December 3, 2014; 5:30pm – 7pm

MEETING HIGHLIGHTS

Meeting Date: Wednesday, December 3, 2014; 5:30pm – 7pm
Meeting Location: Philadelphia Department of Public Health, 500 S. Broad St
Organizations in Attendance: AbbVie, ACT UP, Action AIDS, Burman’s Specialty Pharmacy, CA Difference, Crosslink Medical Services, Drexel School of Medicine, Drexel School of Public Health, Drug Policy Alliance, Gilead, Health Federation, Hep B United, HepTREC, Janssen, Kensington Hospital, Penn Medicine, Philadelphia Department of Behavioral Health/Office of Addiction Services, Philadelphia Department of Public Health, Philadelphia FIGHT/John Bell Clinic, Prevention Point Philadelphia

WELCOME & INTRODUCTIONS

Over 35 people representing over 21 agencies attended our December HepCAP meeting (we think there were over 40 of you there but not all were on the sign-in list… which gives us a chance to offer a friendly remember to sign-in when you attend meetings!)

CONFERENCE REPORT-BACKS

HepCAP members attended several conferences since our October meeting. At the top of our December meeting, members were invited to share highlights from their conference experiences.

NASTAD Viral Hepatitis Technical Assistance Meeting (Washington, DC)

Alex Shirreffs, Viral Hepatitis Prevention Coordinator (VHPC) and Danica Kuncio, Hepatitis Epidemiologist – both staff of the Dept. of Public Health (PDPH) – attended this meeting for health department hepatitis staff. Danica presented on some of the great work PDPH’s Hepatitis Surveillance program has done!

Most attendees were Viral Hepatitis Prevention Coordinators from other states and cities; they were joined by some federal and community partners. Alex noted that the PA VHPC, Sameh Boktor, has transitioned out of his position at the PA Department of Health. It is expected to be several months, at least, until the State fills his position.

Alex noted that Sameh’s departure represents a broader mood of uncertainty among the VHPCs. The VHPC and Enhanced Hepatitis Surveillance grants (of which PDPH is one of seven national recipients) are both up for renewal in 2015. The general sense from CDC at the TA meeting did not leave the VHPCs with 100% certainty that CDC intends to continue to fund all of the currently funded VHPC and/or Surveillance sites. One question that raised a potential red flag was a question of whether VHPCs could create their own state “Epi Profile” without surveillance capacity (to which we would say “No!” in Philadelphia!). The experience at PDPH is that it has been tremendously beneficial to have both a VHPC and a Hepatitis Surveillance team, particularly because they have partnered together so well – internally and with external partners – in Philadelphia.
Another key point from NASTAD was the emphasis on Drug User Health. Many speakers emphasized that CDC and VHPCs must prioritize the health of drug users. Of particular concern was the emerging hep C epidemic among young people who use drugs. “Why has it taken so long to call this a crisis,” Daniel Raymond at Harm Reduction Coalition noted, “If we don’t act it will be a catastrophe; we can’t lose another generation to hep C.” Speakers also encouraged VHPCs to get a seat at the table in areas – like PA – where more attention is being paid to rising heroin use and overdose prevention measures like Naloxone distribution. The challenge to VHPCs and CDC was thinking about how to predict the new waves of hepatitis C cases and how do we design prevention strategies to reach younger people before they become infected. SAMHSA leadership attended the conference and made a commitment to continue coming up with ways to integrate hepatitis activities among their grantees and acknowledging that with ACA there needs to be more work done to bridge the gap between public health and behavioral health services.

NASTAD viral hepatitis resources: http://www.nastad.org/viral_hepatitis/default.aspx

**Harm Reduction Conference (Baltimore, MD)**

Prevention Point, Project SAFE, SWOP and the Philadelphia Department of Public Health presented at this meeting and several reps from Philly/HepCAP attended!

