HIV Learning Network
The CQUIN Project for Differentiated Service Delivery

UNDERSTANDING FACTORS ASSOCIATED WITH IPT COMPLETION AMONG RECIPIENTS OF CARE ON ART/IPT ALIGNED MULTI-MONTH REFILLS ACROSS THE DIFFERENTIATED SERVICE DELIVERY MODELS

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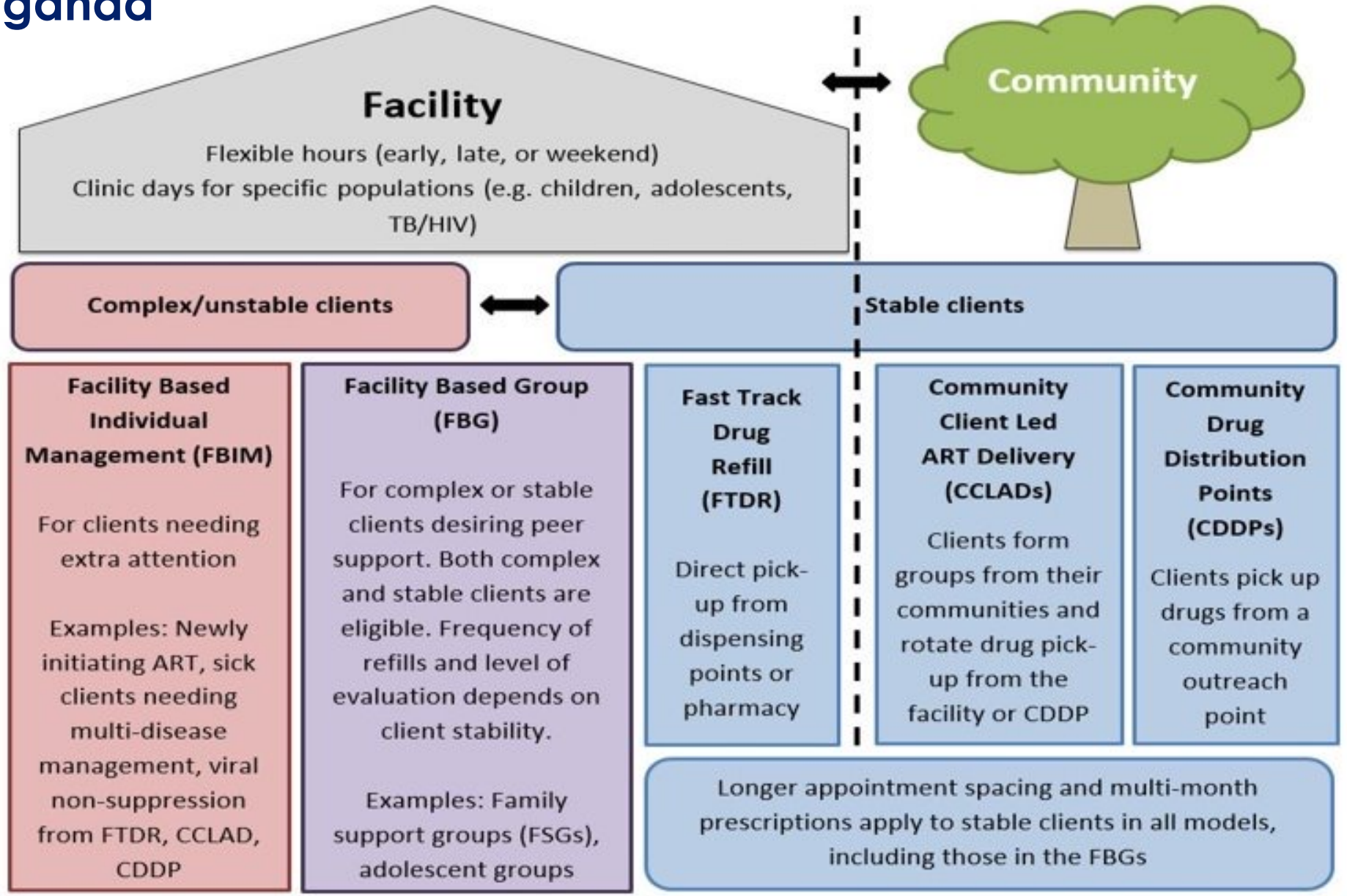
Background

