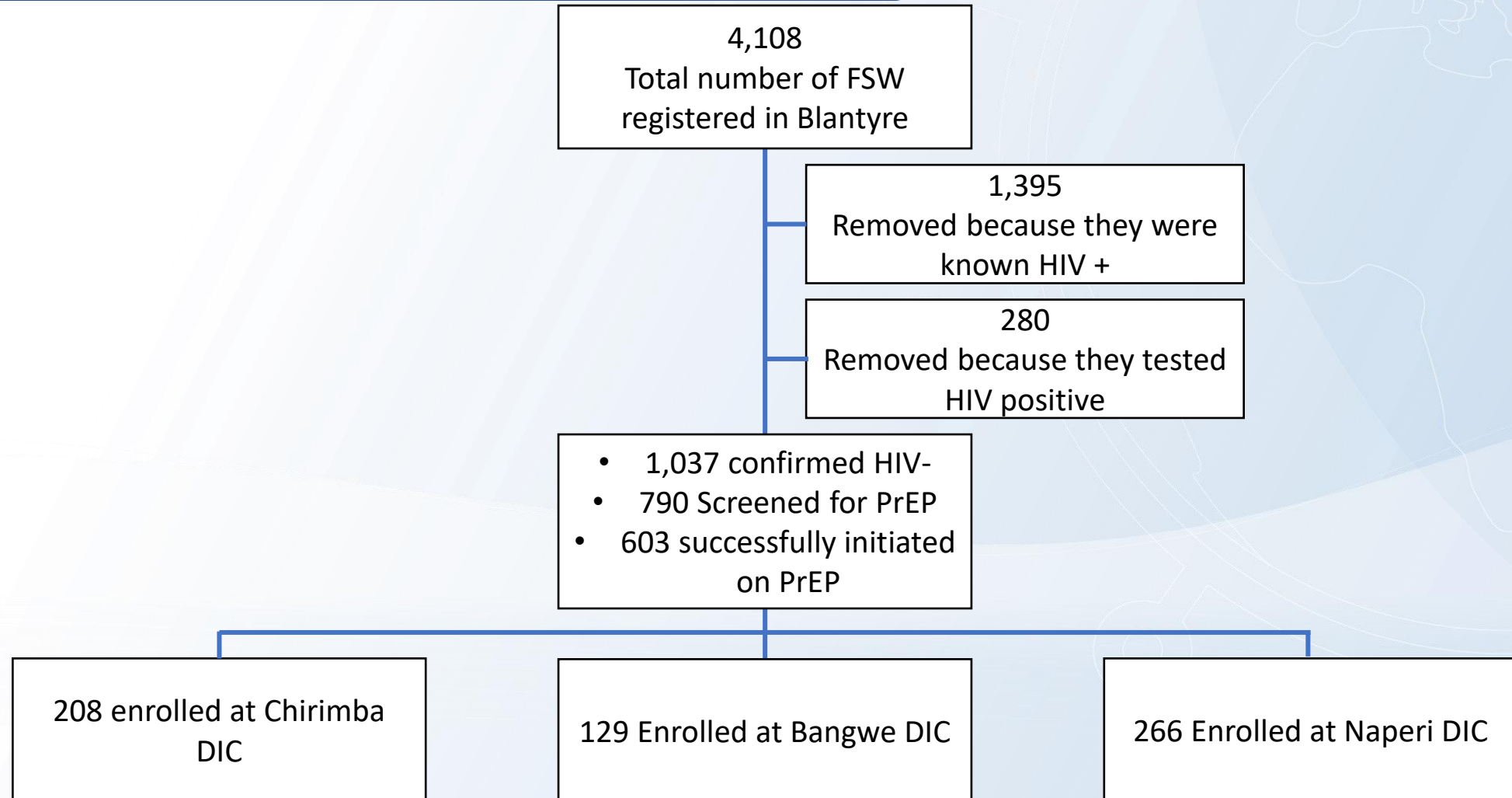


PrEP initiation  
if no contra-  
indications

# Methods

- Following WHO recommendations, creatinine clearance (CrCL) test was used for monitoring kidney function
- Individuals with CrCL less than 60mL/min were excluded from PrEP
- FSWs enrolled for PrEP, consented to blood draws at three drop-in centres (DICs) in Blantyre.
- Whole blood samples were collected at months 0, 1, 3 and 6 visits and transported to MoH Queen Elizabeth Reference Laboratory.
- Cockcroft-Gault equation formula was used to calculate CrCL.
- CrCL test result turnaround time was 2 weeks

