



Expanding pre-exposure prophylaxis for pregnant and breastfeeding women through long-acting options: **Zambia's experience**

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HIV
Impact Network for
Vertical Transmission
Elimination



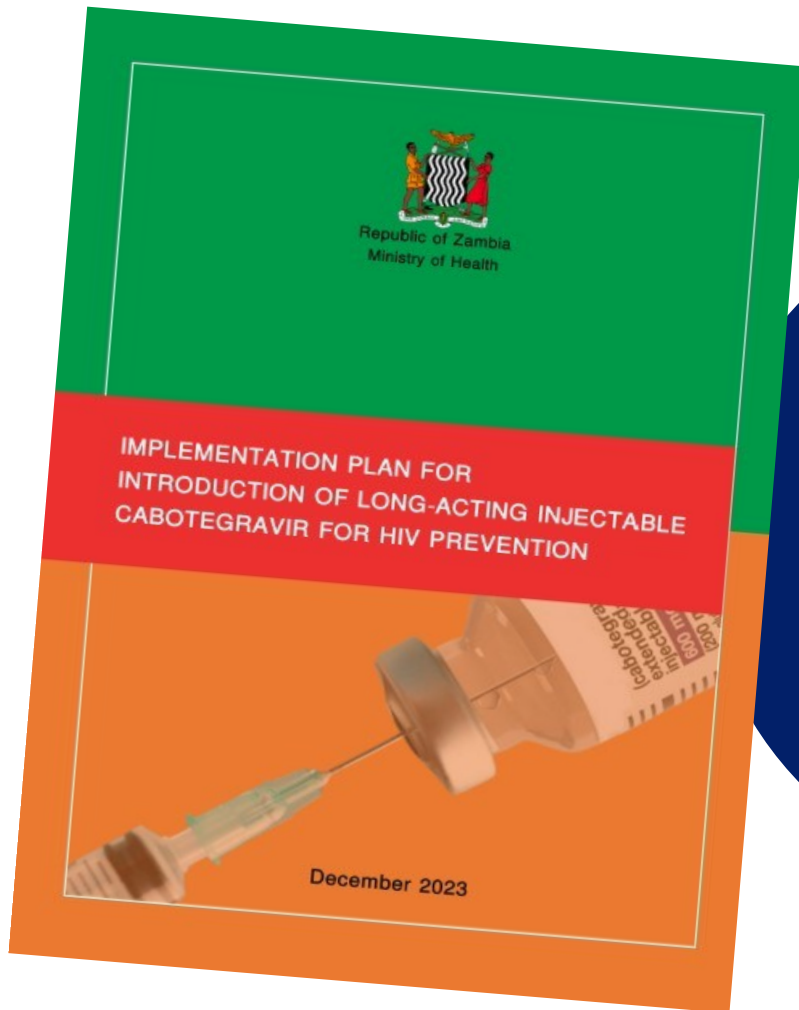
Background

In 2017 Zambia introduced oral pre-exposure using TDF-based ARVs, and to date the country has cumulatively initiated **over a million individuals on PrEP.**

On February 9, 2024 Zambia became the first country outside the United States to implement the Cabotegravir Injectable Long-Acting (CAB-LA) PrEP outside of a study setting.



Zambia's CAB-LA introduction guided by national implementation plan



Introduction initially in 4 sites

CAB-LA service provision expanded to 30 sites across all 10 provinces

Inclusion Criteria

- Individuals who are >16 years of age, with a specific emphasis on adolescents and young people
 - Females 80%
 - Males 20%
 - Intersectionality (*key populations e.g. MSM, FSW and TG*)
 - At risk of HIV acquisition, and anticipates being on PrEP for the coming 12 months
 - Agrees to engage with the facility/site throughout time on CAB-LA and one year thereafter
- 50% with demonstrated PrEP adherence (≥6 months on oral PrEP)
- 50% as new initiators on PrEP

Exclusion Criteria


- **Pregnancy/breastfeeding**
- <16 years old



Process


- 1

Provide **comprehensive counselling** on HIV prevention and available PrEP options




