



www.hepbtaskforce.org

Meeting Notes

Date: Wednesday, March 2, 2022 (every 1st Wednesday of the month)

Time: 3PM ET / 2PM CT / 1PM MT / 12PM PT / 10 AM Hawaii

Email: administrator@hepbtaskforce.org

Zoom Meeting registration link: <https://us02web.zoom.us/meeting/register/tZwkcumtrTwqE9RkoJ1dyu9n7DUuTWD6mSvf>

Attendance (at or after 3:05PM) are as follows:

Executive Board Members (Officers):

- Co-Chair: Carol Brosgart, MD** (San Francisco, CA)
- Co-Chair: Richard So, MPH**, Executive Director, SF Hep B Free – Bay Area (San Francisco, CA)
- Secretary: Catherine Freeland, MPH**, Public Health Program Director, Hepatitis B Foundation (Doylestown, PA)
- Administrator (and notetaker): Amy Trang, PhD, MEd**, Founder and CEO, Social Capital Solutions (Chantilly, VA)

Regional Directors:

- Northeast Regional Director: Ruth Brogden, MPH**, Grants Manager, Center for Asian Health at Saint Barnabas Medical Center (Livingston, NJ)
- Mid-Atlantic Regional Director: Kate Lu, MSW, LCSW-C**, Clinic Director, CCACC-Pan Asian Volunteer Health Clinic (Gaithersburg, MD)
- Southeast Regional Director: Christina Meyers, MPH**, ORISE Fellow, CDC Division of Overdose Prevention (Atlanta, GA)
- Midwest Regional Director: Oyu Tumurtuya, PharmD**, Founder & President, Mongolian Community Health Network (Chicago, IL)
- South Midwest Regional Director: Stephen Fakoyejo, MD, MPH** Medical Resident, HCA Houston Healthcare West (Houston, TX)
- Western Regional Director: Thaddeus Pham**, Viral Hepatitis Prevention Coordinator, Hawaii State Department of Health (Honolulu, HI)

Student Representation

- Sandra Kong**, Medical Student at Johns Hopkins University (Baltimore, MD)

Board Advisors:

- Richard Andrews, MD, MPH, Board Advisor (Houston, TX)
- Moon Chen, PHD, MPH, Board Advisor (UC Davis; Sacramento, CA)
- Chari Cohen, DrPH, MPH, Board Advisor (Hep B Foundation; Doylestown, PA)
- Robert Gish, MD, Board Advisor (Robert G. Gish Consultants; San Diego, CA)
- Lu-yu Hwang, MD, Board Advisory (Department of Epidemiology, University of Texas HSC; Houston, TX)
- Karen Jiobu, Board Advisor (Asian American Community Services; Columbus, OH)
- Amy Tang, MD, Board Advisor (North East Medical Services; San Francisco, CA)

General Members (open to all on listserv; please excuse any typos): Total Number of attendees: 21

- Binh Tran, PharmD, APHF and Hep Free LA (Los Angeles, CA)
- Nancy Fenlon, Hepatitis B Prevention Coordinator, CDC (Atlanta, GA)
- Maggi Li, Hepatitis B Program Coordinator, MAHA (Chicago, IL)
- Rosie Glenn-Finer, Epidemiologist, CA Department of Public Health
- Umaimah Khatun, Program Manager, NYC Health Department (New York, NY)
- Mutasem Shopon, Health Program Coordinator, CPACS (Atlanta, GA)
- Soo Yee, Korean American Outreach Group (Fairfax, VA)
- Dung Hua, Vietnamese American Cancer Foundation (Fountain Valley, CA)
- Mick Del Rosario, SF Hep B Free (San Francisco, CA)
- Bill Harbester, Syneos Health/ VBI Vaccines (Cambridge, MA)
- Kendra Pelz, Syneos Health / VBI Vaccines (Cambridge, MA)
- Thomas Rolain, Syneos Health /VBI Vaccines (Cambridge, MA)

Note: There may be some members missing from this list of attendees; please excuse any omission.

Agenda:

- 1) Welcome Task Force members (Richard So and Catherine Freeland)
- 2) Note any changes to previous meeting's notes
- 3) Project updates:
 - a. HBV universal vaccination guidance promotion among providers
 - b. HBV ECHO program expansion
 - c. HBV workforce development projects
 - d. HBV elimination plan best practices among state Viral Hepatitis Coordinators
 - e. HBV work group on updating screening guidance
 - f. Upcoming trainings or resources
- 4) Action Plan discussion: Next steps?
- 5) Regional Updates (all Regional Directors)
- 6) Other items (all members)

Meeting format:

- strategic discussions and resource sharing to assist members with their local work

Notes:

- 1) Welcome: Introduction / Roll Call of Officers and Regional Directors (Amy Trang)

- a) Opening remarks made by Richard So and Catherine Freeland
- b) Members were asked to introduce themselves in the chat box
- c) Recognize any new members on the call: see list of attendees above

- 2) Note any changes to previous meeting's notes:

There was a "Typo" in Regional Updates for the Western Region. Correction is noted in red; the text should have read:

*Hawaii is working on submitting testimonies for HB1677, a bill aimed at defining "clinical laboratory director" to include certain physicians, licensed laboratory scientists, and pharmacists-in-charge of pharmacies. It amends the definition of "practice of pharmacy" to include the ordering **or** performing of certain Clinical Laboratory Improvement Amendments waived tests.*

- 3) Project Updates

- a) HBV universal vaccination guidance promotion among providers (Catherine Freeland)
 - i) Hep B Foundation has been taking the lead with rolling out a campaign for HBV universal vaccination guidance. Things to be on the lookout for:
 - MMWR publication around March 25th
 - Webinars with CDC and HHS
 - April 25th webinar (Hep B United and NASTAD co-organizers) for April 30th National Hep B Vax Awareness Day; will discuss MMWR roll out and HBV vaccine survey findings
 - Hepatitis B Foundation is developing materials (fact sheets, etc.) and a toolkit to share around April 30th
 - We'll share more at the next Task Force meeting and via email / website when the information and resources become available.

- b) HBV ECHO program expansion (Dr. Richard Andrews, Richard So, Catherine Freeland, and Thaddeus Pham)
 - i) Thaddeus shared updates on the progress of Hawaii's ECHO program planning
 - (1) Survey for comments / suggestions on Hawai'i HBV ECHO open until March 7:
<https://forms.office.com/g/Dc51BBTMD6>
 - (2) Hawaii plans to launch the HBV ECHO program in September this year.
 - ii) West Coast Hub is going strong; Richard is still exploring how to engage other providers outside of the Bay Area to participate since the timing has been challenging for some. Lots of case studies and presenters lined up so far.
 - iii) East Coast Hub in Philly is also going strong with content already full for the year.
 - iv) No Gulf Coast Hub (Texas) session for March; will resume in April.
 - v) Dr. Andrews shared best practices on engaging residents and getting them to submit case studies even if they might not be able to present because of schedule conflicts.
 - (1) At the last HBV ECHO session in Texas, Dr. Andrews presented on behalf of a resident and took notes from experts on the call so he could share those suggestions with the resident.
 - (2) Dr. Andrews suggested for other hubs to reach out to places that have residency programs that may be already serving hepatitis B patients.
 - (3) Catherine commented that they have utilized a similar approach in Philadelphia, and it has worked well.
 - (4) Richard So will look into it. He also mentioned that they have been offering \$50 gift cards for people who present cases, but it hasn't been needed as a motivating factor for many people.
 - vi) Dr. Richard Andrews and Amy Trang are reaching out to Nadine Shiroma in Seattle, WA to explore ways to collaborate with her sites' viral hepatitis ECHO program. Dr. Andrews noted that they have historically had more HCV cases presented. We will explore how the Task Force could assist with building the HBV component of the program. This would be true for other sites who have other types of ECHO disease focus; we would explore how they could do at least one session in a year with a HBV focus for their local area.
- c) HBV workforce development projects (Sandra Kong and Thaddeus)
 - i) Sandra Kong, Thaddeus Pham, and Amy Trang met offline to discuss what mentors could offer for students. The draft survey can be found here: <https://forms.gle/SMv3kXgEiMrQ8CgL7>. We welcome any feedback on the questions!
 - ii) We'll plan to circulate the survey by end of March / early April.
- d) HBV elimination plan best practices among state Viral Hepatitis Coordinators (Amy Trang and Thaddeus Pham)
 - i) Amy Trang is actively involved with the Maryland Viral Hepatitis Elimination Plan with the Maryland Department of Health – Center for Viral Hepatitis; their goal is to have it completed by World Hepatitis Day on July 28, 2022.
 - ii) Amy Trang has also attended the planning sessions coordinated by the Virginia Hepatitis Coalition for the Virginia Viral Hepatitis Elimination Plan.
 - iii) Thaddeus shared in the chat box Hawai'i's ongoing elimination efforts, check out: <https://www.hepfreehawaii.org/hep-free-2030>
 - iv) Thaddeus has also been mentoring the Utah Hepatitis Coalition, which is starting to work on elimination planning as well: <https://www.hepfreeutah.org>
- e) HBV work group on updating screening guidance (Dr. Richard Andrews and Richard So)
 - i) SF Hep B Free is looking into funding from Gilead for their programs this year, which includes possibly organizing a work group for the HBV screening guidance; these are currently just ideas.
 - ii) Amy Trang confirmed that whoever takes on the initiative could use the National Task Force website to host the resources. The Task Force can also provide technical assistance in facilitating the workgroup meetings.
 - iii) Dr. Gish also mentioned that AASLD is looking into updating guidelines too to also include Delta guidelines.

