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Randomized Controlled Trial of Cash Incentives or Peer Mentors to Improve HCV Linkage and Treatment Among HIV/HCV Coinfected Persons Who Inject Drugs: The CHAMPS Study

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Disclosures

- Sulkowski M: Grant: NIH, Consultant: AbbVie, Cocrystal, Gilead, Janssen, Merck, Trek, Sponsored Lectures (National or International): Gilead

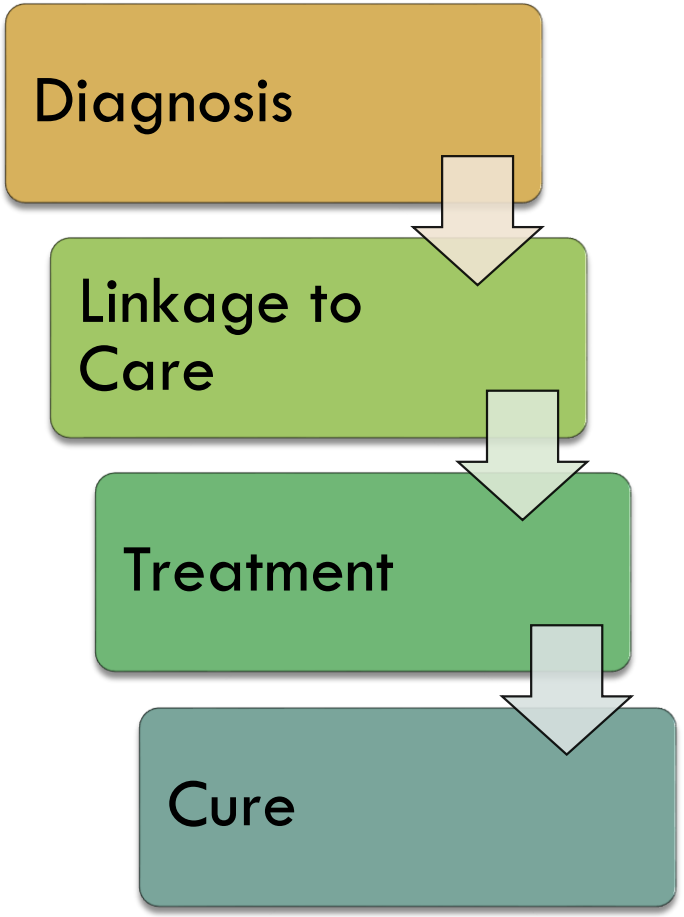
Introduction

- Since 2015, 97% of coinfected patients in the Johns Hopkins HIV clinic treated with DAAs achieved SVR
- HCV elimination seems feasible
- We identified ~560 coinfected patients engaged in HIV care who had not been linked to on-site HCV care

Introduction

- Hypothesis: Novel interventions, peer mentors and contingent financial incentives, will increase HCV treatment initiation and cure in HIV/HCV coinfected persons who use drugs compared to those receiving usual clinical care

- *This presentation reflects data presented at EASL 2017*
- *Final data will be presented at The Liver Meeting, October 2017*



Intervention Groups

Usual Care – All Participants Receive

- HIV clinic-based nursing model with pharmacy support
- Intensity of adherence support determined by HCV clinicians
  - Stop Light Protocol

