Innovative Strategies to Eliminate HCV

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Learning Objectives:

- Identify the challenges that the opioid crisis and hepatitis
 C virus pose
- Understand the benefits of telemedicine as a treatment model, specifically when HCV treatment via telemedicine is integrated into opioid treatment programs
- Understanding social determinants of health and how they influence pursuit of HCV treatment

Hepatitis C-Game half over?

- DAAs have revolutionized HCV treatment
- HCV incidence and prevalence continue to increase
 - Opioid use disorder-with changing demographics
- Telemedicine offers a way to link and to complete the care cascade
- Social determinants of health
 - May affect who is able to eliminate HCV even if treated via telemedicine

HCV and Opioid Injection Rose Dramatically in Younger Americans from 2004-2014



 Among people aged 18-29, HCV increased by 400% and admission for opioid injection by 622%

 Among people aged 30-39, HCV increased by 325% and admission for opioid injection by 83%



Source: Centers for Disease Control and Prevention and Substance Abuse and Mental Health Services Administration

Increasing Deaths Due to Opioids

Age-specific drug overdose death rates, by race/ethnicity and sex during 2000-2003 vs. 2012-2015



CDC: Reported Number of Acute HCV Cases: United States, 2001–2016



Acute Hepatitis C in the United States, 2016



Source: CDC, National Notifiable Diseases Surveillance System (NNDSS)

New Acute HCV Cases and IDU, 2016



Available at: https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm. Accessed March 21, 2019.

Prioritize Treatment of PWUD

- DAAs have revolutionized HCV treatment, but "we are far from having won the war against the virus"
- HCV care among PWUD remains restricted, largely because of their inability to access appropriate HCV management
- More effective tools are needed to screen, diagnose and cure HCVinfected PWUDs
 - e.g. telehealth approaches, integrated care models, and point-of-care diagnostics
- The CDC, NIH, and other federal and industrial partners have active research programs designed to engage HCV-infected PWUDs into care
- Research gaps need to be addressed to eliminate HCV infection in this population

Off-Site Referred Model

HCV providers a limited at OTPs Liver Center of Western New York Patient discomfort Provider stigma Bring the HC 20% vider to a familiar and comfortable environment for patients with seeing and lack of new providers knowledge are and issues barriers to with travel treatment

The Potential of Telemedicine



University at Buffalo The State University of New York

Vinprolv & Bipedi Histn Communication



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42 of 45 patients (93%) telemedicine-treated patients achieved viral eradication

Study Procedures

- •All pre-treatment labs (HCV RNA, HCV genotype, Fibrosure [Labcorp]) is performed onsite.
- •Patients treated for 8 or 12 weeks with 12 week posttreatment follow up to determine SVR status.
- •Telemedicine-based visits occur biweekly during HCV therapy.
- •Social variables obtained from electronic health record.
- •Telemedicine Satisfaction Questionnaire (TSQ) administered at first telemedicine evaluation, at initiation of therapy, and at completion of follow up.
- •Adherence survey is administered biweekly while under HCV therapy.

Baseline Demographics

Variable	Total	Level	Count	Percent	
Condor	67	М	38	61	
Genuer	62	F 24		39	
		AA	38	61	
Ethnicity	62	White	6	10	
		Other	18	29	
Dees	62	Hispanic	16	26	
Race		Non Hispanic	46	74	
	62	No 47		76	
	02	Yes	16	24	
		1a	41	67	
HOV concture	61	1b	16	26	
нсу genotype		2b	1	2	
		3	3	5	
		Mean	SD	Median	
Age	62	57.53	9.92	58.9	
HCV RNA	62	6.35	0.58	6.33	

Inflammation and Fibrosis





Fibrosis Stage Inflammatory Grade

Treatment Participation Data

	All Patients	Treated Patients	Untreated Patients		
Size	62	45	17		

<u>Reason for being untreated</u>	<u>Count</u>	<u>Percent</u>
Discontinued from the program	3	17.65
HIV Adherence Issue	2	11.76
Insurance Issue	10	58.82
Non-adherence	2	11.76
Total	17	100.00

Virologic Results

- •A total of 62 patients were evaluated and 45 received DAA-based therapy.
- •42 (93%) patients achieved SVR
- •1 patient had GI discomfort at week 4 and discontinued treatment prematurely with HCV RNA relapse.
- •2 patient likely had reinfection with negative week 4 and positive week 12 HCV RNA values.