- 2

Administer the **Clinical Eligibility Form** for CAB-LA




- 3

Conduct laboratory tests required for initiation, including **confirming HIV-negative status**




- 4

Complete the **client locator form** for an eligible client, and refer them for CAB-LA service provision



- 5

After service provision, use the **PrEP Adherence Form** to counsel the client about importance of adherence



CAB-LA LABORATORY INVESTIGATION AND ACTION CHECKLIST

Laboratory Investigation	Type of visit			Test Results Action
	Initiation Visit 1	Initiation Visit 2	Reinjection Visits	
Determine Rapid HIV Test	Mandatory for all clients	Mandatory for all clients	Mandatory for all clients	Subject non-reactive result to SD Bioline HIV Self Test
SD Bioline	Mandatory for all clients	Mandatory for all clients	Mandatory for all clients	SD Bioline results negative: Offer CAB LA and take NAAT sample. Discordant results: repeat test in parallel. Positive SD Bioline – Initiation of ART
Nucleic Acid Amplification Test (NAAT)	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA. If there is no NAAT result from first visit, do not inject.	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA	If NAAT result is positive, call client back for initiation on ART in consultation with clinical experts.
Alanine Aminotransferase (ALT)	Mandatory for all clients. Initiate client after reviewing results	Mandatory for all clients. Initiate client after reviewing results	Mandatory for all clients. Initiate client after reviewing results	Do not give CAB-LA to clients with ALT readings of 2.5 times upper limit of normal (Normal values <19 U/L in females and <30 U/L in males)
Hepatitis B Surface Antigen Test (HBsAg)	Mandatory for all clients. Inject client after reviewing results.	Mandatory for all clients. Inject client after reviewing results.	Mandatory for all clients. Inject client after reviewing results.	Positive results: Hepatitis B positivity should not be a barrier to CAB-LA. If ALT levels are elevated, transition to oral PrEP; if necessary, refer to higher level for further management.
Rapid Plasma Reagin (RPR)	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA.	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA.	Collect blood sample, fast track results. Delayed results must not be a barrier to initiation of client on CAB-LA.	RPR positive results: Treat according to National STI guidelines.
Pregnancy Test	Mandatory for all female clients. Initiate client after reviewing results.	Mandatory for all female clients. Initiate client after reviewing results.	Mandatory for all female clients. Initiate client after reviewing results.	Positive results: Counsel client, offer to transition to oral PrEP. If client opts to remain on CAB-LA, client must sign consent form.



Strong community engagement and use of peer mobilizers critical for **demand generation** and **client follow-up**

Injectable PrEP SBC materials to address myths and misconceptions

ZAMBIA ENDING AIDS

INJECTABLE PrEP AFTERCARE

Possible side effects over the next few days:

- Pain at injection site
- Headache
- Tiredness
- Fever
- Dizziness
- Nausea and/or diarrhea

Most side effects are mild and should go away on their own. If the side effects continue, return to the healthcare facility.

Returning For Your Next Injection

- You must ensure that you stick to your appointments for your follow-up injections.
- If you cannot keep your appointment, contact your healthcare provider.

Please Remember

- Injectable PrEP does not protect against other sexually transmitted infections. Remember to practice safer sex and use other prevention methods such as Condoms and VMMC.
- Injectable PrEP does not prevent pregnancy.

ZAMBIA ENDING AIDS

BE READY WITH INJECTABLE PrEP

It's easy to stay safe if you use PrEP to protect you against HIV

How does Injectable PrEP work?

- You must get your second injection at one month after receiving your first injection. After that, you will return for injections every two months.
- Injectable PrEP can cause mild side effects which are short-lived. These include nausea, headache, tiredness, diarrhoea and pain at the injection site.
- It is very important not to miss your scheduled appointment because missing an appointment can increase the risk of contracting HIV.
- It is advisable to use other forms of HIV prevention in the first seven days after receiving the first dose of injectable PrEP.