Six HepCAP members shared their reflections and highlights from the Harm Reduction Conference. Something almost everyone mentioned was that this conference has a very unique and welcoming atmosphere – some attendees compare it to a family reunion. There is a great variety of representation from clinicians, community based agencies, government agencies, and people whose lives have been touched by drug use – current and former users, family members, friends, and advocates. Many HepCAP members felt rejuvenated and inspired by having the opportunity to network with likeminded and passionate people and left feeling part of a larger, national movement. HepCAP participants also reported feeling a better appreciation for the resources we have in Philadelphia after hearing from people working in much more restrictive and under-resourced areas. Other, more specific highlights included:

- **Advocacy for equal access to hep C treatment.** Many high-profile speakers, including Michael Botticelli from the White House Office of National Drug Control Policy emphasized that drug users should not be denied access to hep C meds.

- **Scaling up Naloxone Access.** Massachusetts stakeholders presented a model of training incarcerated people about Naloxone pre-release since people leaving jails or rehab are vulnerable to overdose. Other topics included expansion of pharmacy access and other best practices (including Prevention Point, who shared their presentation at HepCAP!).

- **ACA, Health Care Reform, and Harm Reduction.** New York and DC presented models of harm reduction agencies that have partnered with clinical health care providers. These sort of partnerships help community clinics better serve at-risk populations, by working with agencies who have experience, and help harm reduction orgs tap into new resources that clinical practices may have available through ACA. A specific partnership between HIPS and the Whitman Walker Clinic in DC was provided as an example.

*The next HepCAP meeting will be held on Wednesday, February 4**th** from 5:30pm-7pm at PDPH (500 S. Broad St)*
• *Drug User Organizing.* HepCAP members reported it was good to see models from other cities where drug users had organized for advocacy efforts. From planning to attendance, HRC involves people who use drugs at every step of the conference.

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**AASLD Liver Meeting (Boston, MA)**

Of folks at the HepCAP meeting PDPH, Drexel, Penn, and the National Nursing Centers Consortium each had posters or presentations at this conference. Many more local clinicians and hep experts attended! Several people who have attended noted that the Liver Meeting conference demographics are changing. In addition to seeing more public health, infectious disease, and harm reduction folks there, HepCAP members noticed more international participants (Sandra Khalil from Crosslink noted there was a large delegation from Egypt!).

Amy Jessop from HepTREC participated in a one-day Liver Council Roundtable meeting, convened by the Caring Ambassadors program. This group aims to develop a national strategic plan to address Liver Cancer that would align with the national Viral Hepatitis Action Plan. Amy called this one day meeting, “talking with purpose;” subgroups take on different topics like prevention, treatment, and surveillance. As a roundtable member, Amy will be able to 1) provide input on the plan and 2) can give HepCAP members updates on the plan and ask members for additional input. Thanks for representing Philly, Amy!

Other notable Liver Meeting highlights were:

• *New Treatments.* Of course the new hepatitis C treatments were showcased throughout the conference. While we did not review specific data that was presented at the conference at HepCAP, the websites below have some great summary articles of the most important presentations. Check them out! Now that such great treatments exist, there was a lot of talk of reducing the time of treatment from 12 weeks and there was also talk of a hepatitis C vaccine.

• *Perinatal Transmission.* Danica Kuncio from PDPH presented a poster of the perinatal hep C analysis (presented at the October 2014 HepCAP meeting). She noted that CDC was very interested in her poster and that there seemed to be a growing interest in this topic among other conference participants.

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American Public Health Association Conference (New Orleans, LA)

Hep B United, the National Nursing Center Consortium, and Jefferson/PHOP presented at APHA. Catelyn from NNCC noted that while there were many participants there who were interested in hep C, she didn't think hepatitis was well represented on the agenda. HepCAP members, consider this an opportunity to submit a poster or presentation for APHA 2015 and put hep C (and Philly!) on the agenda!

- **APHA 2015** (Chicago, 10/31-11/4). Theme: Health in All Policies. The call for abstracts is **open**! Most abstracts are due **February 20**th.
  - [https://apha.confex.com/apha/143am/oasys.epl](https://apha.confex.com/apha/143am/oasys.epl)

PARTNER UPDATE: INTEGRATING OVERDOSE RISK ASSESSMENT, EDUCATION, AND NALOXONE DISTRIBUTION AT PREVENTION POINT

Did you know that more people die of drug overdoses than homicides in Philadelphia? In 2012, **497** people died of a drug overdose, mostly from heroin or other opioids (322 were killed in a homicide). Fortunately, in September 2014, PA signed **Act 139** into law to help prevent overdose deaths. This legislation has two main parts:

- **Expansion of Naloxone access:** Naloxone (brand name Narcan) can be administered to reverse an opioid overdose. Under the new PA bill, police and other first responders, as well as family and friends of users, can administer naloxone. The bill also law allows physicians to prescribe naloxone to friends and relatives of drug users.

