Pathway2Health (P2H), A RANDOMIZED CONTROLLED TRIAL OF AN HIV CARE INTERVENTION BUNDLE FOR PEOPLE WITH HIV

Presentation: 1082

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Background

- Prompt initiation of antiretroviral therapy (ART) is now considered the standard of HIV care.
- Delayed/inconsistent HIV care is linked to poverty, lack of transportation, lack of healthcare coverage and fear of HIV stigma.
- Early retention during the HIV care process is a predictor of long-term treatment success and viral suppression.
- Even when linked to care, many persons with HIV (PWH) cancel, 'no-show', or drop out of care early, resulting in significant numbers of individuals failing to achieve long-term viral suppression.
- Strengths-based case management, intensive outreach, and patient navigation are well-supported interventions to improve care that have largely been tested/implemented in isolation.
- Building upon early qualitative work, we developed an HIV care intervention bundle that combines these strategies using pre-/post-visit telehealth calls over the course of the first year of care.

Table 1. Scientific Premise for HIV Care Intervention Bundle

Intervention	Description	Impact on Care	Empirical Support
Strengths-Base Case Management	Identification of individual's internal strengths, skills, and needs	Improved linkage and retention in HIV Care (p<0.05)	ARTAS-I Gardner, AIDS, 2005 ARTAS-II Craw, J Acquir Immune Defic Syndr, 2008
Intensive Outreach	Provision of outreach support services (appointment reminders, health literacy training)	Significant improvement in viral suppression rates (p<0.05)	SPNS Naar-King, AIDS Patient Care STDS 2007
Patient Navigation	Assisted healthcare system navigation (active referral, advocacy)	Improved linkage and retention (p<0.05)	CA Bridge Project Molitor, AIDS Care, 2006 Mizuno, AIDS, 2018

Objectives, Aims and Statistical Approach

Objective:

- Our objective was to assess the impact of an HIV care intervention bundle entitled Pathway2Health (P2H) on virologic outcomes including:

Aim

- Time to viral suppression (HIV-1 RNA <200 cells/mm^3) as measured in *days* between initial contact with the UC-IDC and the first undetectable laboratory result (Intent to treat analysis (ITT) where missing=failure)

Long-Term Goal: To improve health outcomes in PWH, providing immediate and sustained psychosocial and structural support, and ultimately reducing the spread of HIV through treatment as prevention.

Statistical Approach: Categorical analysis by Chi-square and continuous variables by Wilcoxon-rank sum test. Sensitivity analysis included censoring participants without virologic data for the primary endpoint. In the ITT analysis, those without virologic information were set at 420 days from entry.

Methods

- **Design**
  - We used a longitudinal randomized controlled study design to compare participant time to viral suppression and care-related measures (e.g. visit adherence).
- **Inclusion/Exclusion Criteria:**
  - 18 years of age
  - Confirmed diagnosis of HIV as evidenced by HIV + ELISA with Confirmatory PCR or HIV-1-specific antibody assay.
  - No previous history of antiretroviral therapy (Note: PreExposure Prophylaxis (PrEP) was allowed)
  - Baseline viral load of at least 1,000 copies/mm^3
  - Able to understand the English language
- Participants randomized to Intervention (P2H) Group OR Standard of Care (SOC) Comparison Group
- The study team reviewed medical record data for all participants, but only made contact with those participants who received the intervention.
- All participants received at least the standard of care, and no clinical decisions were delayed by the study.

Figure 1: Example Intervention Schema

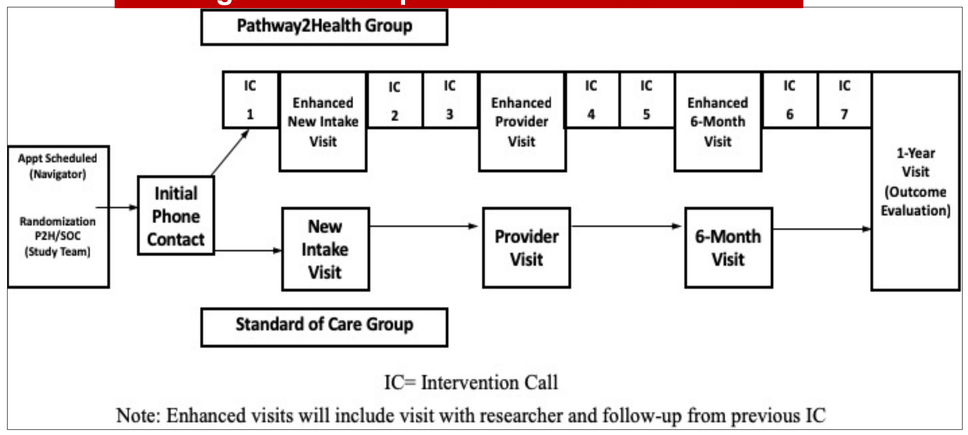

Table 2 - Baseline Characteristics (n=40)