- TB remains the leading cause of death among PLHIV.
- Prevention of active TB disease by treatment of Latent TB Infection is a critical component of WHO's End TB Strategy
  - Six months of Tuberculosis Preventive Treatment (TPT) prevents progression from LTBI to active TB disease.
  - In PLHIV and children under 15 years of age, TPT **reduces the risk** of developing TB by approximately **55%** and TB/HIV deaths by about **40%**
  - MOH in Uganda recommends TPT for PLHIV as part of HIV care package.
- As ART uptake increases, differentiated service delivery (DSD) models which involve multi-month ART refills have been adopted for established clients
  - There is evidence that IPT adherence and completion can be improved with integration of TB and HIV services
  - Hence, it becomes meaningful to consider 3-6 months (instead of monthly) refills of IPT coinciding with ART for established clients
  - MOH in Uganda recommends alignment of IPT with the DSD multi months refills. However, the effect of this on completion of IPT is unknown

DSD Models in Uganda



Study Objectives

1. To compare IPT completion rates among clients across the five DSD models: Facility-Based Individual Management (FBIM), Facility-Based Group (FBG), Fast Track Drug Refill (FTDR), Community Client Led ART Delivery (CDDP), and Community Drug Distribution Points (CCLAD)
2. To understand individual and facility level factors associated with IPT completion across the different DSD models
3. To compare the frequency of adverse events (AEs) reported by clients on IPT across the different DSD models
4. To document patient and healthcare provider knowledge and attitudes toward the IPT/ART integrated model

Study Methods

- A cross-sectional study that examined PLHIV who initiated IPT from July to September 2019 (study period)
- Study population evaluated **for IPT completion at 6-9-month** time point from initiation and description of Adverse events reported

- The study employed a concurrent mixed methods approach:
    1. **Retrospective data review** using **electronic medical records** and **patient registers** for clients who initiated IPT during the study period and were active in care at 6-9-month time point
    2. **A quantitative questionnaire/survey** of selected **clients** who initiated IPT during the study period
    3. **Focus group discussions (FGD) with clients who initiated IPT during the study period**
    4. **Key informant interviews (KII)** with selected **HCPs and expert clients/peer educators** who provide IPT services

Study Methods: Sample Size

Quantitative component

- Chart review= 2,968 (HIBRID database)

	TASO	Katakwi hospital	Soroti RRH	Total
Chart review	766	712	1526	2,968
Sample for survey	112	133	276	521

- Survey sample size=521

Qualitative component

FGDs (n=15)

- IPT completers (n=9)
- Non-completers (n=6)

KIIs (n=21)

- HCWs (n=6)
- Expert clients (n=15)

Study Enrollment

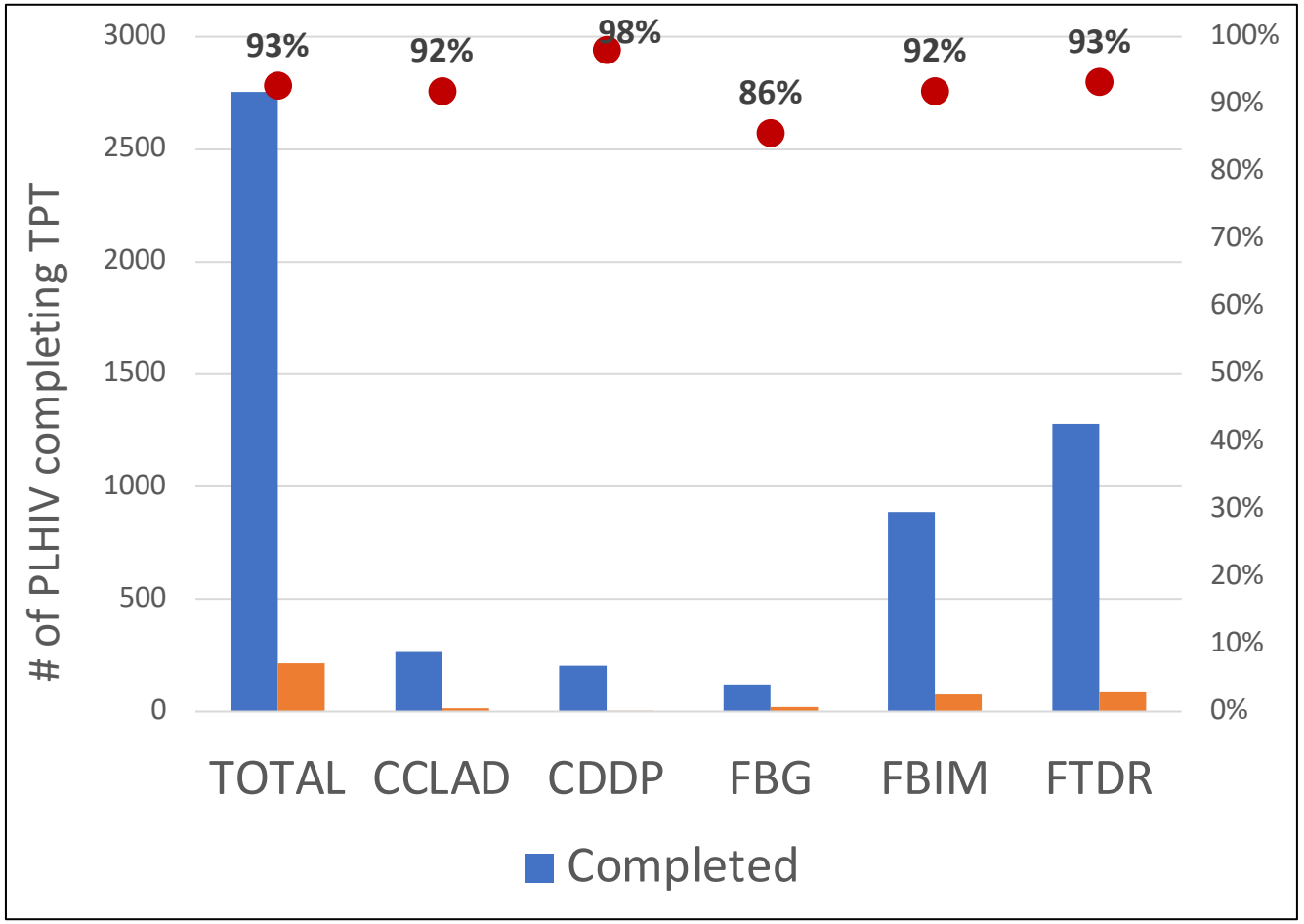
1. Retrospective data review of clients = 2,968
2. Survey with clients = 510
3. FGDs with clients = 88 participants
4. KIIs with selected HCPs and expert clients/peer educators = 9

