ADAP ADVOCACY ASSOCIATION

In partnership with the

COMMUNITY ACCESS NATIONAL NETWORK

Presents…

HIV/HCV ADAP Summit

FINAL REPORT

HIV/HCV Co-Infection Summit
FINAL REPORT
Las Vegas, NV | April 25-26, 2013

FORWARD:

The rapid increase in the number of people co-infected with HIV-infection and Hepatitis C infection is an emerging epidemic in the United States.

The ADAP Advocacy Association (aaa+) – in collaboration with the Community Access National Network (CANN) – hosted an HIV/HCV Co-Infection ADAP Summit in Las Vegas, NV on April 25-26, 2013. The purpose of this Final Report is to convey some of the programmatic changes, improvements and reforms that could be leveraged under the Affordable Care Act (ACA) and the Ryan White CARE Act, and more specifically the AIDS Drug Assistance Program (ADAP), to better serve people co-infected with HIV-infection and Hepatitis C infection. It also examines the intersection between the ACA, Medicaid expansion and insurance exchanges, as well as updates on drug pricing and patient assistance programs for emerging HCV treatments, and various other relevant issues.

The Summit panelists included: **William Arnold** from the Community Access National Network, **Leilani Attilio, MPH, RN** from the North Carolina Harm Reduction Coalition, **Keith Blackmon** from South Carolina representing the patient perspective, **Sherrie Burch, M.S.** from the Community Counseling Center of Southern Nevada, **Rob Caldwell, Ph.D.** representing the medical perspective, **Christine Campbell** from Housing Works, **Lynda Dee** from the Fair Pricing Coalition, **Wayne Greaves, M.D.** from Merck & Co., **John Hellman** from the Latino Commission on AIDS, **Joseph Jefferson** from HealthHIV, **Jason King** from AIDS Healthcare Foundation, **Brandon Macsata** from the ADAP Advocacy Association, **Joshua Montgomery** from the Gay and Lesbian Community Center of Southern Nevada, **Glen Pietrandoni, RPh** from Walgreens, **Coy Stout** from Gilead Sciences, and **Joey Wynn** from the Minority Development & Empowerment. **Michael Shankle**, MPH from HealthHIV, moderated the Summit.

The Final Report recommendations are included hereto, as well as other relevant information. This Final Report is not necessary endorsed by the HIV/HCV Co-Infection ADAP Summit's sponsors, panelists or participating organizations. Additional information, including the event agenda, panelist bio's and speaker's presentations can be viewed online at http://www.adapadvocacyassociation.org/events_04_2013_agenda.html.

Thank you for the opportunity to share the short-term and long-term recommendations identified at the HIV/HCV Co-Infection ADAP Summit.