- f) Upcoming trainings or resources (Amy Trang)
- i) 3/17/2022 (Thursday) at 3PM Eastern Time: Viral Hepatitis Policy and Advocacy Summit – kickoff. This session will feature a discussion around the intersections of stigma, racism, and access to viral hepatitis services from a community and federal perspective. Please find panelists listed in the registration link here: https://us02web.zoom.us/webinar/register/WN_bAqJVnpOQ7214OwT4chr9w. Other upcoming sessions:
 - (a) Hepatitis & Maternal/Child Health – *Thursday, March 24*
 - (b) Hepatitis & the Opioid Epidemic - *Week of March 28*
 - (c) Federal Leadership & Congressional Advocacy – *Week of April 4*
 - ii) Upcoming webinars:
 - (1) 3/17, 9am ET – Hep B Birth Dose in Nigeria
Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_Obe7B9SeTvGPYYOXIjhASQ
 - (2) 3/17, 3pm ET - Hepatitis and Health Equity Micro-Summit; see above in item “i”
 - (3) 3/23, 3pm ET – Hep B and Liver Cancer Disparities Webinar (no link yet)
 - (4) Others:
 - (a) April TBD, South Asian Hepatitis B Disparities (no link yet)
 - (b) May 5, 3pm ET – Management of Hepatitis B in Pregnancy and Postpartum (no link yet)
 - (5) Note from Thaddeus in chat box: We put local events and HBU events at <https://www.hepfreehawaii.org/events>
 - iii) The Hepatitis B Foundation and Hep B United have created a new patient-focused fact sheet on the co-administration of the COVID-19 vaccine with the hepatitis A, hepatitis B, or Flu vaccines. Please find the fact sheet attached, or here: http://www.hepbunited.org/assets/d1c963529a/COVID-19-Co-Administration-HepB_A-v2-01.06.2022.pdf
- 4) Action Plan discussion: Next steps?
- a) Finalize survey for Workforce Development planning group and disseminate among Task Force members to seek mentors for students.
 - b) Follow-up on MMWR information to share with Task Force members.
 - c) Dr. Richard and Amy Trang will follow-up with Nadine to discuss how to involve the Seattle Viral Hepatitis ECHO program.
- 5) Regional Updates
- a) Student Representative (Sandra Kong): provided above in Workforce Development project discussion.
 - b) Western Region (Thaddeus Pham):
 - i) Dr. Binh Tran shared on behalf of the Asian Pacific Health Foundation (APHF):
 - (1) They will be having an event with Medical Education Missions Outreach (MEMO) this coming Saturday, March 5th; the last event with MEMO was in January 2020 (right before the COVID-19 pandemic began).
 - (2) They will be partnering with the Lions Club on Saturday, March 19th for a Vision Screening and Health Clinic event (flyer attached).
 - (3) Also, APhF is currently looking for a new Executive Director since Dr. Kayla Giang has stepped down. This position will start as a volunteer position until additional funding is secured by the new Executive Director. The ideal candidate should be from Southern California so she / he could be actively engaged with the community (job posting attached).
 - ii) Richard also shared that locally in the Bay area, they will be doing a presentation with the Silicon Vally Cyber Lions group. They are interested in actively promoting HBV vaccination; more details and planning need to be discussed. Also, Richard is looking to find ways to promote AB 789; Amy and Richard will discuss offline how this could be incorporated as a dedicated page on the National Task Force on Hepatitis B website.

- iii) Hawaii has a hep B VX talk story on March 16 at 12 pm HST; register: <https://forms.office.com/g/crbnPC9rd9>
 - iv) Dr. Gish has shared two sets of slide decks. This was from a meeting he had this week with CDC; Dr. Gish presented information on hepatitis C rapid testing; the other is on hepatitis Delta.
 - (1) Thaddeus asked Dr. Gish about CTP codes, reflex testing hepatitis, and dried blood spot testing because there's been a lot of movement around it for hep C RNA.
 - (2) See attached presentation slides.
 - c) Midwest Region (Oyu Tumurtuya):
 - i) Maggie Li shared that things are operating as usual at MAHA; they are still screening and testing patients and linking them to care / treatment services as well as HBV vaccinations.
 - d) South Midwest Region (Stephen Fakoyejo): provided above with HBV ECHO program updates.
 - e) Northeast Region (Ruth Brogden): Ruth emailed to confirm no new updates.
 - i) We will continue the discussion about the automated screening process in May when Ruth can attend the call; this will help us strategize how to get more providers to screen and test for HBV before getting them vaccinated.
 - f) Mid-Atlantic Region (Kate Lu):
 - i) Soo provided updates on working with college students for HBV education; it's been a bit challenging and slow because the student groups have not yet fully resumed on-campus gatherings and activities.
 - ii) CCACC Health Center is still actively assisting its community members with COVID-19 vaccination; they are still doing HBV vaccination, but numbers are still low.
 - iii) Amy will work with HBI-DC and CCACC Health Center to brainstorm ideas on how to roll out a HBV vaccination campaign in the Washington DC metropolitan area that leverages the ACIP recommendation for adult vaccination.
 - g) Southeast Region (Christina Meyers): Christina emailed to confirm no new updates.
 - i) Mutasem shared that CPACS is still actively looking for funding opportunities for HBV activities.
 - (1) Amy Trang offered to connect with Mutasem and his team offline to share some best practices from other Task Force members in the past on how they leveraged opportunities to seek support for HBV activities.
 - h) In closing, Dr. Carol Brosgart and Richard So thanked everyone for all their hard work in their respected areas and how important it is to continue sharing their activities as it relates to our strategic objectives, so everyone has resources to access and leverage, especially given the limited funding for hepatitis B. They also reminded everyone that we have this great window of opportunity for hepatitis B and need to keep the momentum going across the country.
- 6) Other items: (not discussed in the meeting)
- a) The National Task Force on Hepatitis B still does not have any new source of funding or support for 2022 activities; all initiatives are currently on a voluntary basis by all members.

Meeting adjourned at 4:00PM Eastern Time.

- Next Hep B Task Force Zoom meeting date: **Wednesday, April 6, 2022 at 3PM Eastern Time /2PM Central /1PM Mountain/ 12PM Pacific / 10 AM Hawaii (1st Wednesday of each month).**
 - Other dates in 2022: May 4, Jun 1, (no regular meetings in Jul and Aug), Sep 7, Oct 5, Nov 2, Dec 7
- Suggestions for the next agenda:
 - i) Follow-up on Action Plan discussed and progress of provider outreach efforts.

Upcoming HBV ECHO sessions: Free CME

West Coast (SF Hep B Free Bay Area): [Hepatitis B ECHO Program \(sfhepbfree.org\)](https://sfhepbfree.org)

- Every 3rd Tuesday of the month
 - 2022: Mar 15, Apr 19, May 17, Jun 21, Jul 19, Aug 16, Sep 20, Oct 18, Nov 15
- 12:30PM – 1:30PM PDT / 3:30PM – 4:30PM EDT / 9:30AM – 10:30AM HST
- To register, email: ECHO@sfhepbfree-bayarea.org

Gulf Coast (Texas Heart Institute with Baylor St. Luke Medical Center): [Project ECHO Interest Form \(bcm.edu\)](#)

- 3rd Wednesday of the month
 - 2022: Apr 20, May 18, Jun 22, Jul 20, Aug 17, Sep 21, Oct 19, Nov 16
- 12:00PM to 1:00PM Central Time
- To register: [Project ECHO Interest Form \(bcm.edu\)](#)

East Coast (Hep B United Philadelphia): Hepatitis B ECHO [Meeting Registration - Zoom](#)

- Every 4th Thursday of the month
 - 2022: Mar 24, Apr 28, May 26, Jun 23, Jul 28, Aug 25, Sep 22, Oct 27
- 12:00PM – 1:00PM Eastern Time
- To register: [Meeting Registration - Zoom](#)

Items shared via email:

Monthly Hepatitis B State Advocacy Call
2nd Tuesday of the Month

Upcoming Meetings

March 8, 2022 - 3pm EST / 2pm CST / 12pm PST / 10am HST

April 12, 2022 - 3pm EDT / 2pm CDT / 12pm PDT / 9am HDT

Register

Join us for our new monthly call series for Hep B United coalition partners, patients, providers, and other community advocates who are interested in organizing or are currently involved in hepatitis B advocacy in their state. These monthly calls aim to provide a space to share updates, exchange resources, get feedback on ideas, discuss challenges/barriers, connect with other advocates, and help identify opportunities for hepatitis B state advocacy across the U.S. We will also reserve time on these calls to highlight case studies/examples of hepatitis B state advocacy wins or to present on specific policy issues that may be addressed at the state or local level.

Topics at our upcoming meetings in March and April will include:

- state budget/appropriations advocacy
- state implementation of ACIP's updated adult HBV vaccination recommendation and 317 funding advocacy
- requesting state/local proclamations/resolutions for Hepatitis Awareness Month
- updates/additions to new state advocacy resource page

The Centers for Disease Control and Prevention (CDC) recommends that **COVID-19 vaccines** and other vaccines can be given on the same day.

Background

While you are thinking about COVID-19 vaccination, it may be a good time to talk to your doctor or pharmacist about other routine vaccinations recommended by the CDC, such as **hepatitis A, hepatitis B, or flu**, to protect you from other viruses that can cause sickness and hospitalization.

You can receive a COVID-19 vaccine and other vaccines at the same time. Learn more about coadministration with other vaccines or view the CDC's COVID-19 vaccine information portal here: <https://bit.ly/COVIDcoadministration>

Hepatitis A Vaccine

Hepatitis A is a highly infectious liver disease that can be spread person-to-person or through contaminated food or drink. While it usually causes a short-term illness (6 months or less), symptoms can be unpleasant and often result in hospitalization, or even death in some cases. **The best protection against hepatitis A is vaccination.**

The CDC recommends vaccination for people who are at an increased risk of exposure, including international travelers, men who have sex with men, people who use drugs or experience homelessness, people with chronic liver disease, pregnant women, and anyone who requests vaccination.

Hepatitis B Vaccine

Hepatitis B is an infection of the liver that is spread through direct contact with infected blood or bodily fluids. It can be transmitted via an infected woman to her newborn during childbirth, unprotected sex, unsterile, or contaminated needles. Hepatitis B often has no symptoms.

The hepatitis B vaccine is recommended for all adults aged 19-59. Adults 60 and older are recommended to follow risk-based guidelines to determine if they should receive the vaccine. Most adults over the age of 30 in the U.S. have not been vaccinated for hepatitis B.

You cannot get hepatitis B from the vaccine. Current hepatitis B vaccines are made synthetically – meaning the hepatitis B vaccines do not contain any blood products.


Flu Vaccine


Influenza (flu) is a potentially serious disease that can lead to hospitalization and sometimes even death. Seasonal flu vaccines are designed to protect against the influenza viruses that research indicates will be most common during the upcoming season.

The CDC recommends annual flu vaccination for everyone 6 months and older with any licensed flu vaccine that is appropriate for the recipient's age and health status. There are many vaccine options to choose from, but the most important thing is to get a flu vaccine every year.

Use the vaccine schedules below to mark the date for your next dose! There is no vaccine schedule for the flu because it is an annual one-dose vaccine. Check with your provider to find the best time for you to get the flu vaccine.

All of the vaccines are considered to be safe and highly effective.

 U.S. Adult Hepatitis A Vaccine Schedules <i>Please note that the entire vaccine series (2-or 3-doses) must be completed for full protection.</i>			
Vaccine	Dose 1	Dose 2	Dose 3
3-dose vaccine series Brand name: Twinrix (hepatitis A and B combination vaccine)	Now	1 month after dose 1	6 months after dose 1
2-dose vaccine series Brand names: Havrix or Vaqta	Now	① 6-12 months after dose 1 ② 6-18 months after dose 1	
Key	① Havrix ② Vaqta		

 U.S. Adult Hepatitis B Vaccine Schedules <i>Please note that the entire vaccine series (2-or 3-doses) must be completed for full protection.</i>			
Vaccine	Dose 1	Dose 2	Dose 3
3-dose vaccine series Brand names: Engerix-B, Recombivax HB, PreHevbrio Twinrix (hepatitis A and B combination vaccine)	Now	1 month after dose 1	6 months after dose 1
2-dose vaccine series Adults ≥ 18 Years Brand name: Heplisav-B	Now	1 month after dose 1	

Reducing Hepatitis B infection in Nigeria:



A CASE FOR IMPROVING TIMELY HEPATITIS B BIRTH DOSE VACCINATION

Nigeria faces one of the highest burdens of HBV prevalence of 20% and accounts for 8.3% of the global burden of disease. In efforts to promote hepatitis B prevention through timely birth dose, the Hepatitis B Foundation invites you to attend a webinar on March 17th at 9 AM Eastern Time, 3 PM West Africa Time.