Peer Mentor Care

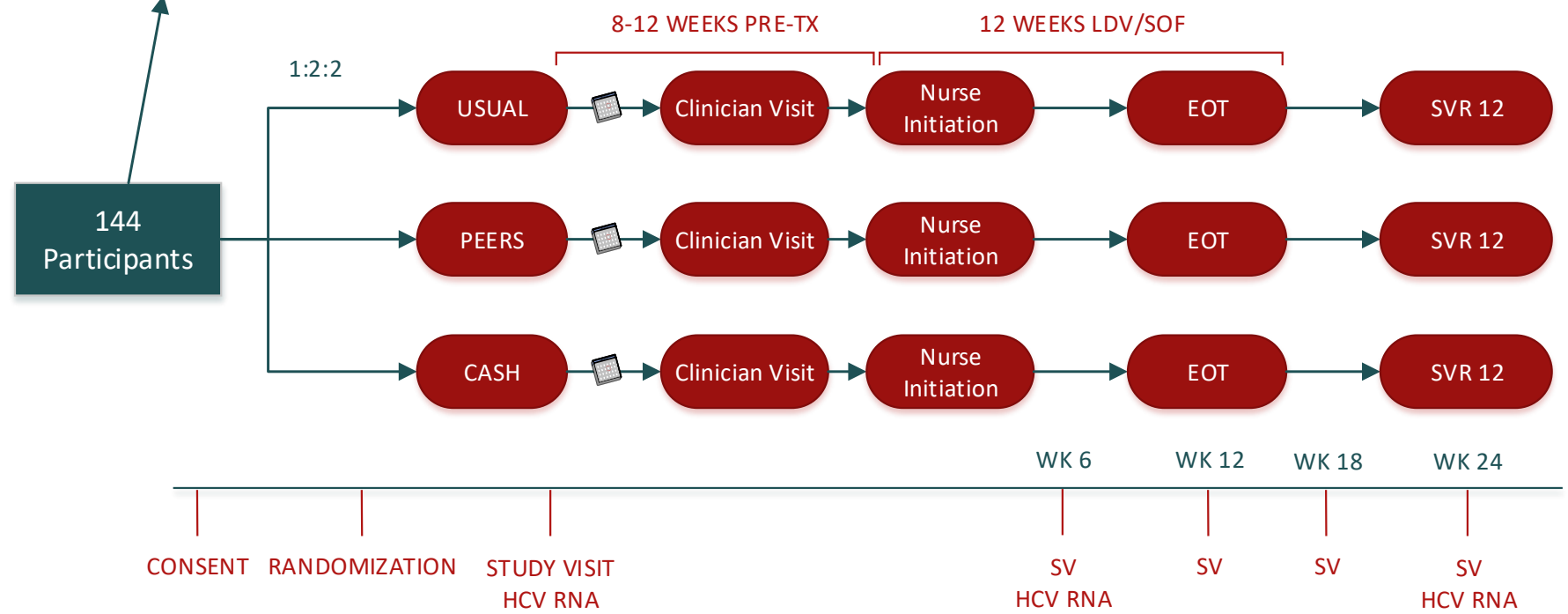
- HIV-infected persons with HCV cure were trained as Peer Mentors
- Contact with participants in person and by study-specific cell phone before, during and after treatment

Cash Incentives

- Cash compensation, contingent on attendance at visits, increases according to an escalating scale: Initial $10 and increases $5 every 2 weeks
- Maximum possible compensation: $220