Results: Patient Characteristics (Medical Records Data Abstraction)

Characteristics	Total	CCLAD	CDDP	FBG	FBIM	FTDR
Number extracted	2,968	288 (9.7)	208 (7.0)	141 (4.8)	963 (32.4)	1,368 (46.1)
Site, n (%)						
TASO Soroti	766 (25.8)	223 (77.4)	160 (76.9)	47 (33.3)	142 (14.8)	194 (14.2)
Soroti RRH	1,490 (50.2)	0 (0.0)	43 (20.7)	73 (51.8)	608 (63.1)	766 (56.0)
Katakwi Hosp.	712 (24.0)	65 (22.6)	5 (2.4)	21 (14.9)	213 (22.1)	408 (29.8)
Female sex, n (%)	1801 (60.7)	202 (70.1)	140 (67.3)	91 (64.5)	584 (60.6)	784 (57.3)
Age at initiation of IPT in yrs, Median (IQR)	43.2 (34.5,52.0)	49.0 (41.0,55.0)	49.5 (44.0,56.0)	15.5 (12.0,26.0)	34.0 (28.0,42.0)	43.0 (36.0,51.0)
ART duration in yrs at IPT* initiation, Median (IQR)	6.0 (3.7,8.6)	6.2 (4.9,7.8)	7.8 (5.6,13.0)	5.9 (3.8, 8.1)	5.6 (2.4,8.0)	6.3 (4.4,9.2)
ART regimen, n (%)	2,967	288	208	141	963	1,367
INSTI*	1837 (61.9)	217 (75.4)	183 (88.0)	80 (56.7)	524 (54.4)	833 (60.9)
NNRTIs*	870 (29.3)	59 (20.5)	18 (8.7)	30 (21.3)	317 (32.9)	446 (32.6)
PI*	260 (8.8)	12 (4.2)	7 (3.4)	31 (22.0)	122 (12.7)	88 (6.4)
ART treatment line, n (%)	2,965	288	206	141	962	1,368
First line	2718 (91.7)	275 (95.5)	197 (95.6)	117 (83.0)	854 (88.8)	1275 (93.2)
Second, third and fourth lines	247 (8.3)	13 (4.5)	9 (4.4)	24 (17.0)	108 (11.2)	93 (6.8)

*INSTI= Integrase strand transfer inhibitor, NNRTIs= Non-nucleoside reverse transcriptase inhibitors, PI= Protease Inhibitors.

Results: IPT Completion Rate (CR) Across DSD models



- 2754 / 2968 PLHIV completed IPT
- CR: 92.8% (95% CI: 91.8-93.7%)

Factors associated with IPT completion across community DSD models

- Among patients in the **CCLAD** model, IPT completion varied by gender and ART regimen

  Completion was higher among the males than females (96.5% vs 90.1%, RR = 1.07, 95%CI: 1.01 - 1.14).