17 MARCH 2022; 9 AM-10 AM EST / 3 PM-4 PM WAT

Special Guests



HON. DR. YUSUF SUNUNU

Chairman of House
Committee on Health Services
Federal House of
Representatives, Nigeria



HON. BENJAMIN O. KALU

Spokesperson, House of
Representatives and Chairman,
Media and Public Affairs, Federal
House of Representatives, Nigeria

Presenters



DR. EMEKA NWACHUKWU

University of Texas Health
Science Center at Houston
(UTHealth) and Office of
Population & Reproductive
Health, USAID/Washington DC



DR. FLORENCE KANU

Lieutenant, U.S. Public Health
Service and Epidemiologist,
Hepatitis B and Tetanus Team,
Global Immunization Division,
U.S. Centers for Disease Control
and Prevention

Convener



CATHERINE FREELAND

Public Health Program
Director
Hepatitis B Foundation



DANJUMA ADDA

President, World Hepatitis
Alliance (WHA) UK Executive
Director, CFID Taraba and
Chagro-Care Trust, Nigeria

REGISTRATION:
[HTTPS://BIT.LY/3IBEVWL](https://bit.ly/3IBEVWL)



LIONS CLUBS INTERNATIONAL DISTRICT 4-L6



Vision Screening and Health Clinic

Recycle Your Eye Glasses

One Day Event COLLECTION

Saturday, March 19, 2022

9:00 AM to 1:00 PM

Host:

Lions Clubs 4-L6

Mira Mesa Senior Center

Participating Clubs & Friends

- San Diego Executive Lions Club
- San Diego United Lions Club
- San Diego TFC Lions Club
- San Diego Vietnamese-American Lions Club
- San Diego Majestic Lions Club
- San Diego Stars Lions Club
- San Diego Roaring Lions Club
- San Diego Cosmopolitan Lions Club
- Chula Vista Visionaries Lions Club
- Imperial Beach Lions Club

FREE Pfizer Dose 1 or Dose 2 vaccine for kids 5-11 years old.

FREE Pfizer Booster for ages 12 years and older

RAPID Testing Available onsite.

We provide screening for:

- Glaucoma
- COVID Free-Vision screening for Children
- Hepatitis B & C
- Blood Pressure
- Blood Glucose (HbA1c), Cholesterol
- BMI (Body Mass Index) assessment
- SSA and SSI Information
- Tuberculosis/Latent TB Infection survey and education
- Vision Acuity
- FREE** reading glasses & eye drops



Ricardo Basila Sr.
Family Foundation



MIRA MESA
SENIOR CENTER

Mira Mesa Senior Center

8460 Mira Mesa Blvd
San Diego, CA 92126

www.miramesacenter.org

Contact Lions: Helen Quintanilla at lionhelenq@gmail.com or Donna Lee at donnamlee47@gmail.com
or Rose Tran at (858) 722-2185

Find more information at www.md4lions.org Facebook: <http://lionseyes.org>



Date: February 9, 2022

Position Opening for Executive Director

Asian Pacific Health Foundation (APHF), a non-profit health organization, is seeking a full-time Executive Director to oversee the health screening programs, and participate in the development of the organization while searching for funding opportunities.

The position is currently unfunded, and future funding of the position is depending on the new leader's ability to raise funds for APHF organization staff, operations, and screening activities. APHF is dedicated to excellence in education, service to the community, and research/scholarship through collaboration with UC San Diego Medical School and Skaggs School of Pharmacy on the students' summer research studies and year-long projects.

Working together with an outstanding team, the Executive Director will realize APHF's goal of raising awareness and screening populations at risk for hepatitis B and C with linkage to care, diabetes, hypertension, cholesterol disorders, and education on tuberculosis and latent tuberculosis infection.

Job Description

- Report and work closely with the APHF Board of Directors which includes Robert Gish, MD, Chairman and Medical Director to seek their involvement in policy and procedure decisions, fundraising, and increase the overall visibility of APHF
- Supervise APHF staff
- Conduct strategic planning and implementation
- Plan and operate annual budget
- Establish and maintain relationships with various organizations and utilize those relationships to strategically enhance APHF's mission
- Engage in fundraising and developing other revenues
- Establishing employment and administrative policies and procedures for all functions and for the day-to-day operation of the nonprofit
- Oversee marketing and other communications efforts
- Oversee organization Board and committee meetings
- Work with APHF director of research to develop and facilitate community/ research projects
- Review and approve contracts for services
- Serve as or identify APHF's primary spokesperson to the organization's constituents, the media and the general public
- Other duties as assigned by the Board of Directors

Desirable professional qualifications:

- A bachelor's degree or Advanced degree in a field relating to public policy, public health, public administration, advocacy, or similar field
- Background and experience in public health, health education, advocacy, public education, media relations, community development, political campaigns, and/or work with diverse ethnic and cultural populations
- Transparent and high integrity leadership
- Strong work ethics
- Experience in management of nonprofit organization
- Experience and skills in working with a Board of Directors
- Excellent written and verbal communication skills
- Strong public speaking ability
- Knowledge of social media and website communications
- Proven track record of fundraising, generating new revenue streams and improving financial results
- Experience in development and management of a yearly operational budget
- Demonstration of professionalism, interpersonal and leadership skills, and management abilities

After a 3-month training with the current staff, the full-time position is effective on **July 1, 2022.**

Salary: unpaid at this time but the salary can be drawn from grants if grants get approved. Strong incentives to be Executive Director include networking with and becoming a member of National and Regional Hepatitis Task force and Associations for policy changes, and participation in research work conducted by the team, with publication in peer-reviewed journals.

Please contact: Binh Tran, PharmD, MS, MBA at binh.tran@aphfsd.org, with a short bio and CV. Thank you.

Asian Pacific Health Foundation

9225 Dowdy Dr, Suite 209, San Diego, CA 92126. www.info@aphfsd.org

Hepatitis Delta Virus: Evaluation & Treatment

Robert Gish MD, FAASLD, AGAF, FAST

Robert G Gish Consultants LLC – Principal

Hepatitis B Foundation - Medical Director

Professor of Medicine:

Loma Linda University

University of Nevada Las Vegas

University of Nevada Reno

UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences



Disclosures

Please see www.robertgish.com

HDV Is the Most Severe Form of Viral Hepatitis



HEPATITIS A¹

RISK FOR
PROGRESSION TO
CHRONIC HEPATITIS

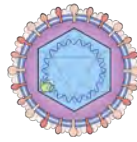


No, but can cause fatal fulminant hepatitis in a very small proportion

RISK FOR
CIRRHOSIS/HCC



No, as infection is generally short-lived



HEPATITIS B²



Adults: 5%
Children: 90%



20%-30% (lifetime)



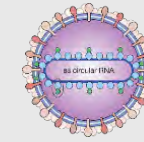
HEPATITIS C³



55%-85%



15%-30% (20 years)



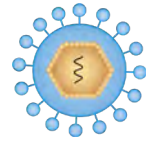
HEPATITIS D⁴



76%



Cirrhosis within 5 years;
HCC within 10 years



HEPATITIS E⁵



Can occur rarely in immunosuppressed individuals



No, as virus does not result in chronic infection

Etiology of HDV^{1,2}



CAUSE

Infection with HDV

Only patients infected with HBV can contract HDV – HDV is acquired simultaneously (coinfection) or as a superinfection in those already infected with HBV



TRANSMISSION

Via percutaneous or mucosal contact with infectious blood or body fluids

Common routes of transmission: contaminated needles or transfusion, sexual transmission, sharing razors and toothbrushes
Not as common routes: Vertical transmission from mother-to-baby, and mucosal contact with infectious blood or body fluids



SYMPTOMS

Often asymptomatic

No particular symptoms related specifically to HDV. Individuals with chronic infection are at high risk for developing severe liver disease, including cirrhosis and HCC



COURSE OF INFECTION

Acute or chronic

Acute: occurs suddenly, may cause severe symptoms, resolves within 6 months. Can clear spontaneously; however, can lead to acute liver failure
Chronic: long-term consequence of infection associated with high risk for liver disease



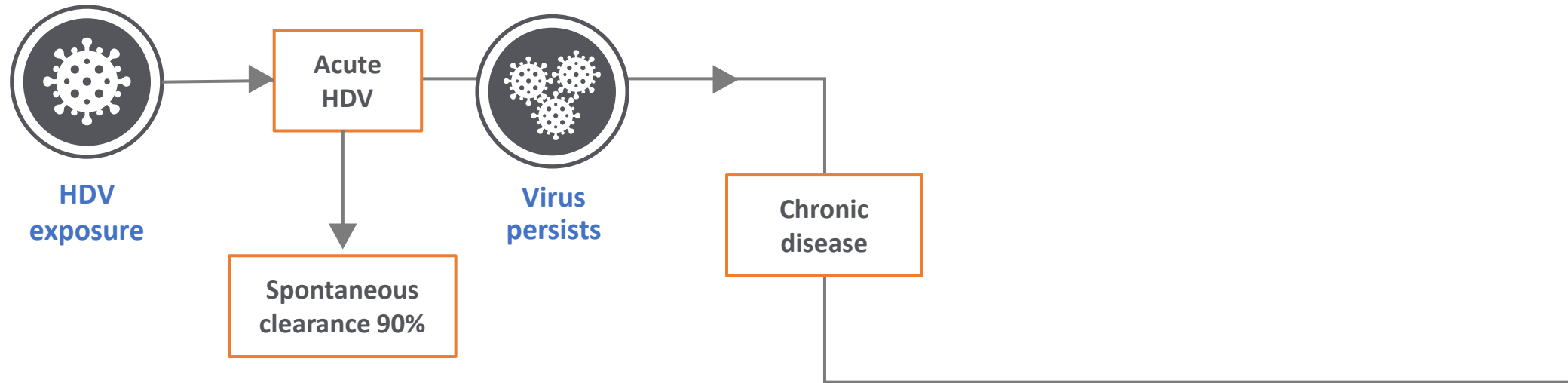
CONSEQUENCES OF INFECTION

Increased risk for cirrhosis and HCC than HBV alone

HDV is the most severe form of chronic viral hepatitis due to more rapid progression to liver-related death and HCC than the other viruses