# PrEP Recruitment Breakdown





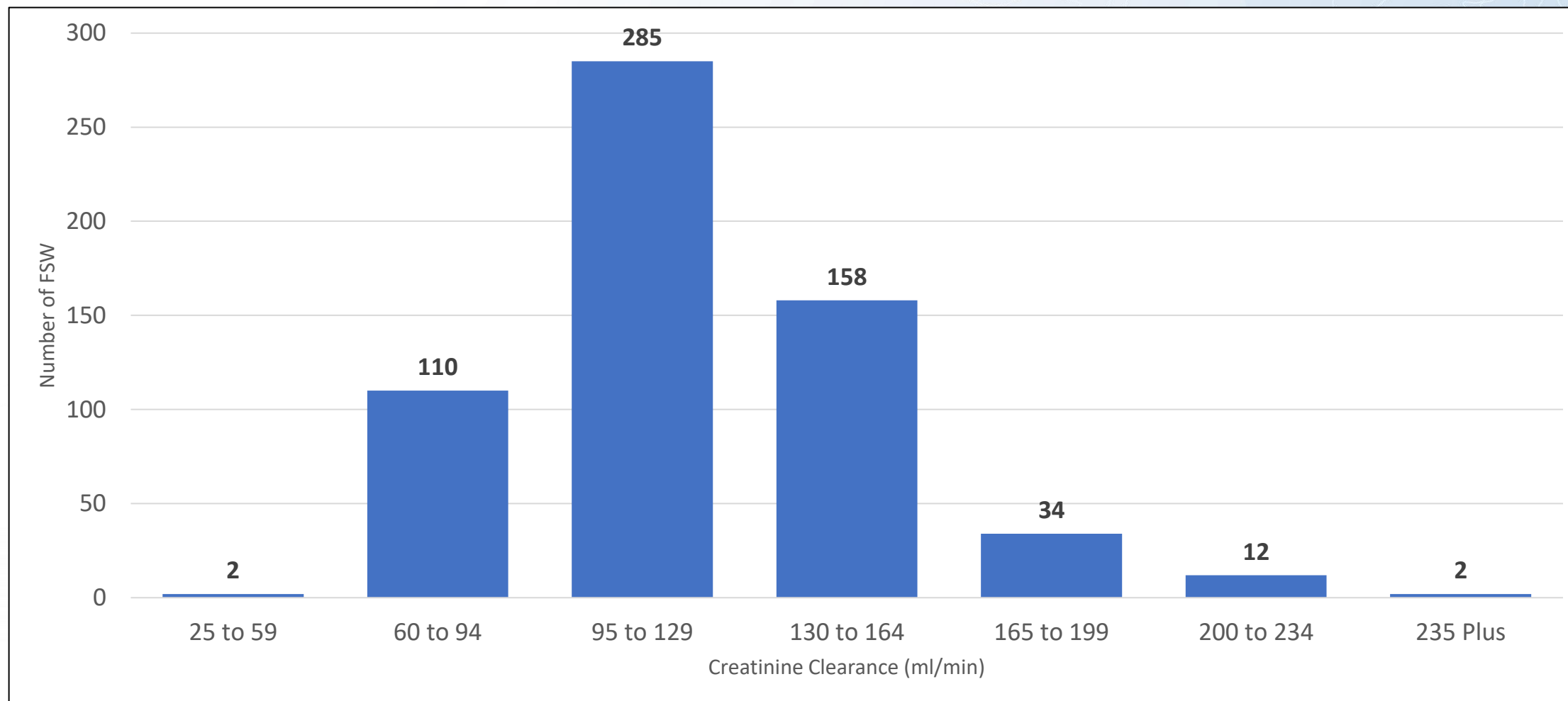
# PrEP Delivery Performance by DIC

No	Indicator	Chirimba	Naperi	Bangwe	Total
1	Screened for PrEP (cumulative)	264	309	217	790
2	PREP_NEW in 2019	151	170	88	409
3	PREP_NEW in 2020	57	96	41	194
4	Currently on PrEP (PREP_CURR)	208	266	129	603
5	Currently active on PrEP	45	51	26	122
6	Discontinued (decided to stop PrEP)	153	212	99	464
7	Removed from the study due to adverse events	10	3	4	17

# Baseline characteristics of FSWs on PrEP

	Median Score	IQR
Median Age	23	8
Median Age at Sex Work Debut	18	5
Median Sex Acts per Week	24	21
Median Years in Sex Work	4	4
Education Level		
None		41
Primary		393
Secondary		166
Missing		3

# Baseline Creatinine Clearance Distribution



# Argument

- Is the use of creatinine clearance test at baseline for oral PrEP enrollment necessary in resource-constrained settings?

## Conclusion 1

- The continued use of CrCL to determine eligibility for PrEP enrollment in resource-constrained settings, where 99.8% of eligible clients have normal CrCL and the test is generally unavailable, especially in primary public health facilities and appear more of a barrier than facilitator to PrEP scale-up.
- The use of CrCL test may not be necessary as a screening test at baseline for oral PrEP enrolment especially in resource-limited settings.

# Principal Investigators Co-Investigators

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EpiC is a global cooperative agreement dedicated to achieving and maintaining HIV epidemic control. It is led by FHI 360 with core partners Right to Care, Palladium, Population Services International (PSI), and Gobe Group.