EXTRA PROTECTION

It is important to note that Injectable PrEP does not prevent pregnancy or protect you against STIs. The Ministry of Health recommends that people taking Injectable PrEP should also use other HIV prevention methods to reduce the risk of HIV infection further. Including:

- Correct and consistent use of condoms (they also prevent other sexually transmitted infections (STIs) and unplanned pregnancies).
- Voluntary Medical Male Circumcision (VMMC).
- Treatment for STIs.
- ARVs for HIV-positive sexual partners.

BE READY WITH injectable PrEP - FACT SHEET Page 5

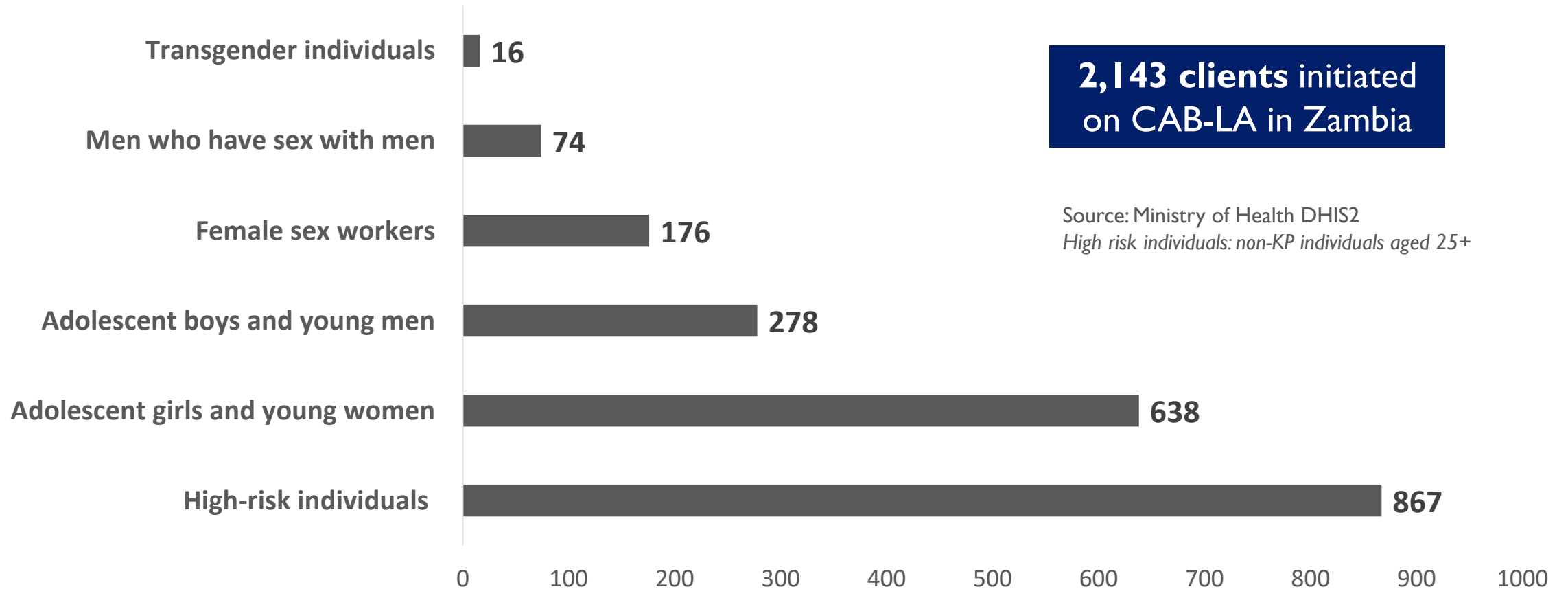


Dorcas Kapupa, first provider to administer CAB-LA in Zambia, in the Prevention room at Mwanjuni Health Post