- **Good Samaritan protection:** This is intended to protect people from prosecution if they summon help for an overdose victim. However, they must give their name to authorities and cooperate, and remain with the overdose victim until help arrives. They will be protected from arrest for offenses including parole and probation violations. But the law will not protect against prosecution for providing the drugs that caused the overdose.

More information about Act 139 can be found here: [http://www.ddap.pa.gov/ACT139Naloxone](http://www.ddap.pa.gov/ACT139Naloxone)

Prevention Point Philadelphia (PPP) implemented an Overdose Prevention Program (OPP) in 2006. Clayton Ruley, Project Coordinator of PPP’s Streetside Health Clinic, provided an overview of PPP’s overdose prevention activities: how it was implemented, what the early challenges were, and how PPP made structural changes to better integrate overdose prevention
activities into the PPP workflow. These changes led to an increased uptake of overdose prevention trainings. Clayton’s slides are included in the meeting highlights.

The point that was emphasized throughout Clayton’s presentation is how empowering it is for PPP clients and family members of drug users to be given the opportunity to save a life. PPP is giving people access to a service that they sometimes do not even know to ask for – and by distributing more naloxone and doing more trainings they are raising awareness that opiate overdoses can be prevented. PPP estimates that they train and distribute naloxone to 16-20 people a day. One ongoing challenge to naloxone distribution is cost – while PPP would like to distribute the intranasal form, the cost is $28 compared to $6 for the injectable naloxone.

With Act 139 increasing access to Naloxone in PA, how can YOUR organization integrate overdose prevention messages and help save lives? You can start by looking up more information about overdose prevention:

- [www.prescribetoprevent.org/video/](http://www.prescribetoprevent.org/video/)
- [www.Stopoverdose.org](http://www.Stopoverdose.org)

**HEP C TREATMENT ACCESS**

Dr. Stacey Trooskin reviewed 1) upcoming new hepatitis C treatment options and 2) the challenge of getting Interferon-free treatment approved for patients on Medicaid insurance plans (patients on private plans and Medicare have been easier to get approved for medication). Summary slides of her presentation are included at the end of these highlights.

Pennsylvania is one of the most restrictive states when it comes to access to new hep C medications. Some of the most challenging barriers to treatment access include:

- **Requirement for either a liver biopsy or a Fibroscan.** The liver biopsy is in most cases medically unnecessary and not without significant risk and discomfort. There are only 6 fibroscan machines in the state of Pennsylvania and 3 in Philadelphia, none of which are readily accessible to most patients. Until January 1st there will not even be an active CPT code for billing purposes. Further limiting access, without biopsy or Fibroscan results, patients are receiving letters that say “provider did not give all the information needed to approve treatment” instead of a “denial” letter. Patients need a specific denial letter from the insurance company in order to access free meds from the drug companies so a letter putting fault on the provider adds another layer of complication to medication access.

- **Abstinence.** To be treated on Medicaid in PA, patients must be 6-months free from drugs/alcohol. Clinicians have reported that some Keystone patients were denied treatment because their urine screen was positive for methadone. Keystone was reportedly going to include methadone in their abstinence requirement but seem to be moving away from this.

Several other clinicians in attendance reported challenges they have had getting patients approved for new treatment. Jody Gilmore from Presbyterian ID Clinic noted that one of her patients had a hearing scheduled with Keystone to get access to Sim/Sof. Jeanmarie Zippo from Action AIDS reported hearing some of her clients on methadone have been having trouble...
accessing medication. She heard that groups of methadone clients were going to be meeting among themselves to discuss treatment access.

What will HepCAP do to improve access to hep C treatment?