Clinical Course of HDV

HBV/HDV coinfection often leads to rapid progression to cirrhosis and HCC

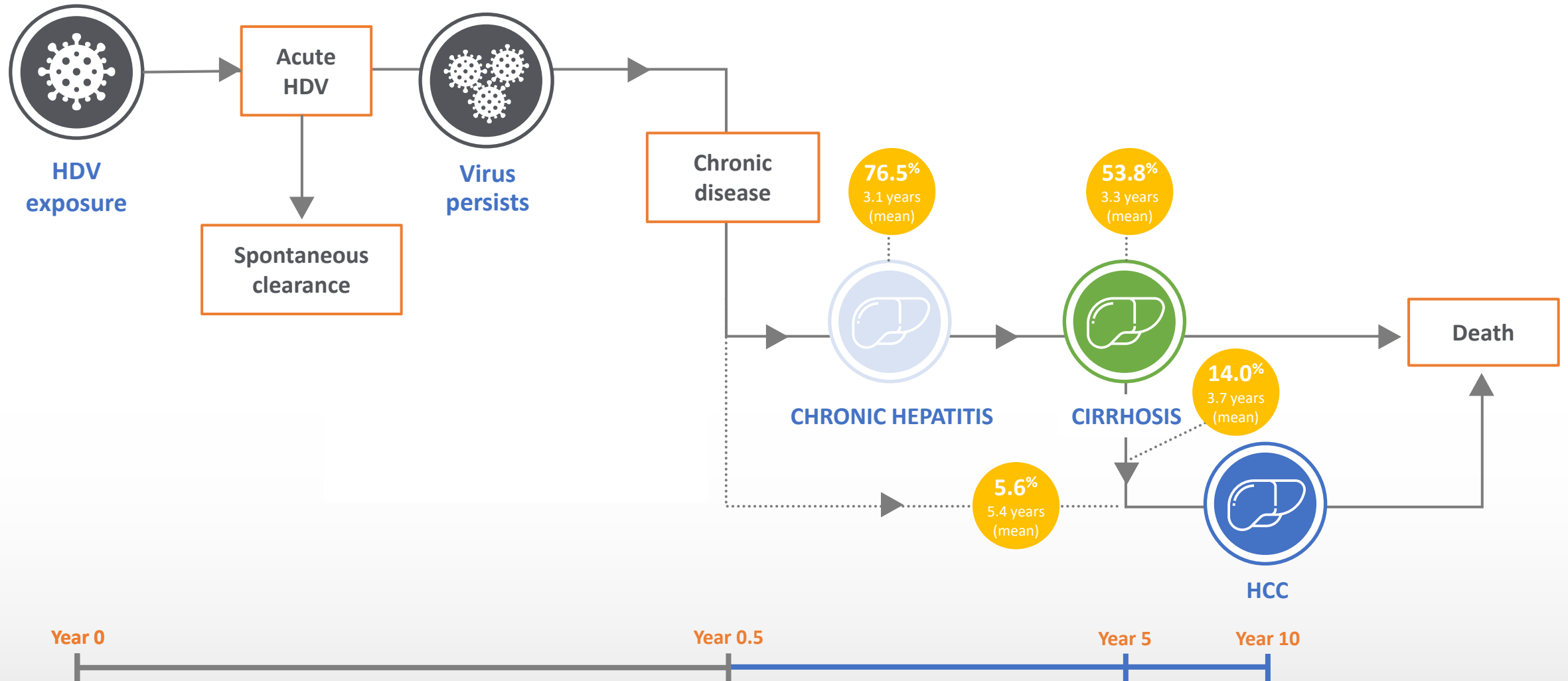


Year 0

Year 0.5

Clinical Course of HDV

Chronic HBV/HDV infection often leads to rapid progression to cirrhosis and HCC



Diagnosis of Different Stages of HDV Infection¹⁻⁴

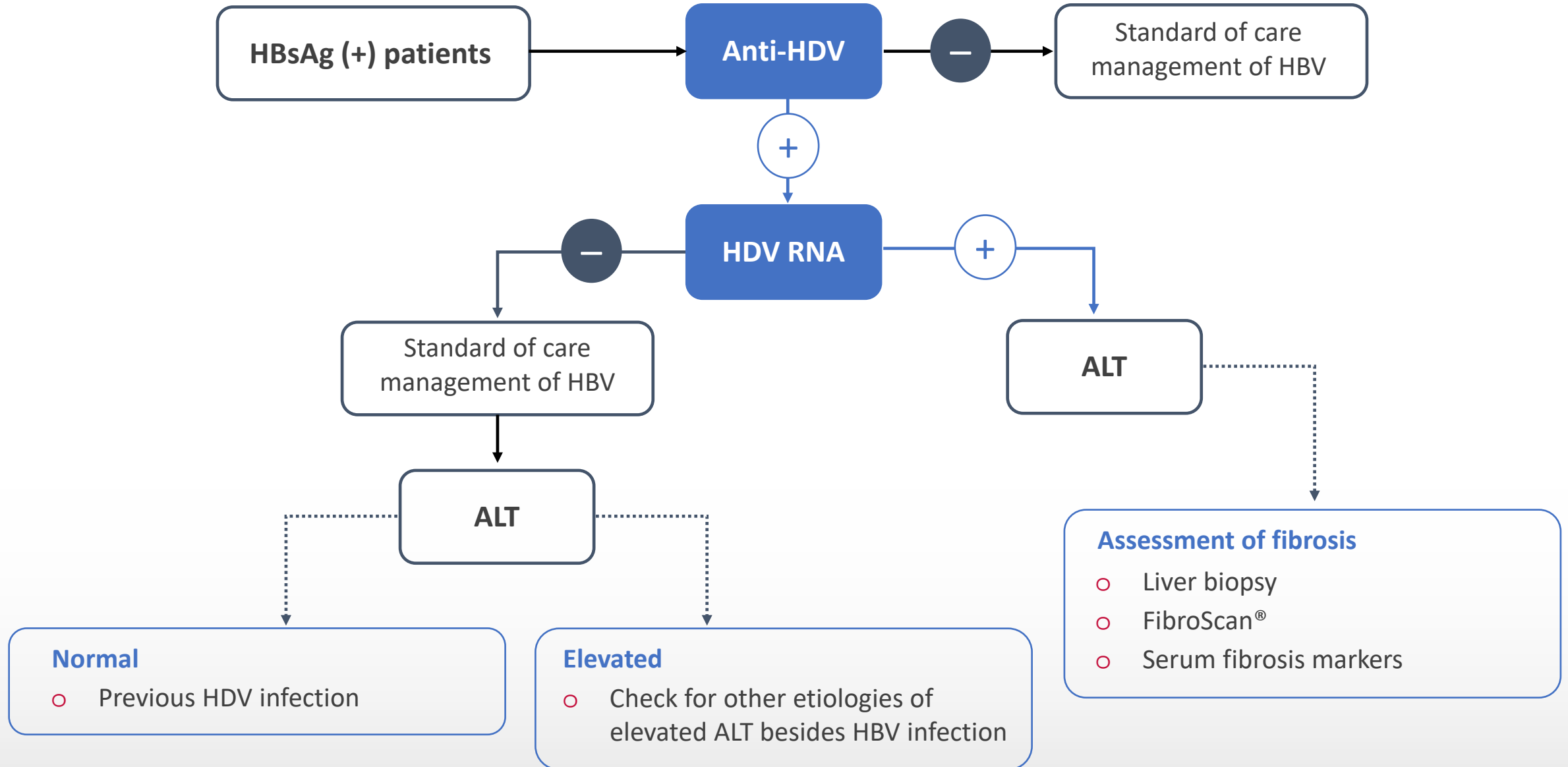
Diagnostic Marker	Acute HDV/HBV Coinfection	Acute HDV Superinfection	Chronic HDV Infection
HBsAg	+	+	+
Anti-HBc, IgM	+	-	-
Serum HDAg (by EIA/RIA)	Early and short-lived, and frequently missed	Early and transient, and frequently missed	Transient and may not be detected
Serum HDV RNA (by RT-PCR)	+	+	+
Anti-HDV, total	Late, low titers	Rapidly increasing titers	High titers
Anti-HDV, IgM	+	Rapidly increasing and persistent titers	Variable titers, usually high titers

Note: HDV genotyping is not done routinely in clinical practice.

EIA=enzyme immunoassay; HBc=hepatitis B core; HBV=hepatitis B virus; HBsAg=hepatitis B surface antigen; HDAg=hepatitis delta antigen; HDV=hepatitis delta virus; IgM=immunoglobulin M; RIA=radio immunoassay; RNA=ribonucleic acid; RT-PCR=reverse transcription polymerase chain reaction.

1. Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. 2. Sarin SK, et al. *Hepatology Int*. 2016;10(1):1-98. 3. WHO. March 2015. Accessed March 30, 2021. https://apps.who.int/iris/bitstream/handle/10665/154590/9789241549059_eng.pdf?sequence=1 4. Cheung A, Kwo P. *Clin Liver Dis*. 2020;24(3):405-419.

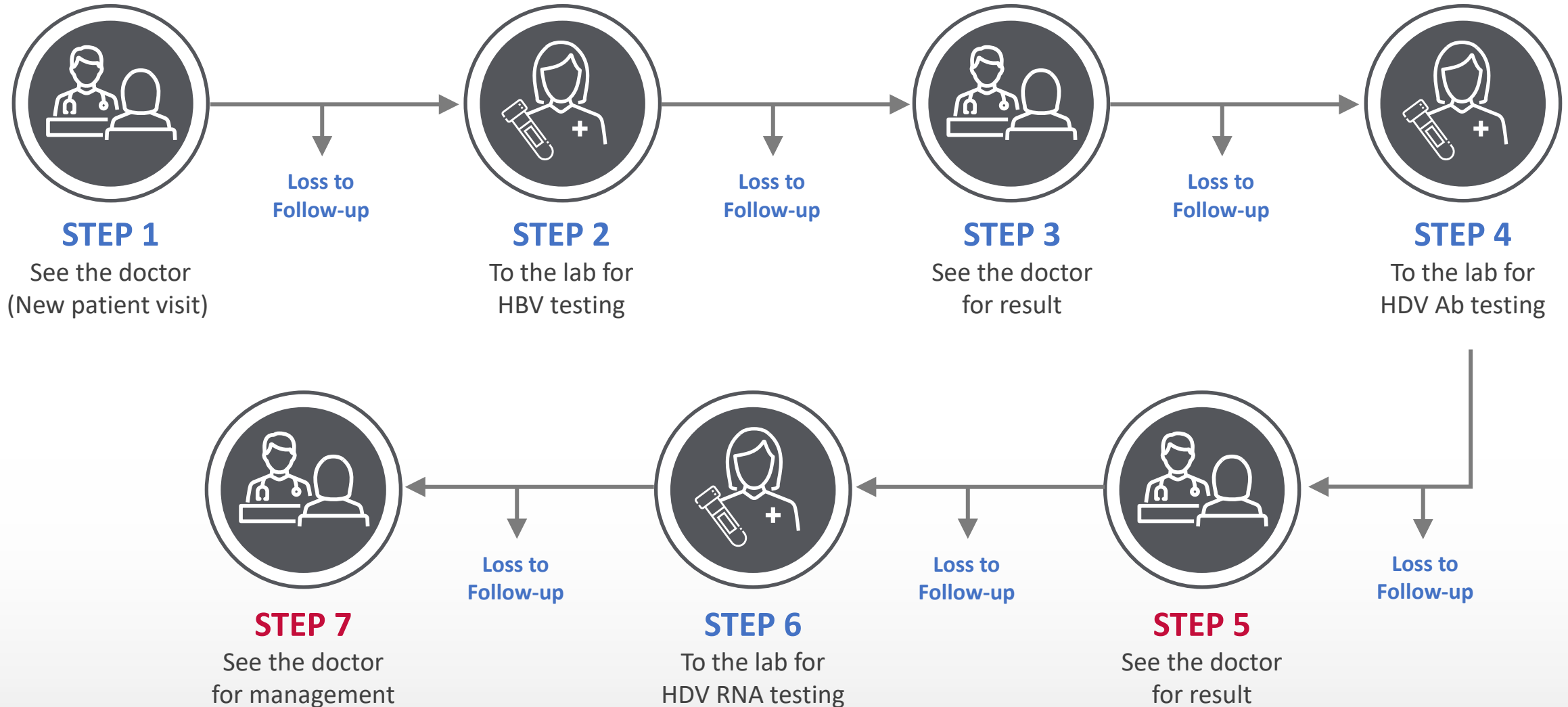
Algorithm for the Evaluation of HDV



Test Name	Test Code	Reference Lab	CPT Code
HDV Antibody, Total	4990	Quest Diagnostics	86692
	20799	ARUP Laboratories	
	20799	Mayo Clinic Laboratories	
	99202	Viracor Eurofins	
HDV Antibody, IgM	20799	BioAgilytix	
	35664	Quest Diagnostics	
	30336	Viracor Eurofins	
	98507	ARUP Laboratories	
HDV RNA, Quantitative	37889	Quest Diagnostics	87799
	2013881	ARUP Laboratories	
HDV RNA, Qualitative	34469	Quest Diagnostics	87798
	3900	Viracor Eurofins	
	1844	Bioreference Laboratories	
HDV Antigen	2006450	ARUP Laboratories	87380
	-	BioAgilytix	
HDV Genotyping and NAT	CDC-10328	CDC	Not CLIA approved