  All patients (100%) on the PI based regimen completed IPT compared to 93.1% on INSTI based regimen and this difference was significant (RR=10.7, 95%CI: 1.04 – 1.11).
- Among patients in the **CDDP** model, none of the factors extracted was found to be associated with IPT completion

- For FTDR

  IPT Completion was higher in Soroti RRH aRR=1.29 (1.19-1.40) and Katakwi Hosp aRR=1.26 (1.16-1.37) compared to TASO Soroti

Factors associated with IPT completion across facility DSD models

- For **all facility DSD models**, completion was highest in Soroti RRH and lowest in TASO Soroti ($p<0.001$ in each case)
- Among patients in **FBG**, IPT completion was significantly lower among males compared to females (76.0% vs 91.2%; RR=0.83, 95% CI: 0.70 - 0.99, p=0.034)
- Among patients in **FBIM**, Adults aged ≥25 years had a significantly higher completion compared to those aged <25 years (91.3% vs. 75.0%; RR= 1.17, 95% CI: 1.01 – 1.36, p=0.039)
- Among patients in **FTDR**, IPT completion varied by treatment:

  Patients on second or third treatment line had significantly lower IPT completion compared to those on first line (CR=85.0% vs 94.0%, RR=0.90, 95% CI: 0.83 – 0.99, p=0.022)

  Patients on ART for a period of 6-10 years had lower completion compared to those who had initiated ART in ≤5 years (CR=94.8% vs 97.4%, RR=0.97, 95% CI: 0.95 – 0.99, p=0.041).

Demographic characteristics of participants surveyed, by type of DSD

Characteristics	Total n (%)	Community n (%)	Facility n (%)
Site	**N=510**	**N=78**	**N=432**
TASO Soroti	110(21.6)	55(70.5)	55(12.7)
Soroti RRH	264(51.8)	16(20.5)	248(57.4)
Katakwi Hosp	136(26.7)	7(9.0)	129(29.9)
Female sex	314(61.6)	54(69.2)	260(60.2)
Median age in years (IQR)	25(18.0,35.0)	31(22.0,36.0)	24(17.0,33.5)
Highest level of school completed			
No formal schooling	94(18.4)	18(23.1)	76(17.6)
Some primary	188(36.9)	41(52.6)	147(34.0)
Completed primary	73(14.3)	7(9.0)	66(15.3)
High school matriculation	26(5.1)	0(0.0)	26(6.0)
More than high school	90(17.7)	11(14.1)	79(18.3)
Married	44(56.4)	251(58.1)	295(57.8)
Residence			
Urban	151(29.6)	9(11.5)	142(32.9)
Semi-urban	83(16.3)	9(11.5)	74(17.1)
Rural	276(54.1)	60(76.9)	216(50.0)

Frequency of adverse events reported by clients on IPT

Characteristics	Total N=510 n (%)	Community N=78 n (%)	Facility N=432 n (%)
Blurred or loss of vision	18(3.5)	5(6.4)	13(3.0)
Convulsions	8(1.6)	1(1.3)	7(1.6)
Dark urine	19(3.7)	1(1.3)	18(4.2)
Mood changes	21(4.1)	3(3.9)	18(4.2)
Unusual bleeding	3(0.6)	1(1.3)	2(0.5)
Dizziness	78(15.3)	9(11.5)	69(16.0)
Fever	26(5.1)	4(5.1)	22(5.1)
Joint pains	37(7.3)	5(6.4)	32(7.4)
Loss of appetite, nausea and vomiting	42(8.2)	6(7.7)	36(8.3)
Numbness, tingling and burning sensation	29(5.7)	4(5.1)	25(5.8)
Skin rash	28(5.5)	3(3.9)	25(5.8)
Sore throat	20(3.9)	2(2.6)	18(4.2)
Other	11(2.2)	5(6.4)	6(1.4)
None	352(69.0)	57(73.1)	295(68.3)