- **Building state support.** HepCAP now has a part-time Public Affairs Coordinator working on outreach to potential partners across the state who would be willing to help HepCAP advocate for equal access to hepatitis C treatment for everyone living with the virus. PDPH and the PA Department of Health are also working with CDC to host a state forum with key stakeholders to address hep C testing and access to care.

- **Developing an advocacy strategy.** Stacey has connected with a lobbying firm that can help HepCAP develop a coordinated strategy for working with state and national policy makers, including individuals in the incoming Wolf administration.

- **Participating in national conversation.** HepCAP is part of the National Viral Hepatitis Roundtable is one of the leading groups to organize groups from around the country on issues related to hepatitis B and C. Stacey and Alex have been participating in calls of the Treatment Access Workgroup to stay informed about national access issues and let national advocates know what is happening in Pennsylvania.

- **Exploring legal options.** Stacey has met with AIDS Law Project and talked to other lawyers interested in exploring legal options for getting patients access to medication. **UPDATE:** Since the HepCAP meeting, a law firm has filed the first class action lawsuit against Gilead on behalf of SEPTA!


**HEPCAP IN 2015**

Alex will be sending out a survey to get YOUR ideas and insight for 2015. She will also be in touch with folks who have submitted their names to participate on HepCAP’s Community Advisory Team. If you are interested but have not yet submitted your name, contact Alex at Alexandra.shirreffs@phila.gov.

**UPDATES & ANNOUNCEMENTS**

**Upcoming HepCAP Meetings!** HepCAP meetings are held on the first Wednesday of every other months at 5:30pm at 500 S. Broad Street):

- **2015 Meetings:** Feb 4th, Apr 1st, Jun 3rd, Aug 5th, Oct 7th, Dec 2nd

Please contact Alex Shirreffs at 215-685-6462 or alexandra.shirreffs@phila.gov if you have edits to these notes or feedback about HepCAP.
Integrating Overdose Risk Assessment, Education, and Medication Dispensing in a Harm Reduction Focused Street Medicine Setting, and Replicating the Model

HISTORY OF OVERDOSE PREVENTION PROJECT

• In 2006, PPP began program in response to rising deaths
• Steep increase in overdose deaths followed by fentanyl epidemic
• Awareness really high and participants began to ask about naloxone
• PPP approached Division of Behavioral Health about beginning program
• Overdose Prevention Intervention & Treatment Education Project (OPIATE)
• Start open dialogue with first responders and police about od response
• Give trainings to service providers who work with clients at risk for or witnessing overdose

• OPIATE goals: reduce risk for overdose and overdose deaths
• OPIATE also designed to train family, friends, and partners in pairs
• Most important: free Naloxone with prescription after medical assessment
HOW OPIATE PROJECT WAS IMPLEMENTED

• Advertised sessions at exchange sites
• Educational sessions held at PPP during busiest exchange site
• Educational sessions held when doctor on site to write prescription
• Additional sessions held on an as-needed basis on clinic days
• Sessions held in group format
• Sessions typically take 20 minutes
• Sessions involve chemistry of opiates and drug interactions, risk factors for overdose, symptoms of overdose, responding effectively to an overdose
• Try to teach S.C.A.R.E. M.E (Stimulate, Call for help, Airway gets cleared, Rescue breathing, Evaluate breathing, Muscular injection, Evaluate again)

CHALLENGES TO IMPROVEMENT IN OPIATE PROJECT

• Even with advertising, low uptake of education sessions
• Very few participants brought in family, friends, partners to be trained
• Did not always have doctor present to sign prescriptions
• Constant training of newer medical staff to get them on board
• Only exchange staff offered training
• Could not always get naloxone
• Low awareness of risk for overdose
• Awareness often based on personal history
• Fentanyl seen as separate issue by many
STRUCTURAL CHANGES IDENTIFIED

• All staff needed to be trained to conduct education, reverse, dispense
• All medical providers needed to be on board and trained
• Providers can’t provide clinical services without prescriptions
• SEP presented bigger opportunity to raise awareness
• Could do greater in-reach in SEP
• We could take advantage of our bad space!
• There is a way to identify individuals at risk who don’t ask for training
• If participants don’t “opt in”, can we start to ask them to “opt out”
• Suboxone clinic first opportunity to make change
• Case management services next opportunity
• Clinics presented huge opportunity to routinize screening for risk
• Clinics presented huge opportunity for training and medication dispensing
• Nursing education sessions presented additional opportunity
• Need to better track reversals and capitalize on feeling of reversal