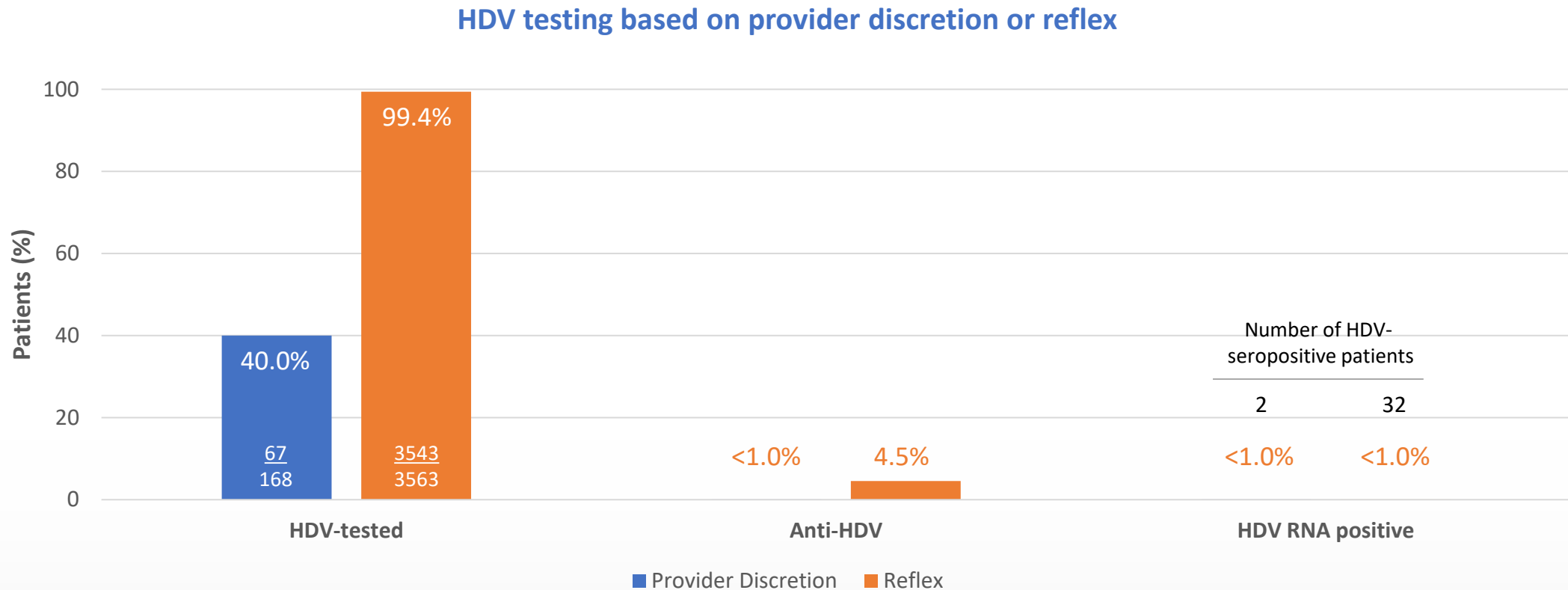
This may not be a comprehensive list of all available codes and labs offering HDV testing. This is for your information only. Each provider must make an individual decision for each patient's needs. Gilead does not guarantee the coverage or reimbursement of any item or service through the use of these codes

Current HDV Testing: Impact on Follow-up



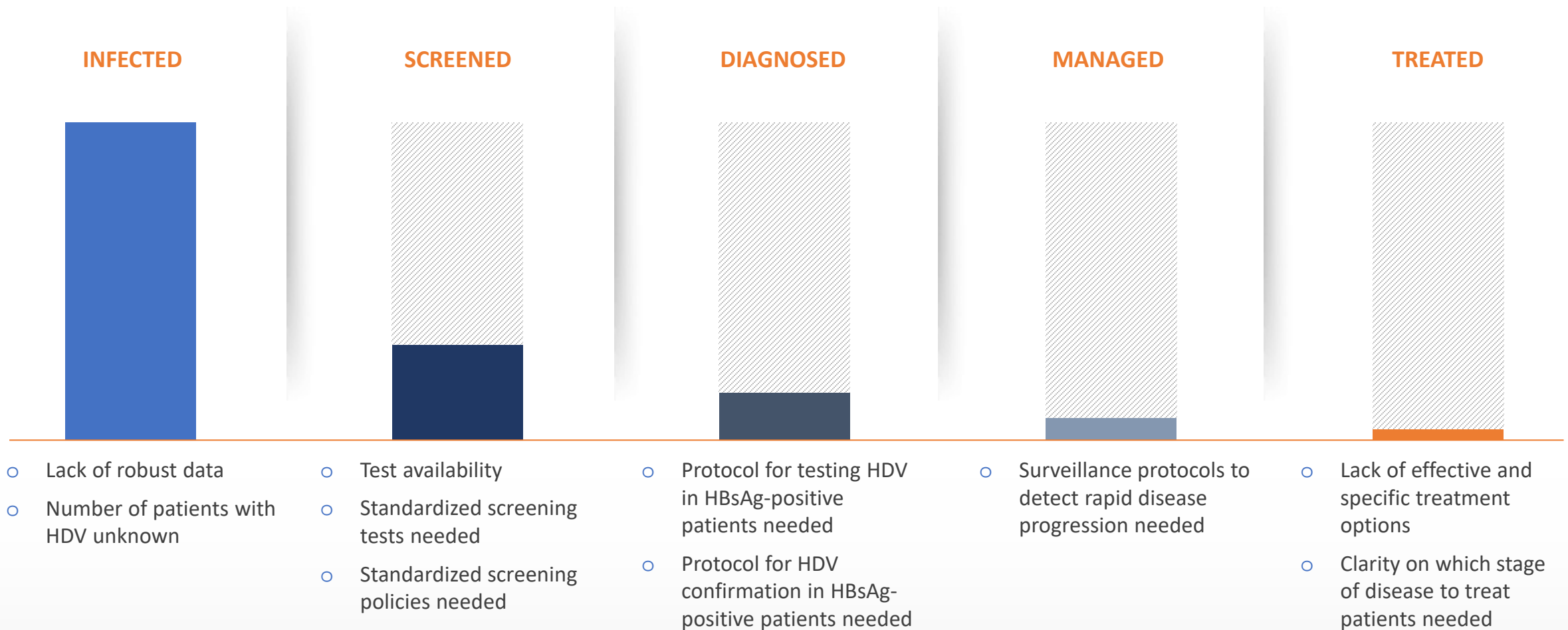
HBsAg-positive Reflex to Anti-HDV: 2 London Centers

Cross-sectional analysis of HDV testing among HBsAg-positive patients at 2 London Centers, 2005-2012



The center with a reflex laboratory algorithm achieved anti-HDV testing of almost all first HBsAg-positive samples over a 12-year period

There Are Unmet Needs Across the HDV Cascade of Care¹⁻³



Testing Recommendations for HDV

WHOM TO TEST?

HOW TO TEST?

AASLD¹
(2018)

- HBsAg+ patients with HDV risk factors
- Low/undetectable HBV DNA and high ALT

- Anti-HDV
- HDV RNA

EASL²
(2017)

- All patients infected with HBV

NO RECOMMENDATION

APASL³
(2016)

- Patients with chronic HBV and chronic liver disease

- HDAg or Anti-HDV
- HDV RNA

WHO⁴
(2015)

NO RECOMMENDATION

- Anti-HDV
- HDV RNA

Barriers to HDV Screening



DIAGNOSTIC CHALLENGES¹⁻³

Not widely available recently in some countries and potentially inconclusive HDV antibody tests

Lack of routine screening of patients with HBsAg

Lack of standardization of HDV RNA tests (although newer assays are better standardized)



EDUCATION CHALLENGES⁴⁻⁶

Limited and conflicting guidance on HDV screening (national and international guidelines)

Limited HCP education/awareness of HDV

Reduced motivation to screen due to no approved treatment options until recently^a



^aNo approved therapy exists in the United States.

