FANMI: A Randomized Trial of Community Cohort Care for Adolescent Girls living with HIV in Haiti

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Background

- Adolescents account for 40% of new HIV infections in Haiti and have worse outcomes than all other age groups. They are more likely than any other age group to disengage from HIV care at all stages of the HIV care cascade. They are the only age group with increases in HIV-related mortality and have persistently suboptimal rates of viral suppression.
- The implementation of a youth-friendly Adolescent HIV clinic in 2009 at GHESKIO in Haiti improved linkage, assessment for antiretroviral therapy (ART) eligibility, and ART initiation, but did not significantly improve long-term retention in care or ART adherence.
- HIV-infected adolescents receiving care at the Adolescent HIV Clinic in Haiti report the largest barriers for retention are: stigma, social isolation, lack of family support, and long clinic appointments.
- FANMI (Haitian Creole for 'My Family') is an integrated, community-based, cohort model of HIV care that addresses key environmental, social, and individual barriers that influence the retention of adolescent girls living with HIV.

Methods

Study Setting:
- Haiti is the poorest country in the Western Hemisphere with the highest adolescent and adult HIV prevalence (0.4% and 1.6%, respectively).
- GHESKIO was established in 1982 and is the largest public HIV clinic in Haiti and located in Port-au-Prince. GHESKIO provides HIV testing, counseling, and treatment free of charge to patients.
- An Adolescent HIV clinic providing youth-friendly HIV services according to WHO guidelines was opened in 2009.

Study Population:
- Adolescent girls ages 16-24 years recently diagnosed with HIV (<3 months from initiation diagnosis) or defaulted from care (>3 months since last ART prescription pick up) were eligible to enroll. The total study population was 120 participants.

Study Objectives:
- Primary outcome is alive and retained in care 12 months after randomization comparing participants in FANMI to standard care.
- Secondary outcomes include: plasma HIV-1 RNA <1,000 copies/ml, sexual risk behavior, stigma, and social support comparing participants in FANMI to standard care

Definitions:
- Alive and retain in care at 12 months defined as being alive with a clinic visit between 9 and 15 months from HIV testing.
- Viral load suppression defined as <1000 copies/µl.

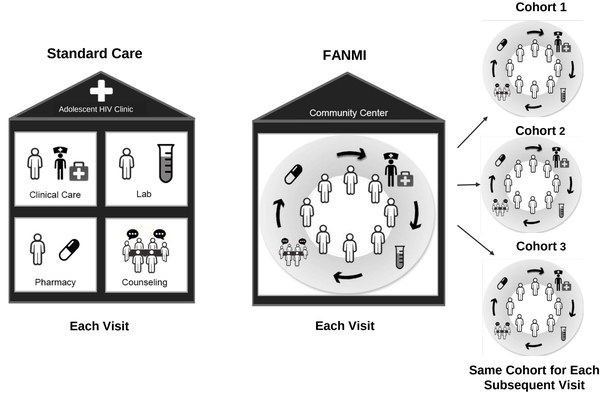
FANMI 'My Family' Intervention vs. Standard HIV Care

Standard care in Adolescent HIV Clinic: Adolescent participants randomized to standard care visited the clinic monthly and all clinical services were provided sequentially with the adolescent rotating to a clinician for medical management, a social worker for counseling, the laboratory for phlebotomy, and visiting the pharmacy for prescription refills. All encounters were done on an individual basis.

FANMI intervention components: Adolescent participants randomized to FANMI receive all monthly HIV care in a community room separate from the HIV clinic. They are grouped in cohorts of 5-8 peers. Monthly cohort visits start with 30 minutes of peer socialization, followed by 45 minutes of group counseling using a structured curriculum, and ending with 30 minutes of a social activity. Participants are seen individually by a nurse for ~10 minutes during peer socialization or the social activity to complete any necessary phlebotomy, ART counseling, and pharmacy refills. The same nurse provided care and counseling each month.

	Standard Care in Adolescent Clinic	FANMI
Patient	**INDIVIDUAL:** Monthly individual clinic session at the Adolescent HIV Clinic	**COHORT:** Monthly cohort session with 5-8 peers in a community room
Setting	**ADOLESCENT HIV CLINIC:** All services including counseling, clinical, laboratory and pharmacy are provided at the Adolescent HIV Clinic at GHESKIO	**COMMUNITY:** All services including counseling, clinical, laboratory and pharmacy are provided in a group setting in the community
HIV Services	**SEQUENTIAL:** Each patient rotates to counselor, clinician, laboratory staff, and pharmacist individually and sequentially	**INTEGRATED:** Each patient receives all services in the cohort group session with one nurse

Figure 1. Illustration of HIV service delivery in Adolescent HIV Clinic and FANMI