Adverse Effects



DAA Adherence



Preference for Integrated HCV Care via Telemedicine



100

Option

Convenience for Integrated HCV Care via Telemedicine

Statement: I think the consultation via the



Sources: Talal et al. Clin Infect Dis; 2018 Oct 17 22 Talal et al. Telemed J E Healthl 2018 Oct 16 University at Buffalo The State University of New York

Patient-to-Patient Referral to Integrated HCV Care via Telemedicine



Sources: Talal et al. Clin Infect Dis; 2018 Oct 17 23 Talal et al. Telemed J E Healthl 2018 Oct 16

Telemedicine Summary

- •No technical difficulties with telemedicine delivery (visual, auditory, interruptions)
- •Subjects prefer telemedicine-based HCV
- treatment delivery compared to off-site referral
 - -Convenience
 - -One-stop shopping
- •Privacy concern early, gradually resolved
 - –Likely mitigated by presence of member of treatment team
- Importance of bedside manner
 - –Method of care delivery (physical or virtual) less important.

Social Determinants of Health

 Social, behavioral, and environmental factors that contribute to health inequalities and health outcomes.



Social Determinants of Health

Economic Stability	Neighborhood and Physical Environment	Education	Food	Community and Social Context	Health Care System			
Employment Income Expenses Debt Medical bills Support	Housing Transportation Safety Parks Playgrounds Walkability	Literacy Language Early childhood education Vocational training Higher education	Hunger Access to healthy options	Social integration Support systems Community engagement Discrimination	Health coverage Provider availability Provider linguistic and cultural competency Quality of care			
Health Outcomes Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations								

SDOH and Drug Use affect HCV Care







Telemedicine

In person

Baseline Social Variables

Variable	Total	Level	Count	Percent
	Divorced/Separated/Widowed 61		20	32.79
Marital.Status			16	26.23
	Never Married		Count Perce 20 32.79 16 26.25 25 40.98 4 6.45 33 53.23 25 40.32 25 40.32 25 40.32 25 40.32 25 40.32 25 40.32 10 16.13 26 41.94 26 41.94 26 41.94 26 41.94 26 41.94 27 35.48 28 23 37.10 39 62.90 3 39 62.90 3 39 62.90 3 38 61.25 3 38 61.25 3 38 61.25 3 38 61.25 3 38 61.25 3 33 53.23 38.98 36 61.02 <td>40.98</td>	40.98
	Employed Unemployed & Disabled 62		4	6.45
Employment Status			33	53.23
	Unemployed & Not Disabled		25	40.32
	At least some college or above		10	16.13
Highest Level Education	GED obtained/high school graduate	62	26	41.94
	No GED/some HS		26	41.94
	Homeless/Shelter		16	25.81
Pt report living	Living alone 62 Living with someone		22	35.48
			24	38.71
	No 62		23	37.10
	Yes	02	39	62.90
	Cocaine		39	62.90
Other illicit drug#1	No	No 62 Other Drugs ^d		4.84
	Other Drugs ^d			32.26
	Cocaine		6	9.68
Other illicit drug#2	No 62		38	61.29
	Other Drugs ^e		18	29.03
Eoropsis Hy	No	FO	23	38.98
FOIEIISICHX	Yes	59	36	61.02
	Depression		16	25.81
Psychiatric Hx	No	62	33	53.23
	Others ^f		13	20.97
	No	67	58	93.55
Devel disability	Yes	02	4	6.45

Social Variable Clustering



Social Variables



- Any category with a positive value could increase the probability of receiving treatment.
- Any category with a negative value could decrease the probability of receiving treatment.

Social Variables Associated with HCV Care

- Use of clustering techniques, multiple correspondence analysis and modern statistical learning, can identify factors associated with pursuit of HCV care
- Positive factors most influential
 - Married
 - Psychiatric diagnosis other than depression
- Negative factors most influential
 - Never married
 - Depression

SDOH and HCV Referral Acceptance

- We reviewed medical records on 161 HCV seropositive individuals at DART Methadone Treatment Program.
 - 450 patients as of Jan 1, 2017
- Acceptance of referral for HCV evaluation was primary outcome variable.
- Dependent variables
 - Demographics
 - SDOH
 - Drug use variables
 - Comorbid medical conditions
- Data analyzed utilizing similar clustering techniques

Williams et al, JSAT, In press





Participants - Demographics

Variable	Level	All (n=161)		Treated (n=33)			Untreated (n=128)			
		N	Mean/ #	SD/%	Ν	Mean/#	SD/%	Ν	Mean /#	SD/%
Age		161	45.1	13.4	33	48.2	13.4	128	44.3	13.3
Condor	Female	161	70	43.5	22	8	24.2	170	62	48.4
Gender	Male	161	91	56.5	33	25	75.8	128	66	51.6
	African American		25	15.7		8	24.2		17	13.5
Race	Caucasian	159	96	60.4	33	17	51.5	126	79	62.7
	Hispanic/Native American		38	23.9		8	24.2		30	23.8
Primary	English	157	133	84.7	21	27	87.1	126	106	84.1
Language	Spanish	12\	24	15.3	31	4	12.9	120	20	15.9

