INTERVENTIONS TO ENHANCE TESTING, LINKAGE TO CARE AND TREATMENT FOR HEPATITIS C INFECTION

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HCV Care Cascade among PWID in Australia



"C Change": HCV care integrated in MOUD program

Philadelphia, PA, USA November 2019 – August 2021 Care cascade used for ongoing program evaluation



Current testing models









Anti-HCV antibody w/ reflex PCR



Rapid anti-HCV antibody test



Visit #2

Phlebotomy

Phlebotomy

Phlebotomy

RNA test

Central Lab

Antibody test

Central Lab

Antibody test

Receive diagnosis

Visit #3

ø

Receive diagnosis

Receive diagnosis



Phlebotomv





Receive diagnosis

Visit #5

Goal: decrease # of visits and decrease the time prior to treatment



What are the strengths and weakness of current diagnostic tools for HCV chronic infection?

	Eliminates need for Phlebotomy	Eliminates need for additional confirmatory testing	Immediate results
Antibody testing alone			
Antibody testing with reflex to PCR			
POC antibody testing			•••
DBS testing	•••	•••	

The Ideal Model of HCV diagnosis and treatment







Initial Treatment testing/diagnosis Minimal/ no monitoring

Posttreatment monitoring for HCV reinfection

Fingerstick Testing for HCV RNA Detection

• Relatively easy-to-use point-of-care HCV RNA test—*GeneXpert*

60 mins

- *Xpert HCV Viral Load Fingerstick*—sensitivity: 100%; specificity: 100%^[1]
- Instrument costs ~ \$17,000 (+ Service \$4000/yr)
- Assays price range ~ \$15 \$40, 60 minutes to result
- 2nd platform: Genedrive HCV IVD kit (Gene-drive Diagnostics)
 - 90 minutes to result, 12 steps
 - Sensitivity: 96%; specificity: 100% [2],

1. Lamoury. J Infect Dis. 2018;217:1889., 2. Lamoury. Diagnostics. 2021 Apr 22;11(5):746.

Traditional Referral Models of HCV Testing and Treatment



Slide courtesy of Dr. Jason Grebely.

Efficacy of Facilitated Referral and Linkage to HCV Care

- Systematic literature review and meta-analysis of PWID interventional studies up to July 20, 2016
- 14 studies included; 57% were RCTs
- Interventions to enhance linkage to care included facilitated referral for HCV assessment and scheduling of specialist appointments for clients
- All studies from IFN treatment era and none in low- or middle-income countries

Effect of Facilitated Referral on HCV Linkage to Care

Author	Yr	Ν			ES (95% CI)
Cullen Hagedorn Masson Rosenberg Tait	2006 2007 2013 2010 2010	114 15 286 37 1305		 	 2.31 (1.24-4.29) 1.56 (0.65-3.72) 1.75 (1.37-2.24) 1.08 (0.76-1.53) 1.26 (1.17-1.35)
	0.233 Ris		Risk	l 1 Ratio	4.29

Patient Navigators: NYC DOH Check Hep C Patient Navigation Program

- HCV services provided at 2 clinical care sites and 2 sites that linked patients to off-site care
- Multidisciplinary team included patient navigators to provide risk assessment, health education, treatment readiness counseling, medication adherence counseling, medication coordination
- March 2014 January 2015: N = 388
 - Initiated treatment: 33% (129/388)
 - SVR: 91% (119/129)
- Odds of treatment initiation higher for participants receiving on-site clinical care vs participants linked to off-site care in bivariate analysis: 46% vs 25% (P < .0001)

Ford. Clin Infect Dis. 2017;64:685.

Redefining Models of HCV Testing and Treatment

 Need to bring HCV care to the community where patients access services



Educate, test and treat model in Egypt: 73 villages



Shiha G. J. Hepatol. 2020, 72, 658–669

HCV Homeless Outreach Intervention: England

Proportion tested, with positive results and treated during homeless outreach interventions Mar-Sept 2020



Wilkinson et al Clin Liv Dis. Vol 17.2, 2021

Same day confirmatory testing and linkage to care: Madrid, Spain



Ryan et al. Int J of Drug Policy. In press. August 21, 2021;7:4

Task Shifting to Address Barrier of Lack of Access to Specialists

- Many different types of providers can deliver HCV treatment:
 - PCPs, addiction medicine specialists, PAs, NPs
 - Specialists can contribute by facilitating mentorship, education, training
- Many different settings can deliver HCV treatment
 - FQHCs, drug treatment centers, prisons, mental health clinics
 - Utilize embedded models of care
- Hepatologists/other subspecialists are only needed for select cases (advanced liver disease, other complicating comorbidities)

Kattakuzhy. Ann Intern Med. 2017;167:311. Arora, 2011. Rossaro, 2013. Miller 2012.

Task Shifting to Community-Based Nonspecialist Providers

- 3-hr education and training
- Overall SVR12 following LDV/SOF: 87%
- No difference in SVR rate by provider type
 - NPs: 90%
 - PCPs: 88%
 - Specialists: 85%

D	SVR	Patients With SVR/	
Provider	Rate	Iotal Patients, n/N	SVR Rate (95%CI)
NPs		22.5	
NP 1	0.77	33/43	-+
NP 2	1.00	12/12	
NP 3	0.80	4/5	
NP 4	1.00	30/30	
NP 5	0.92	55/60	+
PCPs			
PCP 1	0.75	24/32	
PCP 2	1.00	19/19	
PCP 3	0.88	43/49	-+
PCP 4	0.88	21/24	
PCP 5	0.89	32/36	
Specialists			
Specialist 1	0.77	47/61	
Specialist 2	0.85	50/59	
Specialist 3	0.89	34/38	
Specialist 4	0.76	13/17	
Specialist 5	0.94	35/37	· +
Specialist 6	0.82	64/78	+
		+	
		(0.5 1.0

Future Challenges for Enhancing Testing and Linkage to Care

- Barriers to Testing
 - Cost
 - Limited point of care options
 - Limited options that do not require venipuncture
 - Community, health system, government investment
 - Comprehensive and coordinated testing strategies are needed
- Barriers to Linkage to Care
 - Health care silos
 - Integrated models of care are the key
 - Limited numbers of treaters
 - Payer restrictions for DAA approval
 - Prior authorization process

Take Home Messages

- Build integrated test and treat models that bring the care to the patients
 - HCV testing should be integrated into routine services \rightarrow destigmatize
 - GOAL: Single visit diagnosis, with same day treatment start
 - Expand the numbers and types of providers who treat
- Advocate for development and access to affordable, point of care confirmatory testing that does not require venipuncture
- Investment from leadership is key
 - Government, hospital system, community based organization
- Elimination of HCV is possible!