

Access to Care and Treatment for HCV Mono-Infection and HIV/HCV Co-Infection

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Purpose

- To detail the availability of testing, care and treatment for individuals who are mono-infected with hepatitis C (HCV) and co-infected with HCV and HIV in light of newly available curative treatments for HCV and changes in health care delivery following full implementation of the Affordable Care Act.

Agenda

- NASTAD's Work with AIDS Drug Assistance Programs (ADAPs) and Viral Hepatitis Prevention Coordinators (VHPCs)
- Access to HCV Testing
- Availability of HCV Treatment via ADAP Full-Pay Prescription Programs
- Access to HCV Treatment via Insurance
- Opportunities for Collaboration Between ADAPs and VHPCs
- HCV Treatment Pipeline: Next 12 Months
- Discussion

NASTAD's Work with ADAPs

- NASTAD leads training and technical assistance (TA) activities to support Ryan White HIV/AIDS Program (RWHAP) Part B/AIDS Drug Assistance Programs (ADAPs) administered by state health departments. These activities are led primarily by NASTAD's Health Care Access team. Other efforts by the Health Care Access team include production of the National ADAP Monitoring Project's Annual Report and ADAP Formulary Database as well as participation in the ADAP Crisis Task Force (Task Force).

NASTAD's Work with VHPCs

- The CDC funds each state's health department to support the position of viral hepatitis prevention coordinator (VHPCs); it does not include monies for activities such as testing or surveillance. NASTAD's Viral Hepatitis program staff provides technical assistance to VHPCs through conference calls, e-mail communications, the Viral Hepatitis Technical Assistance Meeting, etc.

Access to HCV Testing

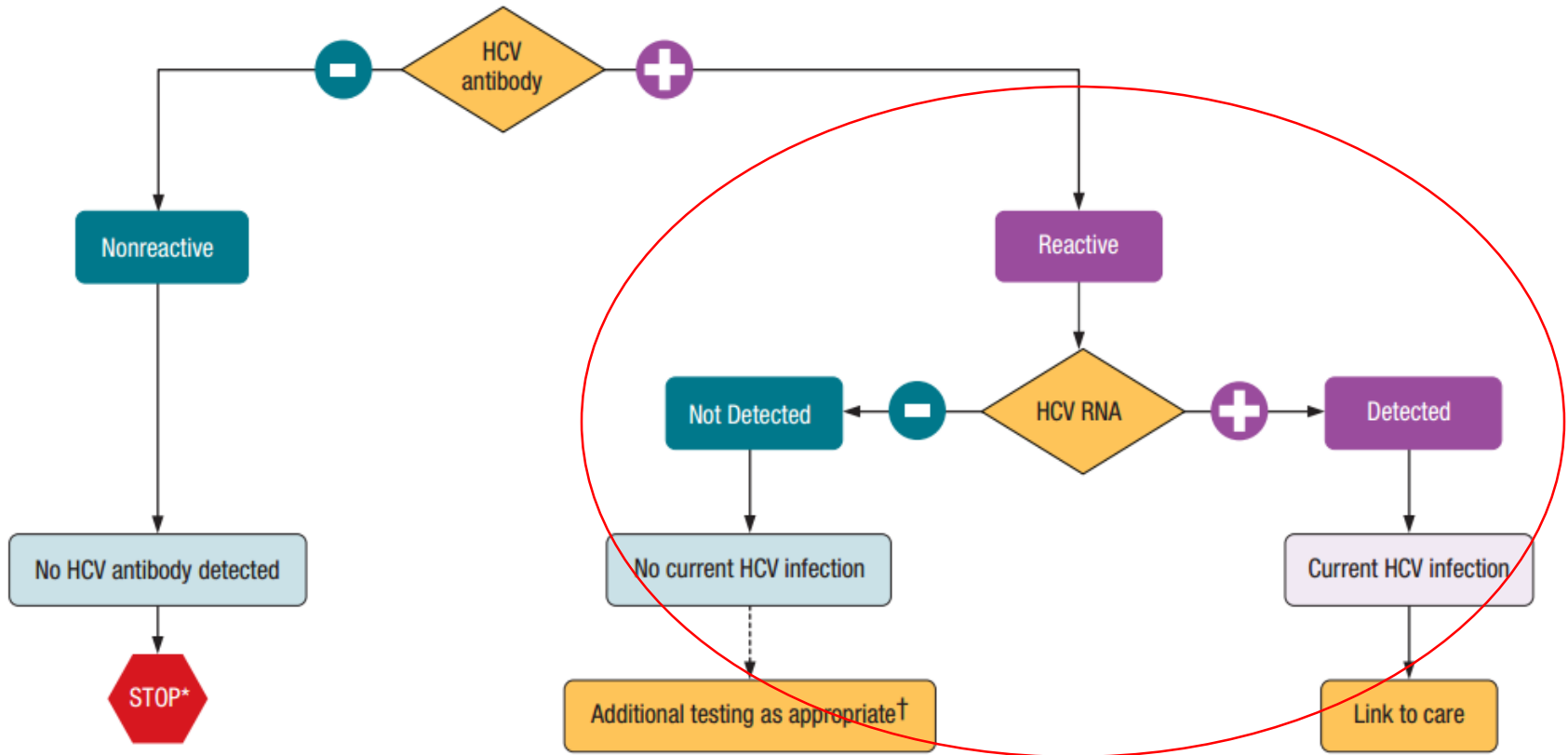
Recommendations for HCV Testing (USPSTF)

