NASTAD ANNUAL MEETING 2024

Leveraging the HIV response for Hepatitis C: Envisioning Rapid Start for Hepatitis C

May 21, 2024

4:30 – 5:45 PM

Format

- Introductions and level setting by Isabel Lechuga, Associate Director, Hepatitis
- Overview of NASTAD-led work on HIV rapid start by Tim Horn, Director, Medication Access
- Discussion with panelists moderated by Thaddeus Pham
- Q&A with attendees

Components of the National Initiative on Hepatitis C

1) Point-Of-Care (POC) diagnostic tests

- Enable hepatitis C **single-visit "test and treat" programs**
- Obtain FDA approval of fingerstick test already in use in Australia and Europe
- Longer term goal: HCV/HBV/HIV multiplex POC test

2) Provide broad access to curative hepatitis C medications

- **National subscription "Netflix" model** (successfully piloted in Louisiana)
- Fixed sum for drug access negotiated by the US Government
- Drugs then provided for free to Medicaid, uninsured, incarcerated, opioid treatment programs, Native American reservations

3) Empower health care delivery

- **Expand screening settings for high-risk populations**, including prisons
- Employ innovative telehealth methods, mobile units
- Expand number of community health workers
- Re-energize vaccine research

Source: Dr. Francis S. Collins, MD, PhD - A National Initiative to Eliminate Hepatitis C in the United States, TAGHCV Elimination among People Living with and at Risk of HIV: Challenges and Possibilities. Oct 2023

Opportunities for CDC and Health Departments to Work together to Advance Hepatitis C Elimination

Prevention

- Develop a perinatal testing and prevention/treatment program building from the Perinatal Hepatitis B Prevention Program

Outreach and Clinical Care

- Increase core hepatitis C funding to jurisdictions for expanding testing, linkage, and treatment in high-impact settings

Tracking and Response

- Enhance outbreak detection and response in health departments and corrections
- Enhance surveillance capacity and translation into dashboards to monitor elimination progress

Source: CDC DVH call with PS21-2103 grantees, March 2024

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Analytic and clinical trial studies of a CLIA-waived POC HCV RNA test are underway.

CDC is working with the Independent Test Assessment Program (ITAP)

- Mid-2023: ITAP identified 1 manufacturer to move through the ITAP process
- Late 2023: Started independent laboratory testing, analytic studies, and clinical trial prep
- Early 2024: Launched clinical trials
- Summer 2024: Anticipated completion of analytic and clinical trial studies for FDA review

Source: Federal Register Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment, April 2024

Envisioning a Same Day Test and Treat Approach for Hepatitis C

POC HCV RNA testing opens the possibility of same-day test and treat.

One-Stop Shop

<u>Remaining Barriers</u>

- Lack of POC HBsAg diagnostics to rule out HCV/HBV co-infection
  - Several POC HBsAg tests exist outside of the U.S.
  - FDA has signaled HBV downclassification to Class II eminent

- Simplified guidelines still require lots of labs and visits
  - The AASLD/IDSA Guidelines Group is working on same-day hepatitis C treatment guidance

Source: Federal Register Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment, April 2024

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Rapid HIV Treatment Initiation: Considerations for Viral Hepatitis Programs

Tim Horn
Director, Medication Access
NASTAD

HIV Rapid Start

- Evidence-based intervention whereby antiretroviral therapy (ART) is initiated on the day of HIV diagnosis – or as soon as possible – in association with an individual's readiness to begin HIV treatment
- Also applies to rapid (re-)initiation of ART in associated with relinkage to care
- HIV systems of testing, linkage, application and enrollment in relevant programs, and treatment initiation all must be tailored to be low barrier

1. Pilcher, et al. J Acquir Immune Defic Syndr. 2017 Jan1;74(1):44-51.
   Ford, et al. AIDS. 2018 Jan 2;32(1):17-23.
2. Colasanti, et al. Open Forum Infect Dis. 2018 Jun 28;5(6):ofy104.
3. Bacon, et al. Clin Infect Dis. 2021 Jul 1;73(1):e122-e128.

Rationale

- In clinic-based studies in U.S. and RCTs in resource-limited settings, immediate ART initiation has been shown to reduce time to care linkage and VL suppression
    - Improvements in LT care engagement and VL suppression is not yet known
- Rapid ART initiation may bring earlier benefits in personal health, and earlier reductions in the risk of onward transmission of HIV (U=U)
- For persons with acute infection, immediate ART may limit the HIV viral reservoir
- Initiating ART on first clinic visit after diagnosis has become standard of care in a number of clinics and jurisdictions

HHS HIV Treatment Guidelines

"the Panel … recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV."

HRSA HAB PCN 21-02

Recipients encouraged to "…develop protocols to facilitate the rapid delivery of RWHAP services, including the provision of antiretrovirals for those newly diagnosed or re-engaged in care."

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.* Department of Health and Human Services.
2. HRSA HAB. *Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program*. Policy Clarification Notice 21-02.