1. Wedemeyer H, Negro F. *Gut*. 2019;68(3):381-382. 2. Safaie P, et al. *Virus Res*. 2018;250:114-117. 3. EASL. *J Hepatol*. 2017;67(2):370-398. 4. Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. 5. Sarin SK, et al. *Hepatol Int*. 2016;10(1):1-98. 6. WHO. March 2015. Accessed March 30, 2021. https://apps.who.int/iris/bitstream/handle/10665/154590/9789241549059_eng.pdf?sequence=1

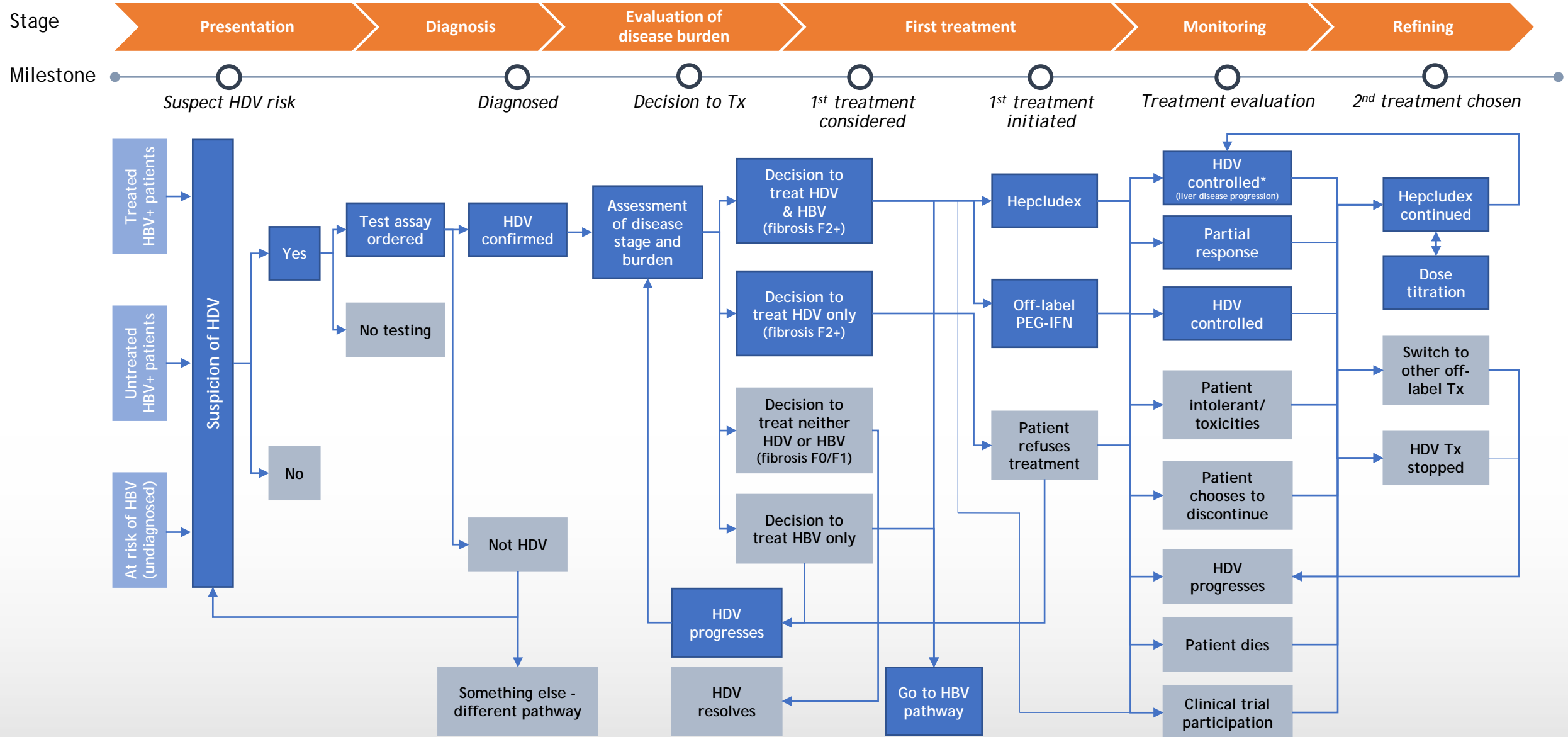
Guideline recommendations for management of HDV - treatment

	Treatment options	Treatment endpoint	Management
AASLD ¹ (2018)	<ul style="list-style-type: none"> • PEG-IFNα for 1 year • Patients with elevated HDV RNA and ALT elevation 	<ul style="list-style-type: none"> • Undetectable HDV RNA • ALT normalisation/ improved histology 	<ul style="list-style-type: none"> • Test for HDV relapse if ALT increases • Manage in specialist centres
APASL ² (2016)	<ul style="list-style-type: none"> • PEG-IFNα for ≥ 1 year • Optimal duration of therapy not well defined 	<ul style="list-style-type: none"> • Undetectable HDV RNA 	<ul style="list-style-type: none"> • Monitor for ≥ 6 months post-treatment
EASL ³ (2017)	<ul style="list-style-type: none"> • PEG-IFNα for ≥ 48 weeks • HDV/HBV patients with compensated liver disease 	<ul style="list-style-type: none"> • Undetectable HDV RNA 	<ul style="list-style-type: none"> • Long-term HDV RNA monitoring required
WHO ⁴ (2015)	<ul style="list-style-type: none"> • PEG-IFNα for ≥ 1 year 	<ul style="list-style-type: none"> • Undetectable HDV RNA 	No recommendation

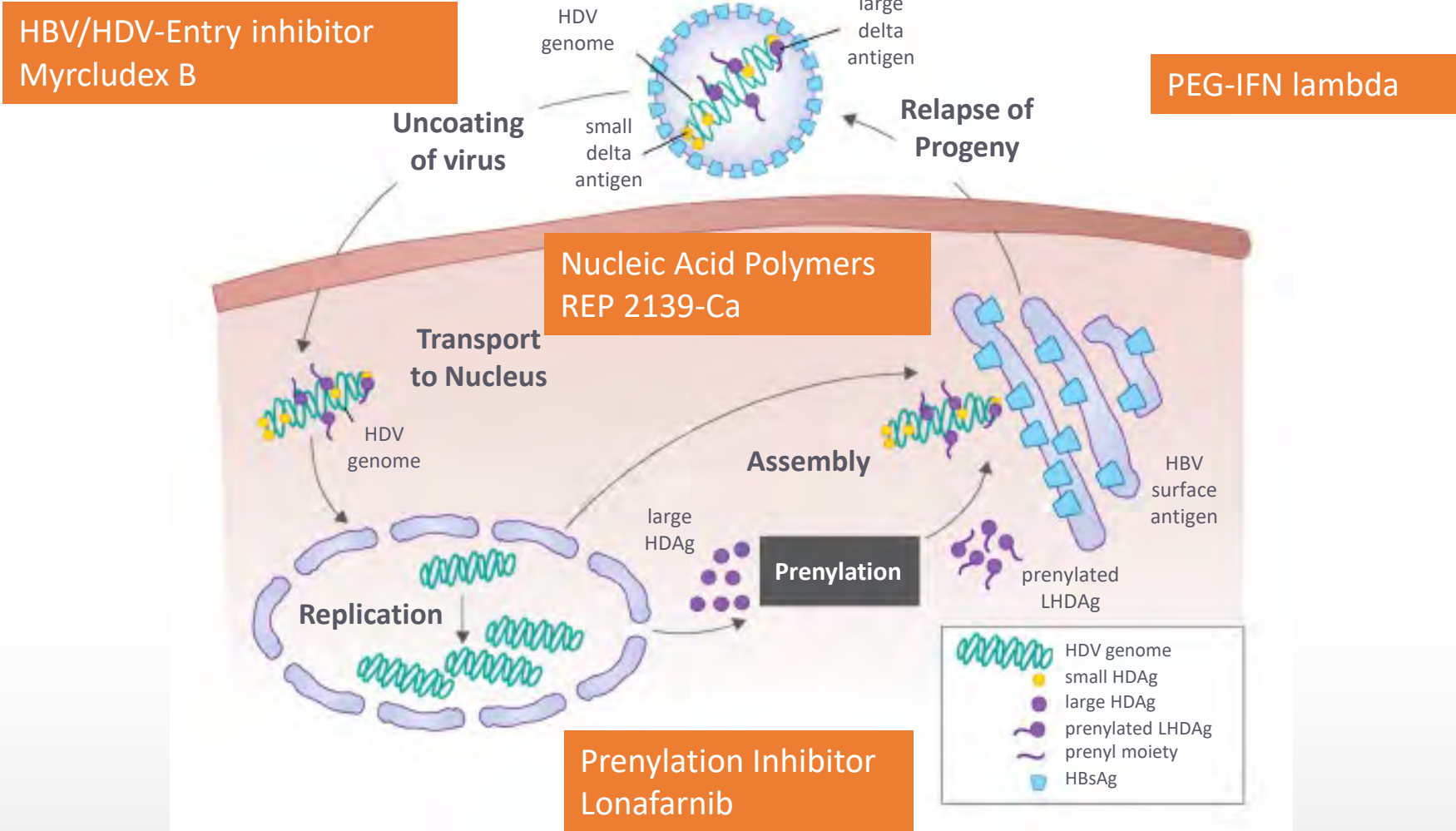
1. Terrault N, et al. Hepatology 2018;67:1560-99; 2. Sarin SK, et al. Hepatol Int 2016;10:1-98;
 3. European Association for the Study of the Liver. J Hepatol 2017;67:370-98;
 4. WHO HBV guidelines. March 2015. Available at:
https://apps.who.int/iris/bitstream/handle/10665/154590/9789241549059_eng.pdf?sequence=1
 (Accessed March 2021).

NOTE: Treatment of HDV with PEG-IFN α is off-label.
 AASLD: American Association for the Study of Liver Diseases;
 ALT: alanine aminotransferase; APASL: Asian Pacific Association for the Study of the Liver; EASL:
 European Association for the Study of the Liver; HDV: hepatitis D virus;
 PEG-IFN: pegylated interferon; RNA: ribonucleic acid; WHO: World Health Organization.

Identification and management of chronic HDV



Hepatitis Delta: New Therapies



Regulatory and guideline efficacy endpoints

Chronic On-Therapy Endpoint



Draft Guidance
November 2019

“...a greater than or equal to 2-log₁₀ decline in HDV RNA and ALT normalization on-treatment could be considered an acceptable surrogate endpoint”

Cure Off-Therapy Endpoint

“The proportion of trial patients with undetectable serum HDV RNA (defined as less than the lower limit of quantification (LLOQ), target not detected (TND)) and ALT normalization.”

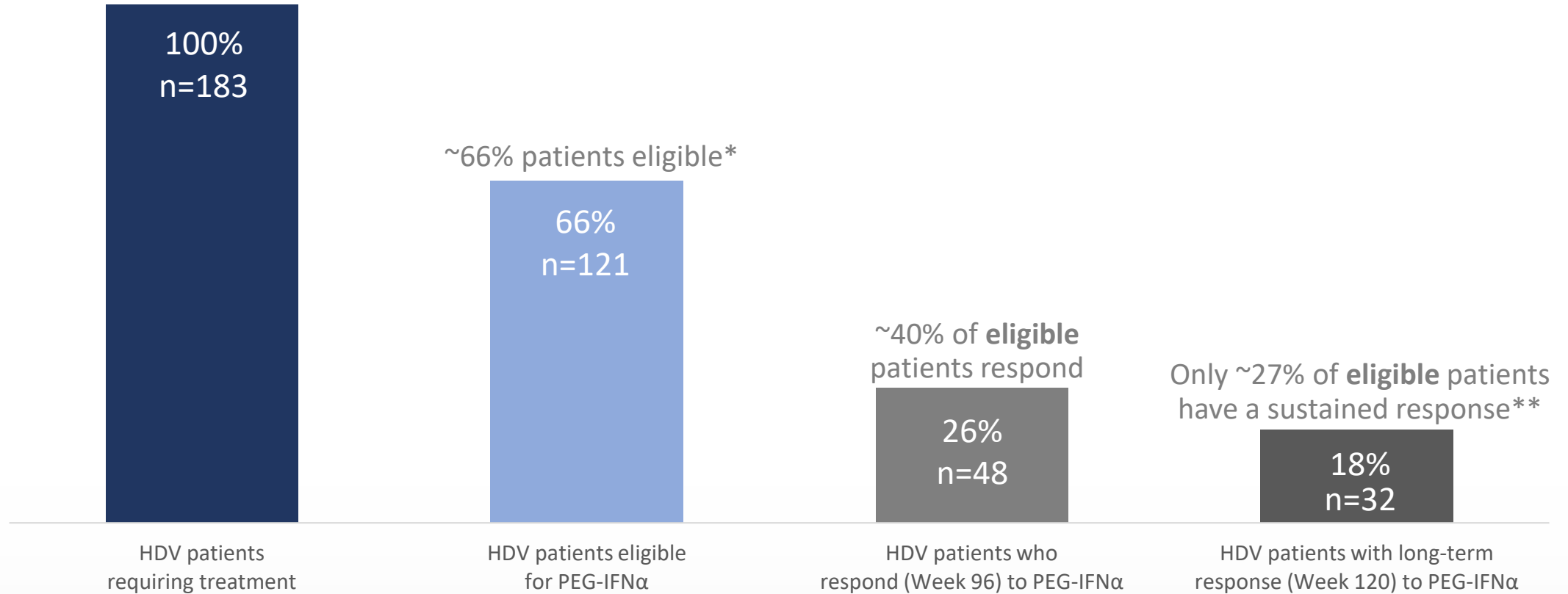


2019 EASL-AASLD HBV
Treatment Endpoints Conference
October 2019

“...a 2-log reduction in HDV RNA might suffice.”

