A Randomized Trial of HIV/HCV Nurse Case Management for Linkage to HCV Care

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BACKGROUND

- The opportunity to eliminate hepatitis C virus (HCV) is at hand, but challenges across the care continuum persist[1,2]
  - Challenges are particularly poignant for individuals co-infected with HIV, who are a high-priority to cure but historically not well engaged in HCV care[3,4]
- Case management interventions have shown success in linking patients to HIV care[5,6]

Objective

To test whether a nurse case management intervention adapted from evidence-based HIV research will improve the hepatitis C care continuum among adults co-infected with HIV compared to enhances usual care

METHODS

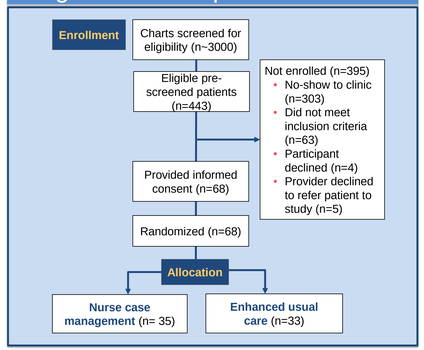
Table 1. Study Overview

Hypotheses	Nurse case management will 1) improve linkage to HCV care and 2) decrease time to treatment initiation among persons with HIV/HCV co-infection
Primary outcome	Linkage to HCV care (attendance at an HCV clinic appointment within 60 days of enrollment)
Secondary outcome	Time to direct acting antiviral (DAA) initiation (number of days from enrollment to first dose of DAAs), censored at 6 months
Design	Prospective randomized controlled trial
Randomization and masking	1:1 block randomization HCV provider and study team extracting results from medical record blinded to assignment
Intervention	Nurse-initiated referral to HCV care, scheduling assistance in the HCV practice, and HCV education
Control	Usual clinic care plus receipt of the CDC HCV Fact Sheet[7]
Eligibility Criteria	HIV infection Chronic hepatitis C infection Age 18+ Did not attend appointment with a viral hepatitis provider in past year Can speak English
Setting	Outpatient infectious disease practice in Baltimore, MD

Table 2. Nurse Case Management Intervention Components

Component	Description
Nurse-Initiated Referral	• Verify insurance and need for referral • Request referral from primary care provider • Confirm referral entrance in electronic health record
Strengths-Based Education	• Handout-guided education on hepatitis C symptoms, transmission, treatment, liver health • Assessment of strengths and needs related to hepatitis C care • Set goals for engagement in liver health/hepatitis C care
Clinical Coordination/ Patient Navigation	• Make appointment with viral hepatitis provider per patient's request and needs • Reschedule as needed • Coordinate ART modifications with primary HIV provider to accommodate DAAs as needed
Appointment reminders	• 1-week and 1-day appointment reminders • Phone, text, or email