Components of HIV Rapid Start

Step 1: HIV testing
Step 2: Linkage from testing program to care and treatment
Step 3: Education/counseling on ART
Step 4: Accelerated access to medical visit
Step 5: Early access to ART
Step 6: Assessment for and linkage to programs and assistance, including public and private insurance, RWHAP services (including ADAP) and other supportive services

HIV Rapid Start Funding Sources		
Funding Source	**Allowable Services**	**Eligibility**
RWHAP Parts A, B, C, D (non-EHE; non-ADAP)	RWHAP service categories: Early intervention services (EIS), medical and non-medical case management, outpatient/ambulatory health services (OAHS), adherence counseling, health insurance premium and cost-sharing assistance (HIP-CS)	HIV diagnosis, low-income, residency
RWHAP ADAP (non-EHE)	Full-pay medication for uninsured clients; insurance assistance for insured clients; "ADAP flex" can be used for medication adherence and monitoring services	HIV diagnosis, low-income, residency
RWHAP Part A (EHE)	Initiative Services and RWHAP service categories above	HIV diagnosis
RWHAP Part B/ADAP (EHE)	Initiative Services and RWHAP service categories above	HIV diagnosis
CDC HIV prevention (EHE and non-EHE)	HIV testing and counseling and linkage to care	No eligibility screening beyond service need

HIV Rapid Start Funding Sources – Continued		
Funding Source	**Allowable Services**	**Eligibility**
340B rebates (ADAP)	Rebates generated by federal RWHAP funds must be invested back into the same program with identical service categories/restrictions	If ADAP rebates are generated by federal RWHAP funds, RWHAP eligibility requirements apply
340B program income	Allowable services depend on if the program income is generated from RWHAP funds. Non-RWHAP 340B entities may have more flexibility to use program income more broadly across programs.	While program income generated from RWHAP funding must be invested back into the program, following the same eligibility rules, program income generated from other funding streams may have more flexibility, including to expand eligibility criteria beyond RWHAP
State/local funding	Allowable services depend on funder	Eligibility requirements depends on funder
Manufacturer assistance programs	ART approved for Rapid Start	Income criteria
ART samples	Limited number of ART medications	No eligibility for patients, but some providers may prohibit acquiring and/or dispensing samples

Scope	Las Vegas (RWHAP Part A Transitional Grant Area)
Funding	RWHAP Part A EHE funding is being used to fund EIS, OAHS, HIP-CS and Medical Transportation for Rapid Start. HRSA EHE funding for mental health and psychosocial services for newly diagnosed individuals. EHE funding also being used to support a Rapid Start Response Team charged with fielding calls from testing sites, providers, and pharmacies supporting linkage efforts; and linking newly diagnosed individuals from testing sites to clinical care and other supportive services. Agencies doing Rapid Start typically use a blend of funding that may also include 340B program income.
Eligibility/Application Process	The program operates on an assumption that some clients are not ready to go through RWHAP application upon initiating care and treatment, and the EHE Rapid Start program allows those clients to initiate treatment before completing a full application and eligibility determination. The Rapid Start program uses a two-page truncated application.
Medication procurement	RWHAP Part A EHE funding is not being used to cover medication costs. Each clinic is procuring Rapid Start medication via samples, PAPs, or 340B discount.
Goal for time to ART	Same day or within 7 calendar days of diagnosis
Provider network	RWHAP Part A subrecipients and expanding to other providers serving underserved populations in the area. The Rapid Start Response Team is charged with building Rapid Start provider capacity and expanding the Rapid Start provider network.
Transition from Rapid Start	The program focuses on transitioning clients to sustainable coverage options within 90 days, using a trauma-informed approach to client readiness.

Scope	Louisiana Statewide
Funding	The ADAP Rapid Start program provides a limited and relatively small safety net payer source for medication and complements other clinic and/or RWHAP Part A supported Rapid Start activities in the state. ADAP uses unrestricted program income dollars generated from the state's PrEP program for individuals discovered to be ineligible after dispensation of medicines, and Medicaid back-billing for the subset that is Medicaid eligible.
Eligibility/Application Process	The ADAP uses a streamlined rapid eligibility application with expedited review and approval (the aim is for four hours). The form relies on self-attestation of income and residency.
Medication procurement	RWHAP Part B/ADAP is funding medication access and the state's PBM flags all Rapid Start claims so that if manual reassignment is necessary, they may be to be paid with non-federal funding. Clients are then required to use ADAP's pharmacy network for access or mail order or pick-up via the central pharmacy.
Goal for time to ART	Seven days for rural areas, much less for urban centers.
Provider network	The provider network mirrors the existing RWHAP network. The state hopes to expand the model to rural areas using a network of parish health units with telemedicine capacity.
Transition from Rapid Start	The Rapid Start expedited application provides 30 days of eligibility as RWHAP providers work to link clients to sustainable coverage options.

Rapid Start Opportunities and Challenges

FACTOR	HIV	HCV
Confirmatory diagnostic testing required	NO	YES
Hepatitis B infection marker testing required	NO	YES
Inclusion in evidence-based practice guidelines	YES	NO
Inclusion in WH/HHS national strategies	YES	Proposed
Federal funds can be used to purchase medications	HRSA: YES	CDC: NO
Manufacturer ART/DAA samples	YES	NO
Rapid start regimen selection considerations	YES	NO*
Rapid PAP enrollment	YES	?

*Patients with compensated cirrhosis and HCV GT3 require baseline NS5A RAS testing if selecting sofosbuvir/velpatasvir

Thank You!

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Discussion

- What infrastructure already exists within your program that can be leveraged for rapid start in your jurisdiction? Thinking about relationships with providers, linkage to care, patient navigation, etc.
- What components from your jurisdiction's HIV program do you think you can leverage?
- What are some of the key challenges you foresee that can possibly be addressed by federal partners, health department leadership and community partners?
- What are some key settings where you think implementing rapid start for HCV treatment would be the easiest to implement? What are some settings that may prove difficult to implement rapid start but would have the greatest reward? How would you navigate these challenges?
- What about hepatitis B?