- Grade: B
 - As a result of the ACA, no cost-sharing
- **Birth Cohort:**
 - The USPSTF concludes that there is also a moderate net benefit to 1-time screening in all adults in the United States born between 1945 and 1965”
- **Risk-Based:**
 - “Persons with continued risk for HCV infection (such as injection drug users) should be screened periodically”

NASTAD HCV Testing Survey

- NASTAD conducted a survey of state health departments' current HCV testing practices in 2013
- Forty-four (85%) health departments responded to the survey, representing 42 states and 2 cities
- Health department respondents funded more than 120,000 HCV tests in 2013 with a positivity rate of 14%. This represents a 41% increase from 2011.
- As increasing numbers of individuals know their HCV status (including those that are co-infected with HIV), demand for linkage to care and treatment will similarly rise.

HCV Testing Algorithm (CDC)



Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Linkage to Care/Confirmatory HCV Testing

- Of the clients testing anti-HCV positive, eleven health departments reported an estimated 6,054 (4.9%) also received NAT for HCV RNA testing to confirm active HCV infection
 - Of these, 2,643 (44%) were confirmed with active HCV infection

Availability of HCV Treatment via Full-Pay Prescription Programs

- ADAP funds can only be used for HIV/HCV co-infection.
- The ADAP Formulary Database details AIDS Drug Assistance Programs' (ADAPs') coverage of medications, both individually and by drug class, including antiretroviral (ARV) treatment, "A1" Opportunistic Infections (A1 OI) medications, treatments for hepatitis B and C, substance use treatment medications as well as vaccines and various laboratory tests.

ADAP Formulary Survey: HCV Treatments

- As of March 31, 2014, 38 ADAPs cover one or more hepatitis B treatment while 30 ADAPs cover one or more hepatitis C treatment.

Generic (Brand Name)	# (%) ADAP Formularies
boceprevir (Victrelis)	8 (15%)
consensus interferon or interferon alfacon-1 (Infergen)	8 (15%)
interferon alfa-2b (Intron A)	21 (40%)
interferon alfa-2b (Intron A) and ribavirin (Rebetol)	19 (36%)
peginterferon alfa-2a (Pegasys)	30 (57%)
peginterferon alfa-2b (PEG-Intron)	26 (49%)
peginterferon alfa-2a (Pegasys) + ribavirin (Copegus)	24 (45%)
peginterferon alfa-2b (PEG-Intron) and ribavirin (Rebetol)	22 (42%)
recombinant interferon alfa-2a (Roferon)	10 (19%)
recombinant interferon alfa-2a (Roferon) and ribavirin	6 (11%)
telaprevir (Incivek)	8 (15%)

ADAP Formulary: Discussion

- **Discussion for ADAPs:**
 - Why or why not did your ADAP choose to add particular HCV medications (cost, access issues, lack of care, etc.)?
 - If your ADAP chose to add one or more HCV medication, did you place any restrictions on who may receive it?

ADAP Formulary Survey: HCV Treatments

- In November 2014, ADAPs were asked to provide updated information regarding the inclusion of recently approved hepatitis C medications on ADAP formularies.