“...undetectable serum HDV RNA 6 months after stopping treatment as the endpoint ...Normalisation of ALT is also desired”

Response to PEG-IFN α treatment



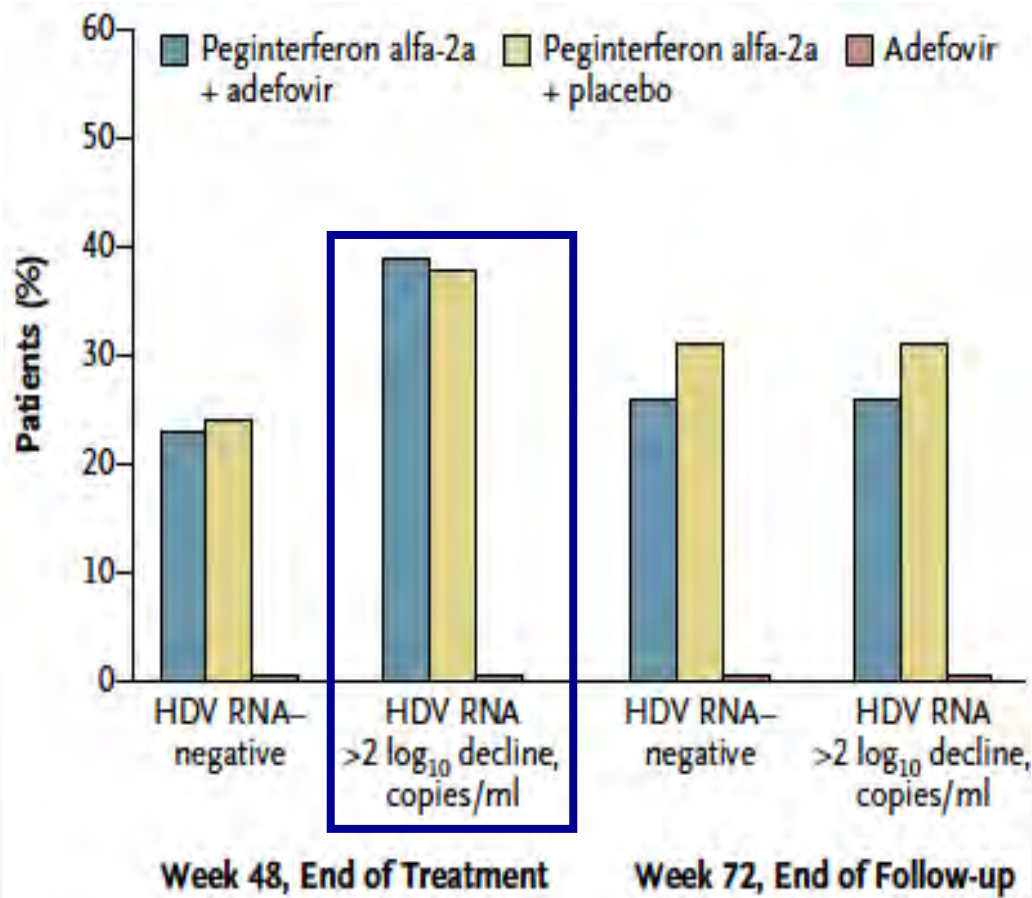
Only a subset of patients are treated with PEG-IFN α , of which a small proportion respond to treatment

*Ineligibility based on contraindications, intolerance and presence of advanced liver disease in HIDIT-II (62 of 183 screened did not meet inclusion criteria or met exclusion criteria);

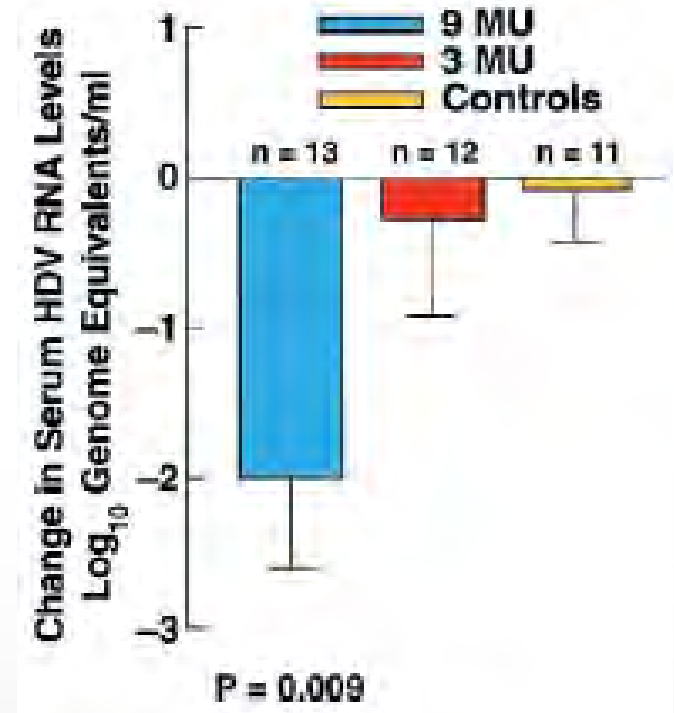
**Response defined as undetectable HDV RNA after 120 weeks of treatment.

HDV: hepatitis D virus; PEG-IFN α : pegylated interferon alpha.

EOT HDV RNA ≥ 2 Log Decline Improves Survival



Of 17 pts with post-tx week 24 HDV RNA negativity, 9 were HDV RNA (+) at EOT



HEPCLUDEX (Bulevirtide) EMA Indication



Indication

- Treatment of chronic hepatitis delta virus (HDV) infection in HDV RNA-positive adult patients with compensated liver disease



Administration

- Administered at 2 mg once daily (every 24 hours \pm 4 hours) by subcutaneous injection
- Monotherapy or in co-administration with a nucleoside/nucleotide analogue for treatment of underlying HBV infection



Instructions for Use

- Treatment should be initiated only by a physician experienced in the treatment of patients with HDV infection
- Optimal treatment duration is unknown. Treatment should be continued as long as associated with clinical benefit

Bulevirtide monotherapy at low and high dose in patients with chronic hepatitis delta: 24 weeks interim data of the phase 3 MYR301 study



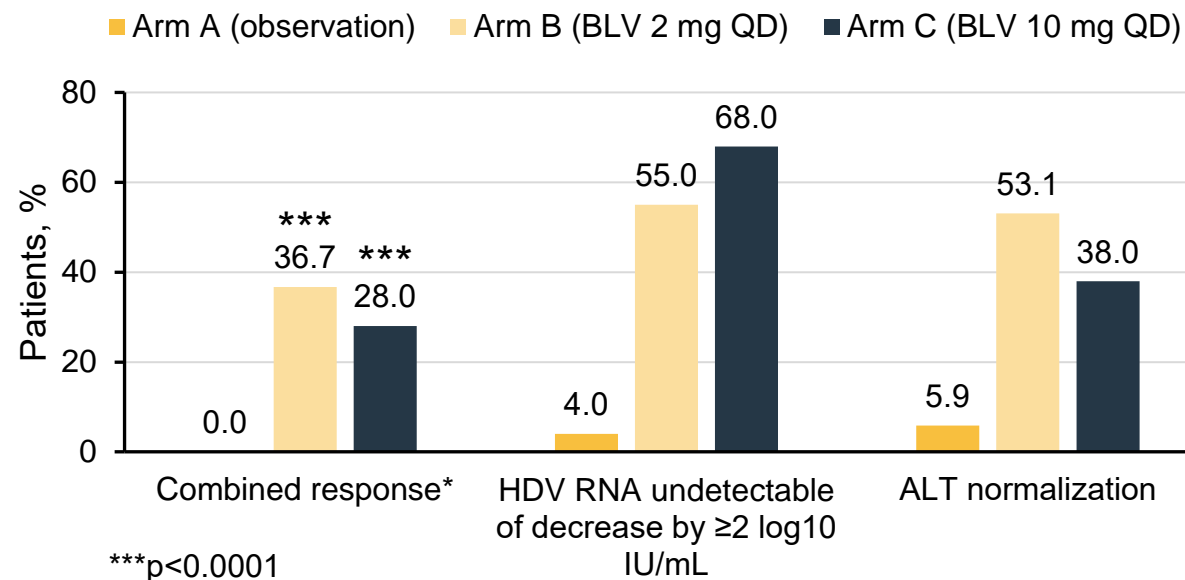
RESULTS

- **Baseline demographics:**
 - 57.3% of patients were male, 82.7% white, and the mean age was 41.8 years
 - HDV RNA levels were 5.05 log₁₀ IU/mL and ALT mean levels were 110.9 U/L
 - 47.3% of patients had compensated liver cirrhosis
- **Safety:** BLV was well tolerated during the first 24 weeks

TEAE (patient n)	Arm A (Observation; n=51)	Arm B (BLV 2 mg QD; n=49)	Arm C (BLV 10 mg QD; n=50)
Any	55 (26)	121 (32)	245 (36)
Grade 3–4 AE	2 (4)	2 (4)	1 (2)
Serious TEAE	1	0	0

- **Efficacy:** after 24 weeks, significantly more patients treated with BLV (2 mg or 10 mg) vs no antiviral treatment achieved:
 - A combined virological and biochemical response*
 - An HDV RNA decrease by ≥ 2 log₁₀ IU/mL
 - ALT normalization

Efficacy endpoints



CONCLUSION

- These interim data from the phase 3 trial confirm that 24 weeks of BLV monotherapy was associated with significant HDV RNA decline and improvement in biochemical disease activity
- BLV is well tolerated in patients with compensated HDV infection
- These findings further support the conditional approval of 2 mg BLV in the EU

Beyond cATU: Bulevirtide ± PegIFNα-2a for Chronic HDV Infection: Virologic Efficacy

Time	HDV RNA Undetectable or Decrease by $\geq 2 \log_{10}$ From Baseline, ^{*†} % (n/N)	
	Bulevirtide (n = 77)	Bulevirtide + PegIFNα-2a (n = 68)
Day 0	0	0
Mo 1	1.5 (1/66)	22.0 (11/50)
Mo 2	14.8 (8/54)	48.8 (20/41)
Mo 3	28.2 (20/71)	68.6 (35/51)
Mo 6	52.3 (34/65)	84.4 (38/45)
Mo 9	59.2 (29/49)	89.5 (34/38)
Mo 12	68.3 (28/41)	93.9 (31/33)

*Missing does not equal failure. †Study not powered to compare bulevirtide vs bulevirtide + pegIFNα-2a.

