Pre-ART Adherence Counseling is Not Associated with Improved MEMS Adherence in Rural Uganda

Rethinking the "Pre" in Pre-Therapy ARV Counseling

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Sub-Saharan Africa ART Guidelines

Country	Comments
Zambia	“Often takes several visits before a patients is truly read to start HAART”
Namibia	“HAART should not be started at the first clinic visit. A period of education and preparation to try to maximize future adherence is important
Mozambique	“Psycho-social counseling visit” must precede ARV initiation
Uganda	“ART should not be started at the first clinic visit. A period of education and preparation to try to maximize future adherence is important.”
Kenya	“Beyond clinical eligibility it is important that the patent’s willingness, readiness and ability to be on ART adherently be assessed and addressed. Psychosocial considerations therefore need to be evaluated before initiation of therapy during several (three to six) pre-treatment visits”
Nigeria	“development of patient-specific adhernce strategy… measures to ensure optimal adherence should be taken before therapy is started”

Transport Costs as a Barrier to Clinic Attendance

It was about the time I fell sick, and I didn't have strength to do some gardening, and it was around the same time that the store collapsed, so there was no money for transport…I was feeling very weak and I was sleeping most of the time, I would be dying any minute.

Tuller AIDS Beh 2010

Pre/Early ART Period

- Resource-limited settings have 4.3 greater odds mortality in first month than resource-rich settings (Braitstein, Lancet 2006)
- 16-61% loss-to-follow with 34-42% mortality from eligibility determination to ART initiation (Bassett, JAIDS 2009; Basset AIDS 2010)

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A Randomized Controlled Trial Comparing the Effects of Counseling and Alarm Device on HAART Adherence and Virologic Outcomes

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- Study Arms:
  - Intensive counseling (three visits)
  - Alarm reminders
  - Both
  - or NOTHING (control arm had no counseling)
- Benefit of counseling (29% decrease in risk of <80% adherence)
- 17% LTFU/died in pre-treatment period in adherence counseling arms vs 5% in control group with no counseling ($p<0.01$).

Is there benefit to Adherence Counseling Before Initiation of Therapy?

- UARTO: Prospective cohort study of HIV-infected patients initiating ART in Mbarara, Uganda
- Primary predictor: Adherence counseling dates abstracted from medical record
- Outcomes:
  - MEMS adherence >90%,
  - >72 hr treatment interruption
- Design: Multivariable regression to test association between receipt of counseling and adherence in first 3 months of therapy

Baseline Characteristics

Characteristic	Pre-Therapy Counseling (n=231)	No Pre-Therapy Counseling (n=69)	p-value
Female (%)	73	62	0.08
Age (median, IQR)	33 (27-39)	33 (30-40)	0.29
Baseline CD4 (%)			0.26
<100	31.2	23.2	
100-249	54.1	65.2	
≥250	14.7	11.6	
Baseline CD4 <100 (%)	31	23	0.26
> 1 hour from clinic (%)	42	45	0.80
Unemployed (%)	32	21	0.07
Ever history of OI (%)	41	46	0.57
Audit-C Screen Positive (%)	16	30	0.01*
Depression (HSCL, %)	29	34	0.41

HSCL: Hopkins Symptoms Checklist Depression Score

Adherence and Viremia by Counselling

Characteristic	Pre-Therapy Counseling (n=231)	No Pre-Therapy Counseling (n=69)	p-value
Average Adherence	94.8	95.6	0.81
Average Adherence > 90%	64.3	72.1	0.26
Any Treatment Gaps > 72 hours	11.7	7.3	0.29
Viral Load > 400 copies/ml	9.7	9.5	0.97

Adherence Counseling Not Significantly Associated with Adherence or Viremia

	Univariable Analyses		Multivariable Analyses*	
Adherence Measure	Measure of Association†	95% CI	Measure of Association†	95% CI
Average Adherence > 90%	OR = 0.69	0.37 – 1.31	AOR = 0.78	0.40 – 1.54
Absence of treatment gaps > 72 hours	OR = 0.59	0.22 – 1.60	AOR = 0.67	0.23 – 1.91
Persistent Viremia > 400 copies/ml	OR = 1.01	0.39 – 2.66	AOR = 1.13	0.41 – 3.12

†OR/AOR: odds ratio for those who completed pre-ARV counseling vs no pre-therapy counseling

*Multivariable analysis adjusted for age, sex, time travel to from clinic, asset index quartile, baseline CD4 count, year of ARV initiation and history of opportunistic infection

Delays in ARV Initiation

Characteristic	Pre-Therapy Counseling (n=231)	No Pre-Therapy Counseling (n=69)	p-value
Days from ARV Eligibility to Initiation (median, IQR)	49 (27 – 83)	14 (0 – 75)	<0.01
Days from ARV Eligibility to Initiation if CD4<100 (median, IQR)	41 (27- 69); n=72	21 (0 – 50); n=16	0.04

Limitations

- Adherence counseling not randomly assigned
- Medical record imperfect record of actual counseling
- Small sample excludes only large effect

Conclusions

- Adherence counseling is an important component of treatment
- Adherence is adequate in majority of those initiating therapy
- Pre-ART adherence counseling is not associated with large difference in adherence
- Pre-ART adherence counseling is associated with a delay in treatment initiation
- Adherence counseling should not delay treatment initiation in those with advanced disease

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- Patients