Characteristic	Intervention-P2H (n=20)	Standard of Care-SOC (n=20)	P-value
	Median (IQ-Range)*	**Median (IQ-Range)***	p
Age	37.50 (22-54)	34.00 (18-65)	.95
HIV-1 RNA copies/mL	41,062 (2926-2173292)	75,771 (3,064-336,263)	.97
Log HIV-1 RNA copies/mL	4.61 (3.47-6.34)	4.88 (3.49-5.53)	.31
CD4+ T-Lymphocyte Count cells/cu mm	283 (7-925)	301 (35-675)	.91
CD8 T-Lymphocyte Count cells/cu mm	533 (255-984)	625 (147-1300)	.17
CD4/CD8 ratio	0.46 (0.02-1.34)	0.43 (0.05-1.04)	.97
	% (N)	**% (N)**	
Natal sex			
Male	60% (n=12)	75% (n=15)	.31
Female	40% (n=8)	25% (n=5)	
Race			
African American	45% (n=9)	55% (n=11)	.54
White	50% n=10)	45% (n=9)	
Multi-Racial	5% (n=1)	0% (n=0)	
Ethnicity			
Hispanic/Latino	5% (n=1)	5% (n=1)	.75
Marital Status			
Married/Partnered	15% (n=3)	5% (n=1)	.09
Single	70% (n=14)	95% (n=19)	
Other	15% (n=3)	0% (n=0)	
Education			
High School	90% (n=18)	95% (n=19)	.55
College/University	5% (n=2)	5% (n=1)	
HIV Risk Category			
MSM	35% (n=7)	30% (n=6)	.25
Heterosexual	30% (n=6)	15% (n=3)	
IVDU	30% (n=6)	40% (n=8)	
Other/Unspecified	0% (n=0)	15% (n=0)	
Multiple	5% (n=1)	0% (n=0)	

*IQ-Range – 25% - 75% interquartile range

Table 3: Results and Key Findings

Table 3: Key Findings	Intervention-P2H (n=20)	Standard of Care-SOC (n=20)	
	Median (IQ-Range)	**Median (IQ-Range)**	***p****
ITT – Time to Undetectable (Days)	58 (29-311)	91 (40-285)	*.004**
Missed Visits	2 (0-8)	3 (0-10)	*.40*
Completed Visits	5 (2-9)	3 (0-10)	*<.0001**
	% (N)	**% (N)**	***p******
Lost to Follow Up			
Yes	5% (n=1)	35% (n=7)	*.04***
No	95% (n=19)	65% (n=13)	
Entered Care			
Yes	100% (n=20)	95% (n=19)	.49
No	0% (n=0)	5% (n=1)	
Entered Care within 14 Days			
Yes	90% (n=18)	65% (n=13)	.13
No	10% (n=2)	35% (n=7)	
Reached Undetectable At Any Time			
Yes	90% (n=18)	65% (n=13)	.06
No	10% (n=2)	35% (n=7)	
Reached Undetectable by 6-month Timepoint			
Yes	80% (n=16)	65% (n=11)	.09
No	20% (n=4)	45% (n=9)	
Reached Undetectable by 12-month Timepoint			
Yes	80% (n=16)	35% (n=7)	*.004***
No	20% (n=4)	65% (n=13)	
Started ART within 30 Days			
Yes	80% (n=16)	80% (n=16)	1.00
No	20% (n=4)	20% (n=4)	

*Significance level reflects Wilcoxin rank-sum test comparison of distributions in each group

**Significance level reflects Fisher's Exact Test when Expected Cell Counts <5

- There were no significant differences in the distribution of gender, age, race, or baseline viral load or antiretroviral uptake between the intervention and control groups.
- **Intervention participants:**
  - Reached undetectable in fewer days than SOC participants (***p=0.004***)
  - Were more likely to complete scheduled visits (***p=<.0001***)
  - Were less likely to be lost to follow-up in the first year (***p=.04***)
  - Were more likely to be undetectable at the 12-month time point (***p=.004***)

Conclusions

- A telehealth intervention bundle integrating strengths-based case management, intensive outreach, and patient navigation has the potential to improve virologic outcomes, help to identify and correct challenges faced early in care, and strengthening the relationships between patients and their providers.
- Such interventions may contribute to reducing the spread of HIV through treatment as prevention.
- A randomized multi-center study should be done to confirm the results of this pilot study and determine the feasibility of operationalizing the bundle at sites providing care for PWH.

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