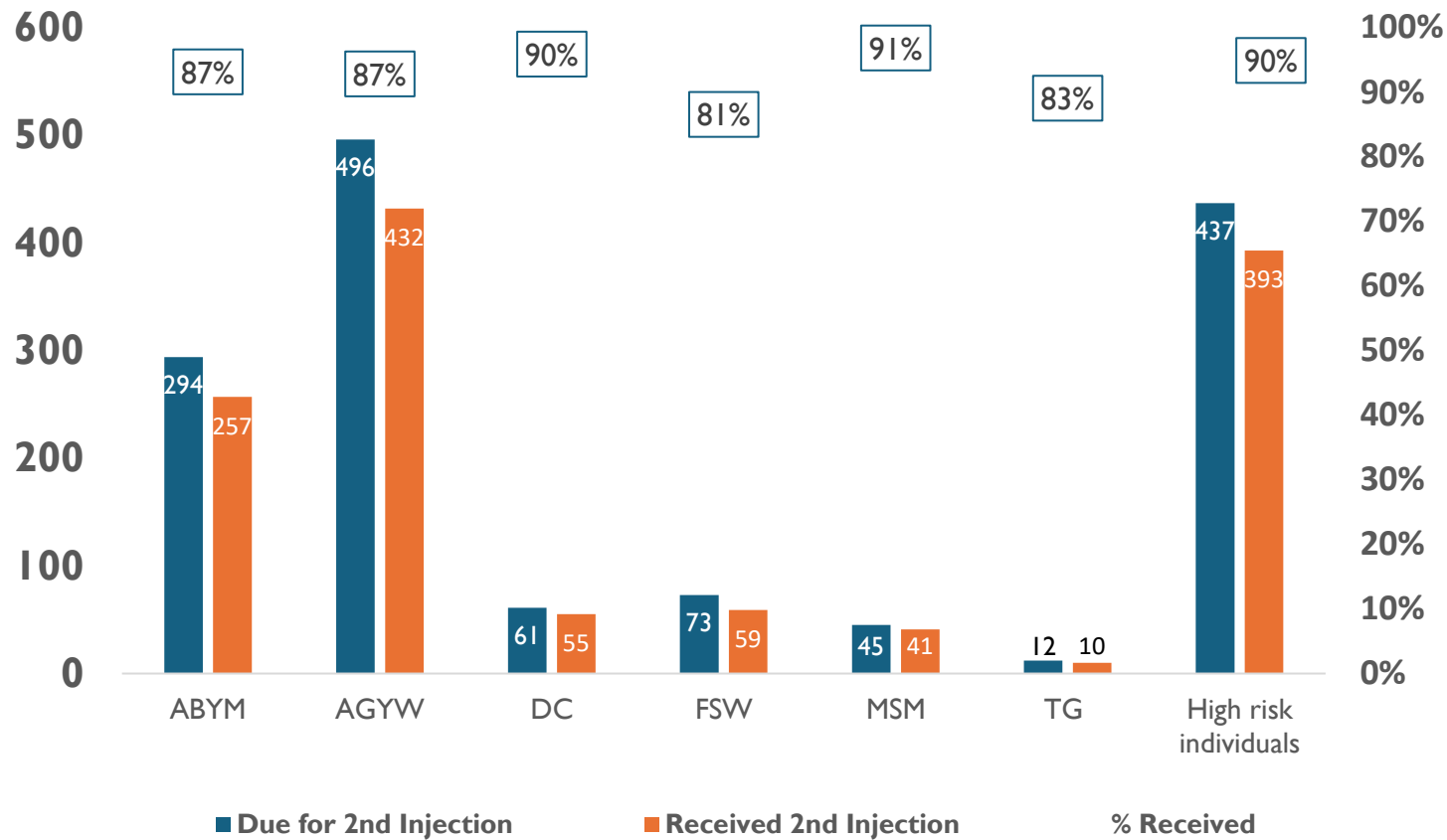


‘Prevention’ rooms: Address *stigma* associated with provision of PrEP in ART

CAB-LA uptake by population type – Feb 9 – Sept 30, 2024



Early data shows promising continuation at 2nd injection, especially among at-risk populations



Population Group	1-month Oral PrEP continuation	1-month CAB-LA continuation
ABYM	47%	87%
AGYW	40%	87%
DC	64%	90%
FSW	51%	81%
MSM	39%	91%

Graph Source:
Implementing partner
program data (July 2024)