CHANGES TO IMPLEMENTATION OF OVERDOSE TRAINING AND NALOXONE DISTRIBUTION IN CLINIC SETTING

• Overdose/Naloxone training to those seeking nursing intervention
  • Patients only getting BP’s, blood sugar checks, and wound care received intervention in an opt out fashion

• Offered to those considered at risk based on the needs assessment form
  • Patients waiting to see doctor offered intervention without asking based on their responses in the paper pre-clinic needs assessment (previous hx of overdose, current or past opiate use, recent discharge from a closed facility, on MAT or suboxone)
STRUCTURAL CHANGES MADE IN THE SEP

• Raising awareness about od risk on the line each exchange with all staff
• Outreach to get people to trainings at every site with every staff member
• Identifying participants who got training to advertise training
• Weekly and daily handouts on fentanyl risks and new stamps at SEP

• Asking each person each time till they say “why is everyone asking me?”

• Special training sessions at outdoor sites
• Identifying parent groups, advertising trainings on web, with providers

CHANGES TO GROUP DELIVERY OF TRAINING THROUGH BEING CREATIVE AND MAKING DROP IN SPACE WORK

• As part of overdose awareness day, needed multiple spaces
• Drop in center presented great opportunity
• A little bit of theater goes a long way in recruitment

• Come, stay, even if you did not plan on it!
• Fill out some forms while you’re at it!
• And take some medication on your way out!

• Designated a specialist to coordinate kits and paperwork
• Pre-signed prescriptions; doctors don’t leave clinic without signing some!
INITIAL DATA

TRAININGS BEFORE STRUCTURAL CHANGE

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WHERE DID WE SUCCEED, WHERE DID WE NOT

- Increase in number of participants trained
- Increase in number of participants trained who turned down training
- Training and naloxone distribution an add on in all suboxone sessions
- Training & naloxone distribution add on in clinic sessions w/ Nurse Coordinator
- Training & naloxone distribution add on in all nursing education sessions
- All staff trained, 80% of staff conducting trainings
- Training & naloxone distribution becoming add on in case management
- Training & naloxone distribution becoming add on in ID clinic
- Trainings every day, all settings
- People coming in to report reversals!
- Five fold increase in trainings in second six month period

- Some staff still not training; training not truly add on to all services
- Many clinicians still not training and giving medication in medical visit
- Missed opportunities in all services
- Only two consistent clinic staff conducting trainings and one is coordinator
DISCUSSION/QUESTIONS AND ANSWERS

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HCV ACCESS TO CARE

HepCAP and beyond

Treatment Updates

• Harvoni© (Ledipasvir/ Sofosbuvir) approved 10/10/14 for GT1
  • Treatment-naïve without cirrhosis with pretreatment HCV RNA < 6 million IU/mL: can consider 8 weeks
  • Treatment-naïve with or without cirrhosis: 12 weeks
  • Treatment-experienced without cirrhosis: 12 weeks
  • Treatment-experienced with cirrhosis: 24 weeks

• Minimal side effects ~15%
  • Fatigue, Headache
Integrated Efficacy Analysis of Four Phase 3 Studies in HCV GT 1a Patients Treated with ABT-450/r + Ombitasvir + Dasabuvir + RBV

- Pooled data from 4 phase 3 clinical trials
  - 3D regimen + RBV in treatment-naive and prior PEG/RBV treated patients with or without cirrhosis
  - Analysis limited to genotype 1a

Non-Cirrhotic GT1a

- 3DAA + RBV improved SVR compared to 3D
- Low rates of RBV dose reduction

![Graphs showing SVR rates for non-cirrhotic patients](image1)

Cirrhotic GT1a

- 3DAA + RBV for 12 or 24 wks achieved generally similar, high rates of SVR
- Numerically higher SVR with 24 wks among cirrhotic prior null responders

![Graphs showing SVR rates for cirrhotic patients](image2)