Generic (Brand Name)	# (%) ADAP Formularies
simeprevir (Olysio)	7 (13%)
sofosbuvir (Sovaldi)	6 (11%)
ledipasvir and sofosbuvir (Harvoni)	2 (4%)

Access to HCV Treatment via PAPs

- A **patient assistance program (PAP)** is a program run through pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare or AIDS Drug Assistance Programs (ADAPs).

Access to HCV Treatment via PAPs

- Gilead declined to negotiate with the ADAP Crisis Task Force in July 2014 in order to set a discounted price for Sovaldi for ADAPs.
 - Gilead cited their patient assistance program (PAP) as a sufficiently robust option to allow for access to care and treatment in lieu of negotiations with ADAPs.
- **Discussion for ADAPs and VHPCs:**
 - What has your experience been in linking clients to these programs?
 - Have your clients encountered any issues in either enrolling or using these programs?

Access to HCV Treatment via Insurance



ADAP-Funded Insurance Programs

- Since 2003, AIDS Drug Assistance Programs (ADAPs) have used program funds to support insurance payments for clients' prescription and medical care (i.e. premiums, deductibles, and co-payments/co-insurance).
- Ryan White Program funds may provide insurance assistance to ADAP-eligible PLWH through: maintenance of COBRA insurance continuation; State High Risk Health Insurance Pools; state-funded health programs; the purchase of individual or group health insurance policies; or through Medicare Part D and Medicaid.

Access to HCV Treatment via Private Insurance

- Both ADAP Coordinators and VHPCs have reported issues in private insurance coverage for HCV treatments anecdotally including:
 - High cost-sharing for client as a result of tiering
 - Prior authorization requirements
 - Substance use/sobriety
 - Disease progression
 - Care supervised by specialist

Access to HCV Treatment via Public Insurance

- Medicaid coverage for HCV treatment:
 - Prior authorization requirements
 - Substance use/sobriety
 - Disease progression
 - Care supervised by specialist

Access to HCV Treatment via Insurance

- **Discussion for ADAPs and VHPCs:**
 - Have you encountered similar issues in your jurisdiction with private and/or public insurance?
 - If so, please describe.
 - With what private insurance plan(s)?
 - Have you encountered similar issues with other forms of public insurance (e.g. Medicare)?
- **Discussion for ADAPs:**
 - Have you provided some form of “wrap around” services for clients as a result?

Access to HCV Treatment via Insurance

- A **co-payment assistance program (CAP)** is a program run through pharmaceutical companies to offer co-payment assistance to people with private health insurance to obtain viral hepatitis drugs at the pharmacy.
- **Discussion for ADAPs and VHPCs:**
 - What has your experience been in linking clients to these programs?
 - Have your clients encountered any issues in either enrolling or using these programs?

Opportunities for Collaboration Between ADAPs and VHPCs

Dr. Jeff Maras



Opportunities for Collaboration

- Updates/additions to ADAP formularies with newly available HCV treatments
- Monitoring challenges in accessing HCV treatment through private insurance, Medicaid, etc.
- For those newly tested positive for HCV, linking those co-infected with HIV to ADAP services
- Linking clients who test positive to HCV antibody tests to care and confirmatory lab testing