Table Source:
USAID DISCOVER-Health
PrEP Management System n

CAB-LA use in PFW: Early experiences from USAID DISCOVER-Health

- 20 instances of pregnancy in USAID DISCOVER-Health supported sites since February 9, 2024 out of 753 women initiated on CAB -LA
- **10 women discontinued CAB-LA**
- **10 women continued CAB-LA**
 - Two deliveries of healthy babies
 - Four terminations
 - One miscarriage
 - Three are still pregnant and continue to be followed up
- Normal findings in all ultrasound scans conducted

SN	Age	CAB-LA status	Ultrasound findings	Pregnancy outcome
1	29	Continued	NAD	Delivered a 2.5Kg female baby
2	23	Discontinued	NAD	Still being followed up.
3	16	Continued	NAD	Delivered a 3.6 Kg female baby
4	36	Continued	N/A	Miscarriage
5	21	Continued	NAD	Terminated
6	26	Discontinued	NAD	Still being followed up
7	36	Discontinued	NAD	Still being followed up.
8	19	Discontinued	Not done	Relocated
9	25	Discontinued	Not done	Still being followed up.
10	20	Discontinued	NAD	Still being followed up.
11	30	Discontinued	NAD	Still being followed up.
12	24	Discontinued	Not done	Still being followed up.
13	25	Discontinued	Not done	Still being followed up.
14	23	Continued	NAD	Still being followed up.
15	17	Continued	NAD	Still being followed up.
16	21	Discontinued	NA	Terminated
17	17	Continued	NAD	Still being followed up.
18	34	Continued.	NA	Terminated
19	27	Continued	NA	Terminated
20	34	Continued	NA	Terminated

CAB-LA Pregnancy Safety

HPTN 084 presented new safety and pharmacokinetic (PK) findings for long-acting injectable cabotegravir (CAB-LA) when used before and during pregnancy.

The findings show that CAB-LA used as pre-exposure prophylaxis (PrEP) was generally well tolerated and generally safe for both pregnant cisgender women and their babies.

While CAB-LA concentrations among participants declined over the three pregnancy trimesters, drug levels remained above protocol-specified target levels



This study analyzed the outcomes of more than 300 pregnant women who used CAB-LA, and no cases of adverse effects or neural tube defects were reported.

However, women who were exposed to CAB-LA within a year before becoming pregnant should have close monitoring of their pregnancy and fetal outcomes

Close monitoring of PBFW on CAB

Pregnancy outcome parameters:

- Ultrasound scan at 12 weeks or 1st contact, then 3rd trimester.
- GA at delivery (37W)
- APGAR score
- Mode of delivery.
- Birth weight and other vital parameter throughout perinatal period.

Mother parameters: routine ANC monitoring

PREGNANT AND BREASTFEEDING WOMEN MONITORING FORM FOR CABOTEGRAVIR LONG-ACTING (CAB-LA) INJECTABLE
Used for additional routine monitoring of pregnant and breastfeeding women on or who have discontinued CAB LA

Facility:	Client Name:
Client Phone No.	Unique Identifier:
Date of birth (dd/mm/yyyy): ___/___/___	
Client Physical Address:	
Client's Next of Kin:	Client's Next of Kin Phone No.:
Date of Initiation of CAB LA (dd/mm/yyyy): ___/___/___	Date of Discontinuation of CAB LA (dd/mm/yyyy): ___/___/___
Last visit date (dd/mm/yyyy): ___/___/___	Date (dd/mm/yyyy): ___/___/___

Physical Examination

Temp:	BP:	Pulse:
Pallor:	Height:	Body Weight:

Obstetric History

1 Gravida:	Parity:
Previous pregnancy Complications (if any) Describe	Is client taking other medication? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify: _____