Respectfully,

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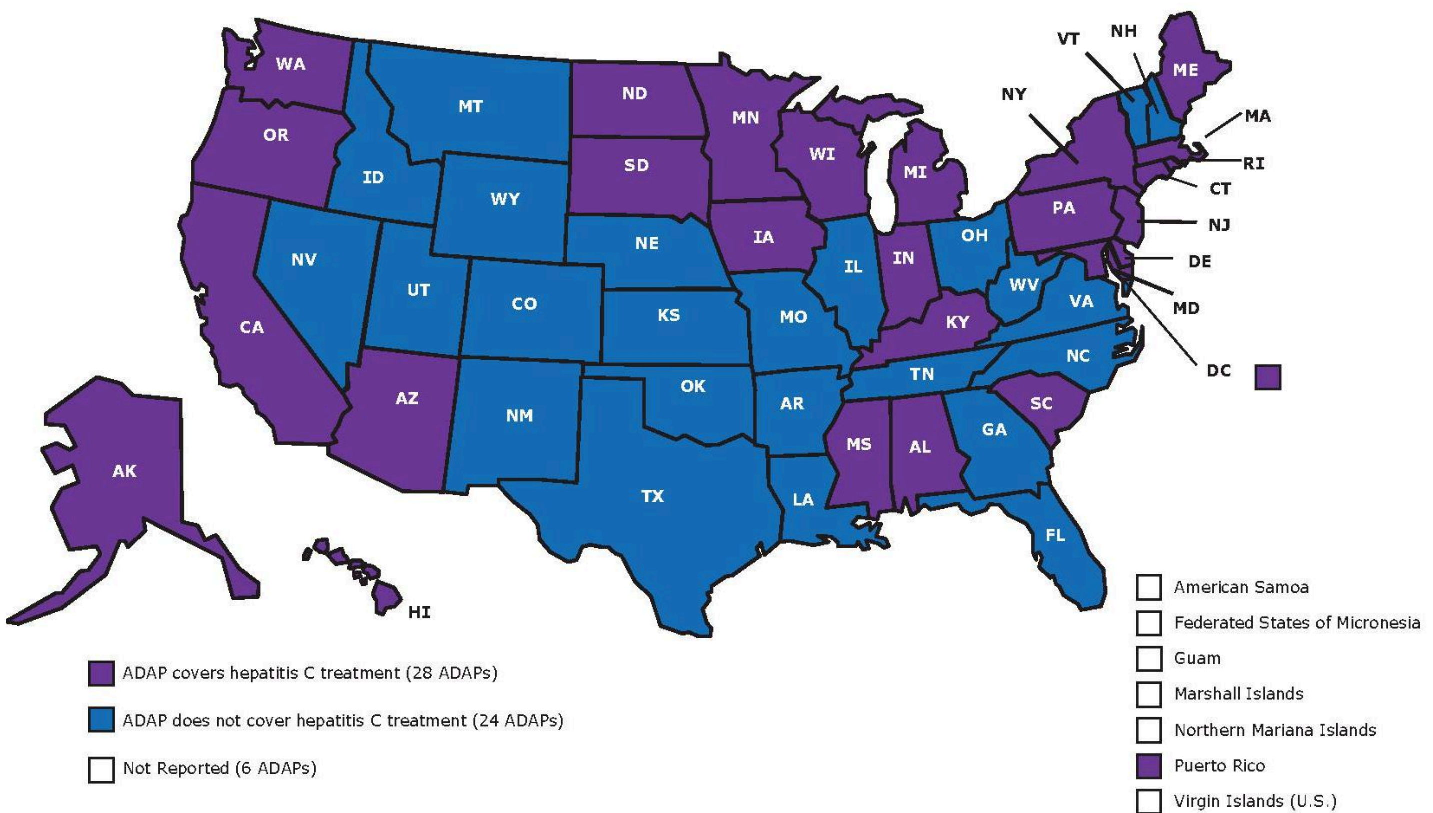
BACKGROUND:

People living with HIV infection are disproportionately affected by viral hepatitis; about one-third of HIV-infected people are co-infected with Hepatitis C, which can cause long-term (chronic) illness and death. Hepatitis C progresses faster among people living with HIV infection and people who are infected with both viruses experience greater liver-related health problems than those who do not have HIV infection. Although antiretroviral therapy has extended the life expectancy of people living with HIV infection, liver disease—much of which is related to Hepatitis C has become the leading cause of non-AIDS-related deaths among this population.

Chart 2: ADAP Coverage of Hepatitis C Treatment, June 2011



Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011. 12

Currently, there are twenty-eight (28) states that have Hepatitis C treatment as part of their drug formulary under the AIDS Drug Assistance Program (ADAP).[1] It is therefore important to examine relevant cross-section between HIV/HCV with respect to ADAPs.

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[1] National Alliance for State and Territorial AIDS Directors (NASTAD), National ADAP Monitoring Project Annual Report, 2011.

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HIV/HCV CO-INFECTION:

- 1.2 million people living with HIV/AIDS in the United States.
- Only 300,000 – 500,00 in care and treatment (estimates vary).
- 4 million people living with HCV in the United States,
- About 25% of people infected with HIV in the U.S. are also infected with HCV.
- About 80% of injection drug users (IDUs) with HIV infection also have HCV.
- HIV/HCV co-infection more than triples the risk for liver disease, liver failure, and liver-related death from HCV.
- Compared with other age groups, a greater proportion (about 1 in 33) of people aged 46–64 years are infected with HCV.
- Chronic HCV is often "silent," and many people can have the infection for 20 to 30 years without having symptoms or feeling sick.
- In the U.S., HCV is twice as prevalent among blacks as among whites.
- New data suggest that sexual transmission of HCV between MSM living with HIV occurs more commonly than previously believed and that sexual transmission can occur undetected between HIV-infected MSM in the absence of injection drug use. [2]
- FDA labeling for new HCV treatments for co-infection (HIV/HCV) is underway.