Adverse events reported by clients on IPT

Characteristics	Total n (%)	Community n (%)	Facility n (%)
When were AEs experienced	**158**	**21**	**137**
Before IPT	3(1.9)	0(0.0)	3(2.2)
Immediately	134(84.8)	16(76.2)	118(86.1)
Months after IPT	21(13.3)	5(23.8)	16(11.7)
Reported AEs	94(59.5)	9(42.9)	85(62.0)
If yes, reported AEs to	**94**	**9**	**85**
Client expert	4(4.3)	3(33.3)	1(1.2)
Clinician	57(60.6)	4(44.4)	53(62.4)
Counsellor	7(7.5)	0(0.0)	7(8.2)
Different facility from where IPT was received	2(2.1)	2(22.2)	0(0.0)
Facility where I receive IPT	24(25.5)	0(0.0)	24(28.2)
No, why didn't report	**64**	**12**	**52**
Minor	20(31.3)	5(41.7)	15(28.9)
Thought from something else	10(15.6)	1(8.3)	9(17.3)
Disappeared by themselves	4(6.3)	1(8.3)	3(5.8)
Expected side effects	23(35.9)	3(25.0)	20(38.5)
Other	7(10.9)	2(16.7)	5(9.6)

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IPT Knowledge & Attitudes – Clients

- Majority of participants (79%) reported receiving knowledge about IPT from HCP
- Most participants received information on IPT at every refill (community 60%, facility 76%, p= 0.031)
  'I heard about this from our health care workers who bring medication to us who live with HIV. …in mid last year then this program came and they told us that they were bringing drugs which will help prevent TB. Time came these drugs were brought together with ARVs and we were taught how to swallow them.' (FGD-FTD, female)
- Participants were well counseled and reported high quality care
  'I was screened before I was given the IPT by the health worker. He also gave me the instructions of how to take the medicine. That I should ensure I swallow one tablet every day after having a meal and also take a lot of fluids.' (FGD-FTDR, male)
- Most respondents who initiated IPT (88% community, 76% facility, p=0.297) knew IPT pills are taken for six months
  'Everyone is supposed to receive and take the IPT for six months.' (FGD-CDDP, female)
- Almost all (community 93%, facility 93%, p= 0.602) knew that IPT prevents them from getting active TB disease
- In total, 283/499 (57%) had knowledge of at least on side effect for IPT
  The commonly cited side effects were joint pains (14%), dizziness (14%), and loss of appetite (13%)
  '… it is not wise to swallow all the drugs at the same time because they can easily make you to feel dizzy.' (FGD-CCLAD, male)
- Knowledge of eligibility of IPT was high with majority (community 96%, facility 98%) who knew that IPT is given to all patients with HIV, and that it is also given to HIV+ with no TB signs (community 89%, facility 89%, p=0.319).
  'We were given these drugs to swallow even when you were not diagnosed with TB. It was good to swallow to prevent us from catching TB and when we finished our therapy there were no side effects noted.' (FDG-FTDR. female)
  'I decided to enroll for IPT because I knew that I was HIV+, and I understood that it is the other diseases beside HIV that further weaken the immunity of people like us who are living with HIV. I decided to enroll on IPT so that I am protected against TB.' (FGD-FTDR, female)

IPT Knowledge & Attitudes – HCP

- Majority of HCP demonstrated good understanding of IPT eligibility and prescription to eligible recipients
- IPT/ART management- staff roles reflect the field that they are specialized in with some of them playing multiple roles
- HCP reported adherence to the MOH recommended guidelines and SOPs for IPT service provision
- HCP observed that clients' reasons for enrolling on IPT were:
  - Convenience of service
  - Peer influence
  - Accurate information given
- HCP reported that clients declined IPT due to:
  - Fear of side effects
  - Misconceptions
  - Pill burden
- To improve IPT/ART service uptake, HCP participants recommended:
  - Recruitment of more HCP for the ART clinic
  - Changing staff attitudes towards patients
  - Combining ART and IPT into a single drug
  - Provision of food supplements for the sick and weak

'Adherence is now very okay, it has increased. Previously when we were introducing it, they were skeptical, some were fearing, and others understood it as a TB treatment. We kept educating and counselling them as a preventive therapy.'

Recommendations from Providers and Participants

- To improve IPT/ART service uptake, the providers and participants recommended the following:
  - Recruitment of more health workers for the ART clinic
  - Changing staff attitude towards patients
  - Combining ART and IPT into a single drug
  - Provision of food supplements for the sick and weak

Conclusion

- Completion rates for TPT was a high (92.8%)
- CDDP and FTDR had the highest completion rates and FBG the lowest
- Majority of AEs were mild
- Patient knowledge on IPT and ART was high

Recommendations

- Our findings provide evidence that supports integration of IPT within DSD models for ART delivery in Uganda and similar resource-limited settings
- Strategic interventions aiming at improving completion of IPT among peer-led models (CCLAD and FBG) remain critical for better treatment outcomes among clients in these DSD models
- We recommend scale-up of using health workers in educating the patients about the use of IPT

Acknowledgements

Study Participants: chart review

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Thank you!