Pregnancy Monitoring

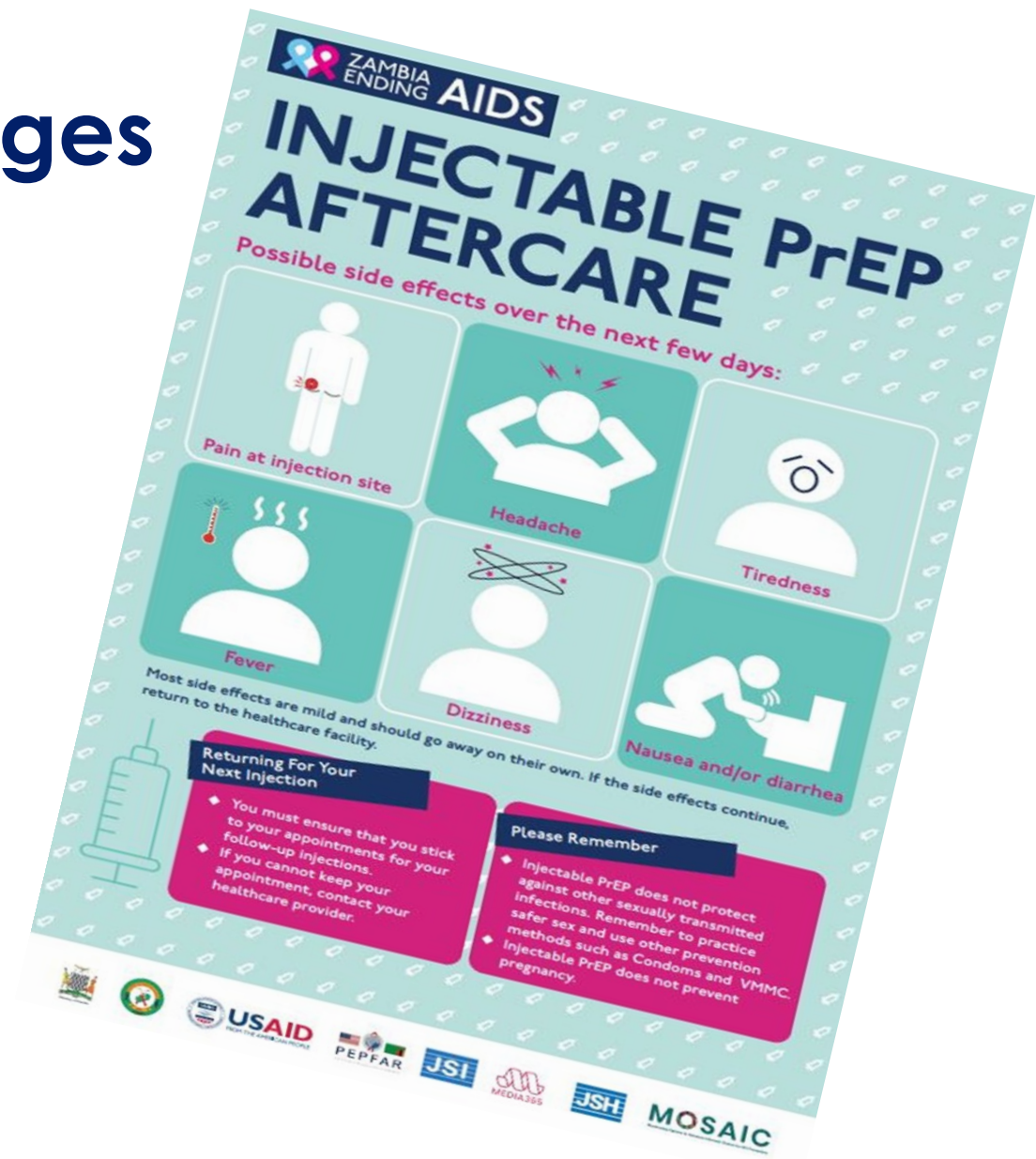
ANC #:	HIV test result:	Date (dd/mm/yyyy): ___/___/___
EDD (dd/mm/yyyy): ___/___/___	LMP: (dd/mm/yyyy): ___/___/___	Gestational Age:

Lessons learnt and challenges

Unmet need for HIV prevention options among PBFW.

Routine obstetric ultrasound scan not accessible to all.

Anticipated confounders between CAB exposure and pregnancy outcome.



Thank You!



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