IMPACT on ADAPs:

HIV/HCV co-infection remains a growing and evolving epidemic. Advances in HIV medication since the introduction of HAART in 1996 has increased a detection of sexually transmitted HCV infection. Sexual transmission of HCV is becoming a growing concern amongst MSM as discussed in an MMWR report released July 22, 2011.[3]

The AIDS Drug Assistance Programs (ADAPs) provide HIV-related prescription drugs to low-income people with HIV/AIDS who have limited or no prescription drug coverage. With nearly 200,000 enrollees, ADAPs reach approximately one-third of people with HIV estimated to be receiving care nationally. In June 2008 alone, ADAPs provided medications to about 110,000 clients and insurance coverage to thousands more.

HCV is a common co-infection in people living with HIV/AIDS. An estimated 200,000-300,000 people in the United States are co-infected with both HIV and HCV infections. Experts believe that about 25% - 30% of Americans living with HIV are also co-infected with HCV; conversely some 10% of people with HCV are thought to also have HIV infection. Currently specific ADAP funding does not exist to support treatment for Hepatitis C. However, some states with robust ADAP budgets use Part B money to pay for HCV treatment for co-infected clients.

The existing systems for the eligible ADAP population is clearly strained and do not appear likely to be capable of handling potential changes (including health care delivery system shifts combined with potential increases in demand) without serious basic system change.

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[2] Centers for Disease Control & Prevention, HIV and Viral Hepatitis Fact Sheet, November 2011.
[3] U.S. Centers for Disease Control & Prevention, MMWR Vol. 60 No.28, July 22, 2011.

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SHORT-TERM RECOMMENDATIONS:

1) Identify national coalitions (i.e., Federal AIDS Policy Partnership, National ADAP Working Group, HCV Coalition for the Cure) and their respective partners, and develop strategic objectives to advance the treatment of HIV/HCV Co-Infection, as well as access to them.

2) Develop universal messaging campaign surrounding access to care under the AIDS Drug Assistance Programs, using "success stories" from co-infected patients. (Editor's Note: Some of this is already being done by the Campaign to End AIDS).

3) Analyze existing ADAPs covering HCV treatments to determine the pros/cons of recommending other ADAPs covering HCV treatments for co-infected patients. Using a mathematical model, establish guidelines and tiers for co-infected treatment options.

4) Determine feasibility of ADAPs purchasing insurance continuation plans that cover HCV treatments.

5) Ensure that ACA Essential Health Benefits include benchmarks for treatment guidelines, as well as sufficient appeals process.

6) Establish emerging treatment guidelines using existing medical data and consumer experience. It is premature to evaluate "gold standard" for treatment because too many HCV treatments are in the development pipeline, including some already being evaluated by the Food & Drug Administration (FDA).

7) Develop "Fact Sheets" on existing plans for treatment for co-infected patients, including "navigator" information and resources.

8) Expand testing.

LONG-TERM RECOMMENDATIONS:

1) Commission study to identify the potential treatment gaps for HIV/HCV Co-Infection.

2) Develop pharmaceutical industry "Report Card" to evaluate access to timely and appropriate care of people living with HIV/HCV Co-Infection; grading new should take into consideration drug pricing, patient assistance programs, drug rebates (if available), community education/participation initiatives, and accessibility of user-friendly product information (aside from what is legally required by the FDA).

3) Implement "Common Portal" for ADAP.

4) Evaluate adding a new Part under the Ryan White CARE Act, specifically addressing HIV/HCV Co-Infection modeling after the Minority AIDS Initiative.