Figure 1. Participant Enrollment

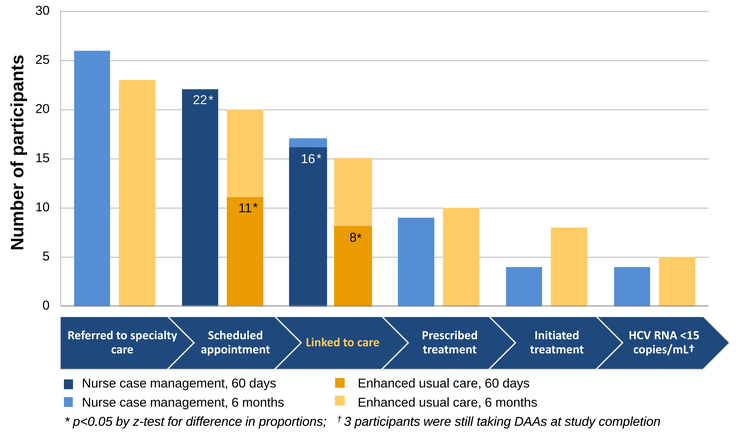


RESULTS: EFFECT OF NURSE CASE MANAGEMENT ON THE HCV CARE CONTINUUM

Table 3. Participant Baseline Characteristics

Baseline characteristics	Nurse case management, n (%)	Enhanced usual care, n (%)
Male	22 (63)	20 (61)
Age, mean years (SD)	55 (8)	55 (8)
Race/Ethnicity		
Black/African American	29 (83)	26 (79)
White/Caucasian	6 (17)	4 (12)
Other	0 (0)	3 (9)
Education: no high school diploma	17 (49)	11 (33)
Health insurance		
Medicaid	32 (91)	26 (79)
Medicare	9 (26)	8 (24)
Private	1 (3)	0 (0)
HIV viral load <20 copies/mL	14 (40)	15 (45)
CD4 cell count, median (IQR)	361 (125 – 540)	379 (266 – 676)
Liver fibrosis score (n=38)		
F0-F1	7 (39)	7 (35)
F2-F4	11 (61)	13 (65)
Hepatitis C genotype (n=61)		
1a	23 (77)	21 (68)
1b	5 (17)	9 (29)
Other (2b, 3a, 4)	2 (6)	1 (3)
Previously treated for HCV	7 (20)	8 (24)
Any illicit drug use, past 12 months	18 (51)	13 (39)
Injection drug use, past 12 months	11 (31)	15 (45)
Medication-assisted treatment for opioid use	18 (51)	17 (52)
Alcohol use, past 6 months	18 (51)	10 (30)
Depressive symptoms (PHQ-9 score ≥10)	11 (31)	18 (55)
No significant differences between the two groups at baseline		

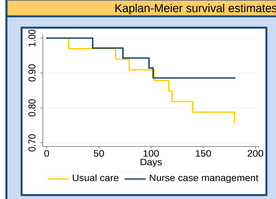
Figure 2. HCV Care Continuum at 60 and 180 Days



** p<0.05 by z-test for difference in proportions; † 3 participants were still taking DAAs at study completion*

Figure 3. Difference in time to treatment initiation

Kaplan-Meier survival estimates



p=0.192 by logrank test

Figure 4. Provider reasons for not referring to HCV care

Reported by HIV primary care provider

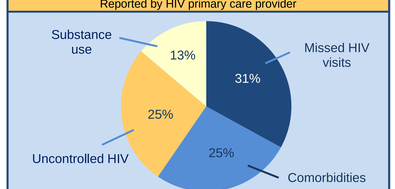
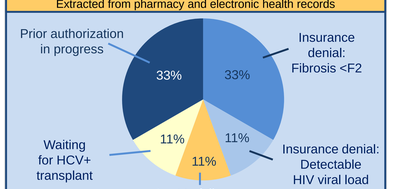


Figure 5. Barriers to HCV treatment initiation

Extracted from pharmacy and electronic health records



SUMMARY OF FINDINGS

- We enrolled 68 high-priority adults with HIV co-infection who were not engaged in HCV care despite a clinic campaign to cure all patients, representing a very hard-to-reach population
- At day 60, a greater proportion of participants in the intervention arm **linked to HCV care** (47%) compared to the comparison arm (25%) (p=0.031; 95% confidence bound for difference, 3.2-40.9)
- At day 180, the median **time to treatment initiation** was 100 days (interquartile range [IQR] 69.5-118.5 days) among those who initiated treatment
  - Intervention arm=86 days (IQR, 59-100)
  - Comparison arm=110 days (IQR, 73-130)
  - No significant difference in time to treatment initiation between the two arms by logrank test (p=0.192)

DISCUSSION

Implications

- Nurse case management is a successful strategy to link otherwise unengaged patients co-infected with HIV to HCV care, but linking to care alone is not sufficient to cure HCV in those who remain untreated
- Interventions that address the intersection of HCV and HIV through treatment initiation and completion are needed to achieve HCV elimination in this high-priority population

Limitations

- Use of proximal outcomes (linkage to care and treatment initiation) to assess care continuum; future studies should extend beyond 6 months and measure SVR
- Co-located HIV and HCV practice may limit generalizability

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