Study Design

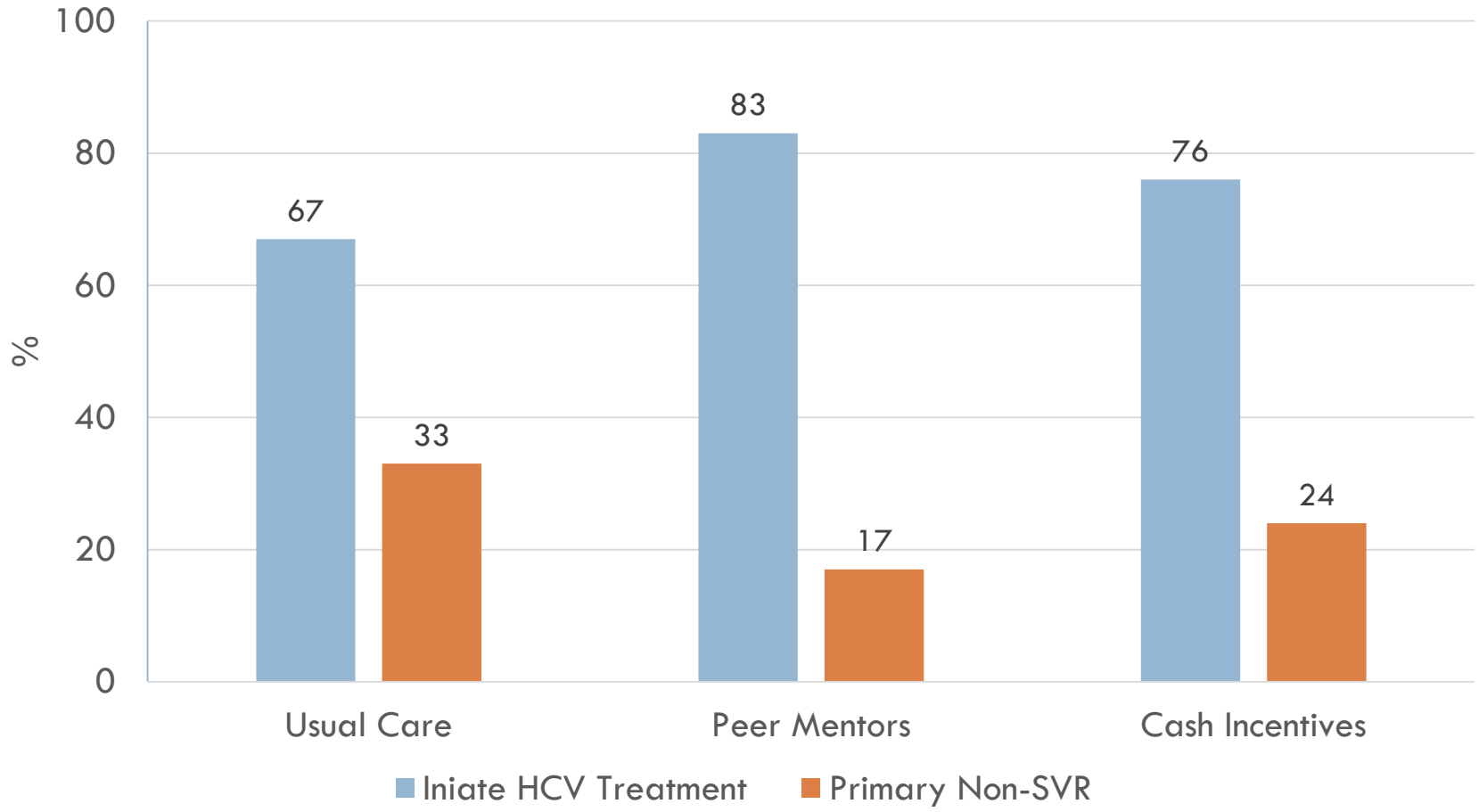
- HCV GT 1
- TX NAÏVE
- NO HCC/DECOMP
- HIV+
- CD4 >100mm^3
- JH HIV CARE
- NO HCV CARE ≥8 MONTHS



Results: Demographics and Clinical Characteristics

	Usual Care (N=36) (n,%)	Peer Mentors (N=54) (n,%)	Cash Incentives (N=54) (n,%)	Total (N=144) (n,%)
Age, median years (IQR)	56 (52, 60)	55 (50, 59)	54 (48, 59)	55 (51, 59)
Male	22 (61)	35 (65)	31 (57)	88 (61)
Black	33 (92)	52 (96)	48 (89)	133 (93)
Unemployed	30 (84)	47 (87)	45 (83)	122 (85)
Urine + for Cocaine or Heroin	12 (39)	12 (24)	19 (35)	43 (32)
Moderate to Heavy Alcohol Use (PEth)	15 (42)	19 (35)	13 (24)	47 (33)
Depression (CES-D ≥ 21)	14 (39)	25 (46)	23 (43)	62 (43)
Antiretroviral Therapy	35 (97)	52 (96)	52 (96)	139 (97)
Undetectable HIV RNA	30 (83)	44 (81)	43 (80)	117 (81)
HCV Genotype 1a	29 (81)	40 (74)	43 (80)	112 (78)
Cirrhosis by Elastography	4 (11)	5 (10)	7 (14)	16 (12)