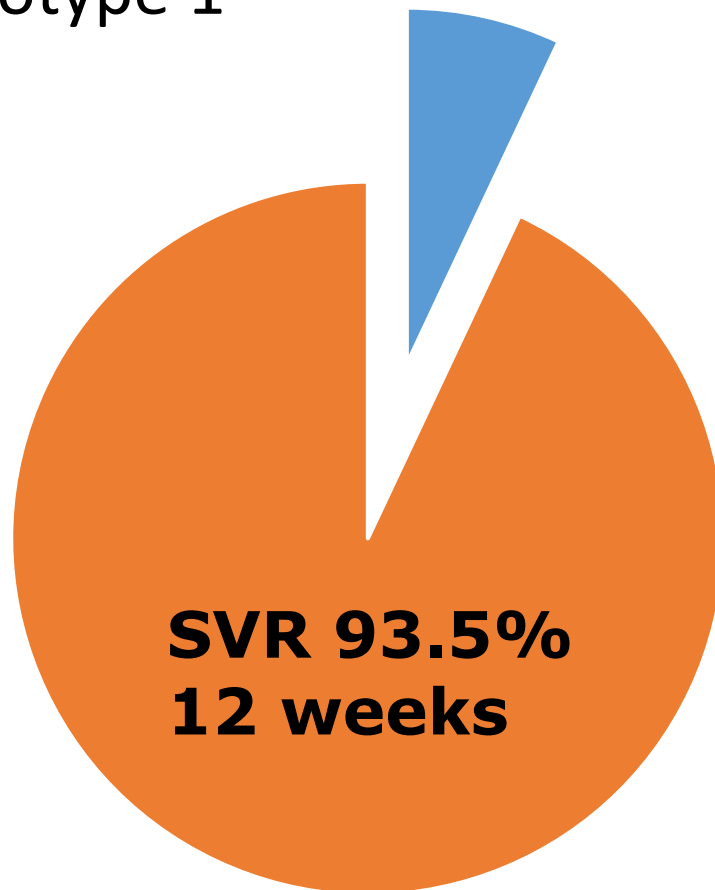
HCV Treatment Pipeline: Next 12 Months

Dr. Jeff Maras

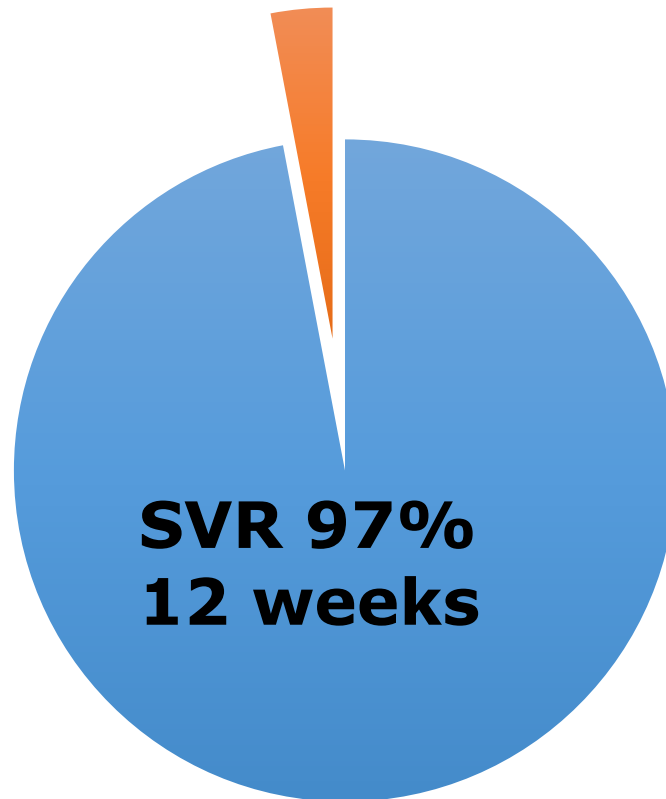


What's Coming

- Viekirax and Exviera + ribavirin, for 12 or 24 weeks in HIV/HCV genotype 1



Viekirax and Exviera + Ribavirin in HCV (AbbVie)



Feld et al: NEJM 2014; Poordad et al; NEJM 2014; Zeuzem et al; NEJM 2014

Viekirax and Exviera (AbbVie)

- FDA approval expected in Q4, 2014 or Q1, 2015
- Viekirax is a ritonavir-boosted hepatitis C protease inhibitor, co-formulated with an NS5A inhibitor; it is used with Exviera, a non-nucleoside polymerase inhibitor, with or without ribavirin, twice-daily
- In clinical trials, Viekirax and Exviera cured ~97%
- The regimen has primarily been developed in, and is likely to be approved for, HCV genotype 1 (it is also effective in genotype 4)

Viekirax and Exviera (AbbVie)

- Price likely to be close to Harvoni (\$95,000), and this regimen has similar limitations
 - People with cirrhosis may require 24 weeks of treatment
 - Less effective in null responders with cirrhosis and HCV genotype 1a
 - Has some tricky drug-drug interactions with certain HIV medications

Daclatasvir (Bristol-Myers Squibb)

- Phase III trials with sofosbuvir are underway
 - Approval expected in 2015
 - In a phase II trial, this combination cured ~98% of people with HCV genotype 1, regardless of their treatment history
 - Less effective for people with genotype 3 who have cirrhosis

Discussion