Factors Affecting Treatment Status

Employed · No support systems Foster care history No forensic history Married Victim of sexual assault Family history of chemical dependency Incarceration Homeless/shelter/others High school(+VOC) Initial use of heroin/opiates and/or others Initial use of alcohol and/or others Age of initial use >16 Other use of heroin/cocaine/opiate and others Divorced/others GED Other use of only heroin/cocaine/opiate Age of initial use <=16. No foster care history Living with someone Single Not a victim of sexual assault Less than high school Lives alone Higher education Unemployed · Support systems is available No family history of chemical dependency Criminal activity without incarceration · Initial use of crack/cocaine



- Any category with a positive value could increase the probability of receiving treatment.
- Any category with a negative value could decrease the probability of receiving treatment.

Factors Associated with In Person vs. Telemedicine Adherence with HCV Evaluation

In Person

• Positive

- Employed
- No support systems
- Foster care history
- No forensic history
- Married

Negative

- Initial use of crack/cocaine
- Criminal activity w/o incarceration
- No family history of chemical dependency
- Support systems available
- Unemployed

Telemedicine

- Positive
 - Mental health diagnosis other than depression
 - Married
 - Living alone
 - Use of three illicit drugs
 - No forensic history
- Negative
 - Divorced, separated, or widowed
 - Some high school, no GED
 - Living with someone
 - No secondary drug use
 - Depression

Limitations

- Retrospective nature of the data
- Categorization rare categories cannot be trusted.
- Sample size total sample size and differences in sample size between studies.
- Medical record inconsistencies
- Treatment (i.e., interferon versus DAAs)

TEAM-C: Telemedicine Evaluation, Adherence and Medication for Hepatitis C

- Compare effectiveness of telemedicine to usual care among patients on opiate substitution therapy (OST)
 - Patient-Centered Outcomes Research Institute (PCORI) supported 5-year project.
- Secondary aims
 - Compare treatment initiation and completion rates.
 - Assessment of:
 - Satisfaction with health care delivery
 - Satisfaction with telemedicine
 - Sociodemographics

Statewide Telemedicine Network

- Patient-Centered Outcomes Research Institute (PCORI) funded a study to integrate HCV treatment into OTPs via telemedicine
- 12 sites across NYS
 - 6 upstate, 6 in NYC
- Provides coverage to almost all metropolitan areas in NYS
- Telemedicine:
 - Removes geography from highquality, cost-effective healthcare
 - Permits providers to treat patients statewide from the same location





Stepped Wedge Study Design

Referral versus Telemedicine

				We
		here		
Group (4 clinics each)	Period 1	Period 2	Period 3	Period 4
Group 1	Referral	Referral	Referral	Telemedicine
Group 2	Referral	Referral	Telemedicine	Telemedicine
Group 3	Referral	Telemedicine	Telemedicine	Telemedicine

Referrals to HCV providers are ineffective

Can we bring HCV treatment to the patient through **treatment integration** into Opioid Treatment Programs (OTP)?

Why integrate HCV treatment into an OTP?

- HCV has high prevalence and incidence among OTP patients
- Addressing HCV tends to improve overall patient health
- OTPs have strict attendance and medication adherence requirements
- Model appears to improve HCV treatment uptake and medication adherence
- OTPs are a familiar and comfortable setting for patients
- Many OTPs have mission statements to deliver comprehensive healthcare

Implementing Telemedicine Model in the Real World

Multiple levels of support are needed for the successful integration of telemedicine services:

- A local champion (provider or administrator) to lead the effort
- Ensure that integration of services aligns with the OTP's mission
- Support from executive leadership
- Participation from frontline staff (e.g. nurses, case managers, receptionist).

Challenges

- Different OTPs have different motivations
- Liability concerns for treating HCV
- Lack of experience and knowledge treating HCV
- Overtaxed staff OTPs have high staff turnover



Conclusions

 Opioid epidemic continues to increase HCV prevalence and incidence

Changing demographics

•HCV care via telemedicine is a feasible, reimbursable model for substance users

- Excellent patient acceptance that improved over time
- Excellent treatment efficacy

Telemedicine is acceptable to substance users

- Prefer "one stop" shopping and convenience of co-located medical care
- Privacy is not issue.
- Social determinants of health and drug use characterics
 - Affect linkage to HCV care and completion
 - HCV elimination strategies need to consider these factors

Questions / Discussion

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