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ASSUMPTIONS MADE FOR THIS FINAL REPORT:

- The Ryan White CARE Act – including the AIDS Drug Assistance Program – is *NOT* going away, as some advocates have suggested.
- The Affordable Care Act will not fix everything, nor will it be the "silver lining" for health care delivery.
- ACA will not adequately address health disparities and health equality.
- There still exists considerable "push-back" to various elements of the ACA and its implementation timeline.
- January 2014 will not be the date of the ACA's full implementation.
- Additional health care "reforms" are still needed.
- There is a lack of baseline data available.
- The impact of the funding cuts under Sequestration is still yet not entirely known, but the cuts will have negative consequences for ADAPs nationwide.
- Overall, HIV advocacy remains in good standing but HCV advocacy needs improvement.
- There is a considerable "disconnect" between national, state and local advocacy.
- Standardized advocacy documents are needed for consistent messaging.
- There still exists fragmentation in ideology, advocacy, goals and outcomes among the 56 ADAPs nationwide.
- The National AIDS Strategy needs to integrate more awareness, information, and resources with respect to HIV/HCV co-infection.
- Access to care and treatment should be synonymous with access to affordable housing.
- There is a complete lack of transparency at every level, including government agencies, pharmaceutical companies and advocacy organizations.

OBSERVATIONS FOR FUTURE CONSIDERATION:

- Is it possible to organize a broader coalition of stakeholders to address emerging HCV epidemic, including co-infection rates?
  - Where does Hepatitis A and Hepatitis B fit into this coalition?
  - What groups representing other chronic disease conditions might want to partner and build partnerships?
  - Does an information-sharing platform already exist, which can be replicated?
- How effective is current public health education on HIV-infection and HCV-infection?
  - Is the messaging being used today reflective of the "real world" experiences?
  - What methods exist to expand public health education?
  - Would it be more beneficial to shift public health education to other providers (i.e., pharmacists)?
- Are there too many variations in HCV testing efforts and protocols?
  - Who should be doing the testing?
  - Who should be reimbursing the costs of testing?
- Where does the U.S.P.H.T.F. stand on HCV testing?
  - What research is needed to ensure that the U.S.P.H.T.F. issues either an "A" or "B" grade for universal HCV testing?
- What should be included in Essential Health Benefits for con-infected patients?

- What role does monitoring standards have with respect to the following:
  - Access to care and treatment?
  - Health inequity?
  - Standard benefits?
- What monitoring systems are in place to speed-up data reporting?
  - Are ADAPs equipped to collect HCV-related infection data?
  - Is information being collected by the National Alliance of State & Territorial AIDS Directors (NASTAD)?
- What role does Information Technology (IT) play in enhancing access to care and treatment for co-infected patients?
- Is an HCV-specific program under ADAP a realistic programmatic change?
  - Should it include HCV mono infection, or only HCV co-infection?
  - Will HCV co-infection treatment integration in the HIV treatment infrastructure lead to greater neglect of existing HIV populations (i.e., ADAP waiting lists)?
- What is the impact of morbidity and mortality trends?
- How can potential cost-savings achieved under the ACA be re-invested back into RW?
- What steps can be taken to leverage existing resources to achieve better program efficiencies and outcomes?
- What is the ROI on including co-infection supports and services under ADAP?
- What inequities will exist between States that expand their Medicaid programs, versus others that opt-out of the expansion?
  - Will coverage gaps in the South increase?
  - Consequences of expansion States "subsidizing" the non-expansion States?
- Is there a way to determine how many of the patients on ADAP waiting lists are also co-infected with HCV?
- How can national organizations better support state-level advocacy efforts?
  - What advocacy can be done beyond legislatures to target other policy-influences, such as Plan Administrators and Insurance Providers?
  - What is the role of local advocacy groups, where they exist?
- What is the role of social media to link consumers to more effective advocacy?
- What is the potential political backlash from the respective HIV & HCV advocacy communities over "meshing" the two disease advocacy efforts?
- Is there a way to evaluate the power to impact public policy via advocacy?
- What can be done to establish better educational partnerships with access to care representatives from pharmaceutical companies?
- How feasible is it to develop a community system to "rate" pharmaceutical companies on access to care issues, including – but not limited to – drug pricing?
  - How to identify the "business interest" for the company?
  - How it benefits patients (i.e., PAPs)?
  - How it improve treatment adherence; for example, 14% of Rx scripts are not picked-up by patients?
- How can pharmaceutical companies, as well as the community, better disseminate information about available patient assistance programs?
- Is a temporary "price freeze" feasible considering the high-cost of the new HCV treatments?

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