Results

Table 1. Baseline Demographic and Clinical Characteristics

	FANMI (N=60)	Standard Care (N=60)
Demographic Characteristics		
Median Age	21 (IQR 16-23)	21 (IQR 17-23)
Female	60 (100%)	60 (100%)
Currently in school	14 (23%)	22 (37%)
Highest previous education		
None	4 (7%)	3 (5%)
Primary	16 (27%)	14 (23%)
Secondary	38 (63%)	39 (65%)
University	2 (3%)	4 (7%)
Orphaned status	9 (15%)	8 (13%)
Marital Status		
Single	44 (73%)	47 (78%)
Living with partner	18 (30%)	13 (22%)
Ever pregnant	42 (70%)	35 (58%)
Num children		
0	30 (50%)	32 (53%)
1	23 (38%)	21 (35%)
2+	7 (12%)	7 (12%)
Clinical Characteristics		
Location of HIV testing		
Clinic	20 (33%)	36 (60%)
Community	40 (67%)	24 (40%)
ART regimen at enrollment		
TDF/3TC/DTG	30 (50%)	31 (52%)
TDF/3TC/EFV	29 (48%)	29 (48%)
TDF/3TC/LPV/r	1 (2%)	0 (0%)
CD4 at ART initiation		
<200	4 (7%)	6 (10%)
201-350	7 (12%)	5 (8%)
351-500	11 (18%)	10 (17%)
>500	38 (63%)	39 (65%)
HIV-1 RNA (copies/ml) at ART initiation		
<40	15 (25%)	11 (18%)
41-1000	13 (22%)	13 (22%)
1001-50,000	24 (40%)	25 (42%)
>50,000	8 (13%)	11 (18%)

Table 2. Effect of FANMI intervention on retention in care at 12 months in intent-to-treat and per-protocol analyses

	FANMI	Standard Care	Unadjusted RR (95%CI)
Intent-to-treat	47/60 (78%)	51/60 (85%)	0.92 (0.78-1.09)
Per-protocol*	47/53 (89%)	51/58 (88%)	1.01 (0.88-1.15)

*participants who received intervention. Excludes 9 participants who never attended study visit after enrollment.

- A total of 120 adolescents ages 16-24 were enrolled between May 2018-January 2021. Median age was 21, 91% were newly diagnosed and 9% had defaulted from ART >3 months.
- The proportion of participants who achieved the primary outcome of alive and retained in care 12 months from ART initiation did not significantly differ by arm (78% in the FANMI arm and 85% in the standard arm).
- In both arms, participants who self-presented to the adolescent HIV and were subsequently enrolled were more likely to achieve the primary outcome of retained in care at 12 months from ART initiation, compared to those who were recruited from a community setting and subsequently enrolled – 95% vs. 70% in the FANMI arm and 88% vs. 83% in the standard arm.
- Among participants retained at 12 months who had an available HIV-1 RNA viral load test between 9-15 months from the study endpoint, 54% (22/41) in the FANMI arm 60% (24/40) in the standard arm achieved a VL <1,000 copies/ml.
- Providers preferred FANMI reporting increased time for counseling and peer support.
- FANMI participants reported high acceptability, decreased stigma, and increased social support with no breaches in privacy or confidentiality.
- Limitations included interrupted study operations during the COVOD-19 pandemic and the heightened political instability and gang-related violence in Haiti.

Discussion

- FANMI is a differentiated service delivery model of HIV care that re-structured the clinical experience by organizing participants into cohorts of 5-8 adolescent girls and young adults who met together monthly in a community setting. Designed to address barriers of stigma, social isolation and limited patient-provider interaction, this intervention achieved high acceptability by patients and was preferred by providers.
- The cohort aspect of FANMI provided adolescents social support and many participants felt the cohorts became surrogate families.
- FANMI was designed to normalize HIV care management by providing clinical care in the context of a cohort meeting in the community such that adolescents experience HIV management as a group norm and can share experiences and challenges
- FANMI also integrated clinical care with peer counseling at the same session by the same providers to streamline services and increase longitudinal relationships with providers.
- We did not find significantly improved outcomes by participants in the FANMI intervention arm for the primary outcome of retention in care by 12 months.
- Limitations included shifting in national guidelines during the course of the study including guidelines decreasing the frequency of regular visits from monthly to bi-annually in the standard arm. COVID-19 and heightened security concerns related to political instability and gang-related violence impacted both arms throughout the study.
- No social harms including any breaches of confidentiality were reported.

Summary

Participant outcomes for the primary objective of retention in care 12 months from ART initiation did not differ significantly by arm, but FANMI was preferred by providers and was highly acceptable to participants. FANMI offers a complementary program for high-risk adolescents and young adults living with HIV in low-income settings facing barriers to clinic-based care.

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