Evanston, Abstr #E3

SVR12 Rate of 98.6% in 992 HCV Genotype 1b patients treated with ABT-450/r/Ombitasvir + Dasabuvir With or Without Ribavirin

- Pooled analysis of phase 3 trials restricted to patients with GT 1b (Naive and experienced)
- Non-cirrhotics treated with 12 wks of 3D or 3D + RBV
- Cirrhotics treated with 12 or 24 weeks of 3D + RBV

Non-cirrhotics: No impact of RBV treated for 12 wks w/ 3D regimen

![Graphs showing SVR rates for non-cirrhotic patients treated with 3D and RBV](image3)

Cirrhosis: No impact of extended duration treated with 3D + RBV

![Graphs showing SVR rates for cirrhotic patients treated with 3D and RBV](image4)

Colombo, Abstr #1931
Current Challenges in HCV Care

• Cost of drugs
  • Sofosbuvir + IFN + Ribavirin x 12 weeks: $94,245
  • Sofosbuvir + Ribavirin x 24 weeks: $169,980
  • Simeprevir 12 wks+ IFN/ Ribavirin x 24 wks: $87,239
  • Sofosbuvir + Simeprevir x 12 weeks: $150,360
  • Harvoni x 8 weeks $63,000
  • Harvoni x 12 weeks $94,500
  • Harvoni x 24 weeks $189,000
  • AbbVie 3D regimen ?

• Disease burden: 3-5 million Americans living with HCV
  • But 50 to 75% don’t know it

http://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug
Ratchford, F. Gilead Sciences, Arlene Price, Janssen (Personal Communication)
www.fairpricingcoalition.org

AASLD/ IDSA Guidance: When and In Whom to Initiate Treatment

• Recent update: “Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons. Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. Urgent initiation of treatment is recommended for some patients, such as those with advanced fibrosis or compensated cirrhosis”.
  • “Treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C”

• Updated treatment guidelines expected early December
Current Challenges in HCV Care

- **Restrictive criteria for drug approval for most payers**
  - PA Medicaid MCOs are more restrictive with limited flexibility
    - Documented history of abstinence from alcohol and drugs for at least 6 months prior to treatment
    - Blood alcohol level and UDS to document abstinence: Methadone now considered + UDS
  - Metavir fibrosis score of F3 or F4: **Requirement for fibroscan or biopsy**
  - HIV no longer mitigating factor
  - **Criteria for Interferon-Ineligibility: Awaiting new guidelines**
    - “History of depression with suicidality or resulting in hospital admission and the recipient is currently receiving antidepressant therapy”

- **Other states seeing similar restrictions…**
  - **AL, CT, DE, LA, OR:** F4
  - **IL:** F3/F4; 12-month abstinence; non-FDA approved treatments barred
    - “Spending on hepatitis C treatment dropped from $1 million per week to about $200,000 per week after the department adopted the restrictions”
  - **IA, FL, GA, MN, MT, NE, NV, SD, VI:** Won’t make prior authorization policies until spring 2015; some allowing drug on case-by-case basis
    - Waiting for pharmacy and therapeutics committees or drug utilization review boards to convene again; these committees only meet a few times/yr

- **While a few states are less restrictive…**
  - **MA:** No Metavir score required; no overarching abstinence rules; tx not limited to specialists
    - May get more restrictive
  - **NY:** FibroSure results accepted in addition to biopsy or Fibroscan; no overarching abstinence rules; PCPs can treat
When insurance will not cover drugs what are the options?

- Wait for new drugs to be approved
  - ? price competition, can Medicaid even afford to take advantage
  - No guarantee that those will be covered/ patient will qualify
- Wait until patient qualifies
  - Sobriety
  - Worsening fibrosis
- Take legal action
- Apply to patient assistance programs to obtain free drug
  - Financial information to qualify
  - Proof that patient does not qualify for insurance
  - Challenging to navigate

The Plan

- Part time Public Affairs personnel
  - Connected through the Health Federation
- Treatment advocacy- Political Consulting/ Lobbying Firm
  - Pennsylvania advocacy strategy
  - National Advocacy in collaboration with National Viral Hepatitis Roundtable
- AIDS Law Project, private law firms