Primary Endpoint: HCV Treatment Initiation



Results: Predictors of HCV Treatment Initiation

	Treatment Initiated (n=110)	Treatment Not Initiated (n=34)	Unadjusted Relative Risk (95% CI)
Treatment Group			
Usual Care	24 (67)	12 (33)	1
Peer Mentors	45 (83)	9 (17)	2.00 (0.94, 4.17)
Cash Incentives	41 (76)	13 (24)	1.39 (0.71, 2.70)
Recent Cocaine or Heroin Use (self-report)			
No	87 (81)	21 (19)	1
Yes	23 (64)	13 (36)	0.54 (0.30, 0.96)
On ART			
Yes	108 (78)	31 (22)	1
No	2 (40)	3 (60)	0.37 (0.17, 0.81)
Number of Missed Visits for Initial Clinician Visit			
None	85 (86)	14 (14)	1
1 or 2	23 (66)	12 (34)	0.41 (0.21, 0.81)
> 3	1 (11)	8 (89)	0.16 (0.09, 0.27)

Secondary Endpoint: SVR (Incomplete)

- Of the 110 participants who initiated LDV/SOF
  - 12 had not reached the SVR12 time point as of March 2017
  - 88 achieved SVR (90% of those who reached the SVR12 time point)
  - 10 did not achieve SVR12
    - 1 reinfection; GT 1B → 1A
    - 2 HCV relapse
    - 6 stopped treatment early; 5 prior to day 28
    - 1 death after completion of LDV/SOF (HCV RNA not detected)

Results: Safety and Tolerability of LDV/SOF

	Usual Care (N= 24) (n,%)	Peer Mentors (N=45) (n,%)	Cash Incentives (N=41) (n,%)	Total (N=110) (n,%)
Adverse Events at Any Visit	13 (54)	24 (53)	20 (49)	57 (52)
Headache	5 (21)	9 (20)	12 (29)	26 (24)
Fatigue	6 (25)	7 (16)	6 (15)	19 (17)
Nausea	2 (8)	4 (9)	4 (10)	10 (9)
Diarrhea	1 (4)	3 (7)	3 (7)	7 (6)
Insomnia	0	0	6 (15)	6 (5)
Other	5 (21)	11 (24)	10 (24)	26 (24)
Serious Adverse Events	3 (13)	9 (20)	6 (15)	20 (18)
Discontinued Prior to Week 12	1 (4)	3 (6)	2 (5)	6 (5)
Death (unrelated to treatment)	1 (4)	0	0	1 (<1)
Pregnancy	1 (4)	0	0	1 (<1)

- Pregnancy occurred in one participant at treatment week 10, SVR achieved
- **SAEs included**: Pneumonia, COPD Exacerbation, Pancreatitis, CHF Exacerbation, Polyarthritis, Suicidal Ideation, Syncopal, Nephrolithiasis, Hypertension, Abscess

Conclusions

- Treatment initiation rates were higher in persons randomized to Peer Mentors (83%) or Cash Incentives (76%) compared to Usual Care (66%)
  - One-third of usual care participants did not initiate HCV treatment despite access to expert clinicians and LDV/SOF at no cost
- Peer mentors and/or cash incentives may improve HCV outcomes along the care continuum

Acknowledgements

- We would like to thank the study participants and their families, our dedicated Peer Mentors, as well as the Johns Hopkins HCV and HIV care teams at the John G. Bartlett Specialty Practice

- This work was supported by NIH/NIDA grants R01DA16065, R37DA013806, U01DA036935, K24DA034621 (MS), P30 AI094189, DAR37013806 (to DT), K23DA041294 (OFN), the Johns Hopkins Institute for Clinical and Translational Research (ICTR) which is funded in part by NIH grant UL1 TR001079 and the Johns Hopkins Center for Clinical Data Analytics

- LDV/SOF was provided by Gilead Sciences (Foster City, CA, USA)