Other Drug classes by therapeutic target in clinical development

	HBsAg secretion inhibitors	Prenylation inhibitors	Immune modulators
Therapies in development (Company)	<ul style="list-style-type: none"> • REP2139 (Replicor) 	<ul style="list-style-type: none"> • Lonafarnib (Eiger Biopharmaceuticals) 	<ul style="list-style-type: none"> • PEG-IFNλ (Eiger Biopharmaceuticals)
Stage of replication cycle affected	<ul style="list-style-type: none"> • Broad-spectrum antiviral activity 	<ul style="list-style-type: none"> • Inhibits L-HDAg prenylation 	<ul style="list-style-type: none"> • Induces IFN-stimulated genes and activates JAK and STAT
Consequence(s)	<ul style="list-style-type: none"> • Inhibits export of HBsAg to serum • HDV virions cannot be formed without HBsAg 	<ul style="list-style-type: none"> • Essential for interaction with HBsAg • Lack of prenylation prevents HDV virion formation 	<ul style="list-style-type: none"> • General broad antiviral response
Progress	<ul style="list-style-type: none"> • Phase 2 trials 	<ul style="list-style-type: none"> • Phase 3 trials* 	<ul style="list-style-type: none"> • Phase 2 trials

*Lonafarnib is boosted with ritonavir.

Do we need HDV cure in the era of HBV cure?

- HDV is the most severe form of hepatitis
- 15 – 20 Million chronically infected, presumably more
- Lack of global epidemiology data
- HDV requires only small amounts of HBsAg to complete viral packaging
- Only sterilizing HBV cure will obviate a need for an HDV cure
- Functional HBV cure: Maybe, but when ? Sufficient for HDV cure/control ?
- Sterilizing HBV cure: Not in sight, seems necessary for HDV cure !
- **Do we need HDV cure: YES !**

HDV Treatments Are Needed – HDV Cure is the Objective!

- HDV is the most severe form of hepatitis
- HDV requires only small amounts of HBsAg to complete viral packaging
- Theoretically, Sterilizing HBV cure is the only way to obviate a need for an HDV cure
- **Sterilizing HBV cure**: Nowhere in sight, remove all cccDNA and all integrants
- **Functional HBV cure**: Can it be discovered, developed and approved in our lifetime?
 - I expect 30% Functional Cure with 4 drug combination therapies, 60% Sustained HBV DNA Suppression and 10% Relapse < 4 years

**HDV treatments:
In Phase 3; on track to be approved within the next 2-3 years!**

Thank you!

Acknowledgements:



Hepatitis C:

What is the role of Reflex Testing, Point of Care, in HCV
Viral Hepatitis Elimination ?

Robert G Gish MD

See robertgish.com for all affiliations

Disclosures

Advisor and speaker for:

Abbvie and Gilead

Advisor and Stock Options: Genlantis

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Program Head, Virology/Molecular Diagnostics

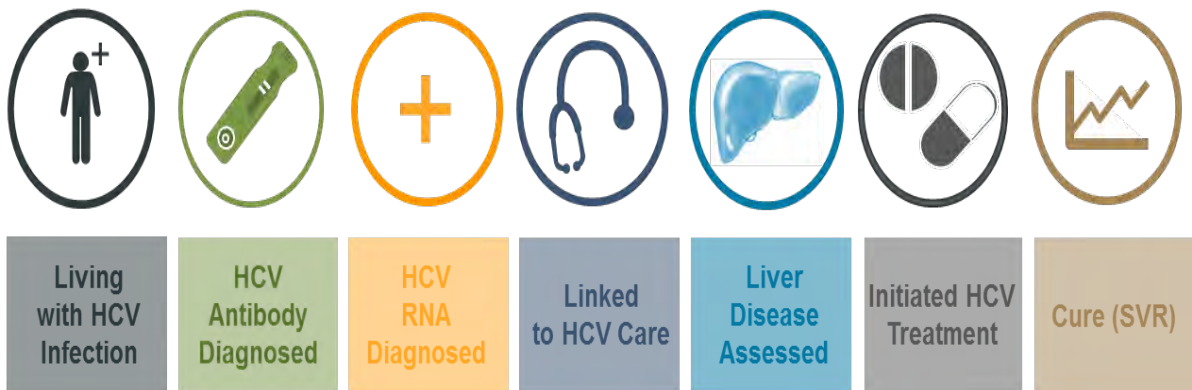
BCCDC Public Health Laboratory

Andrew Seaman, MD

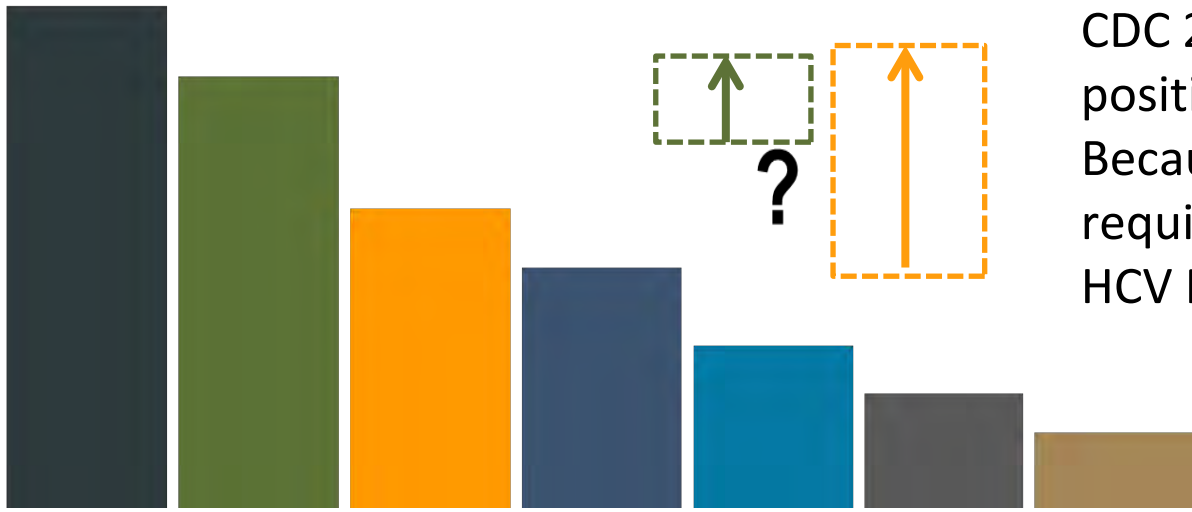
Assistant Professor of Medicine, Oregon Health & Sciences University

Director of Hepatitis and HIV Services, Central City Concern

Multi-step Diagnostic Process: Bottleneck in HCV Cascade to Cure



“56% of people in the U.S. were **aware** of their HCV infection from 2013-2016 (Kim HS et al, J Viral Hepat, 2019). This increased to **61%** for 2013-2018 data (Ryerson et al, MMWR, 2020).”



CDC 2013: We lose nearly 50% of positive HCV Ab screens to follow-up Because persons with reactive HCV Ab require subsequent delayed HCV RNA testing



CDC. *MMRW* 2013; Graphics adapted from Grebely J, et al. *Int J Drug Policy*. 2015.

Current Laboratory Test Methods for Dx of HCV Infection

Laboratory-based

EIA or CIA

- HCV IgG Ab
- HCV Ag

Line IA

- HCV IgG Ab

NAT (Qual or Quant)

- RNA (PCR or TMA)

Point-of-Care

Line IA

- HCV IgG Ab *

NAT (Qual or Quant)

- RNA (PCR)

At-Home Collection

EIA or CIA on DBS

- HCV IgG Ab

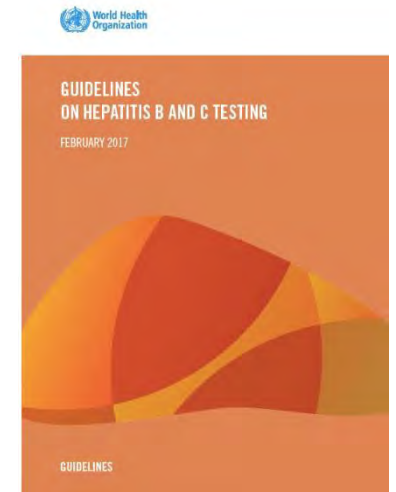
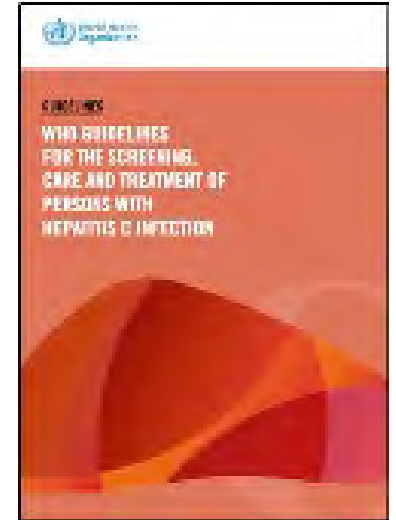
Not FDA-approved or –cleared

** CLIA-waived*

Analysis. Answers. Action.

New Directions - Updating WHO global guidelines

- **HCV treatment:**
 - Simplified service delivery
 - Reconciling paediatric and adult DAA regimens
 - Re-treatment approaches and regimens
- **Testing:** ongoing UNITAID funded portfolio
 - Use of PoC viral load
 - HCV Self-testing
 - Dried Blood spots
- **HBV treatment:**
 - Simplifying service delivery
 - Expanding criteria for treatment (lower APRI score and HBV DNA threshold)
 - TAF vs. TDF



Updating HCV Guideline Recommendations Proposed interventions to promote uptake and linkage

IMPROVING THE UPTAKE OF TESTING AND LINKAGE TO CARE AND PREVENTION UPDATED RECOMMENDATIONS

10.1. Recommendations

Topic	Recommendations
Uptake of testing and linkage to care	<ul style="list-style-type: none"> • All facility- and community-based hepatitis testing services should adopt and implement strategies to enhance uptake of testing and linkage to care. <i>Strong recommendation, moderate quality of evidence</i> • The following evidence-based interventions should be considered to promote uptake of hepatitis testing and linkage to care and treatment initiation: (Conditional recommendations) <ul style="list-style-type: none"> ○ Decentralised HCV testing and treatment ○ Provision of hepatitis testing and treatment as part of integrated services within mental health/substance use services (<i>Conditional recommendation, very low quality of evidence</i>). ○ Task-sharing of hepatitis testing and treatment ○ Peer and lay health worker support in community-based settings (<i>Conditional recommendation, moderate quality of evidence</i>). ○ Clinician reminders to prompt provider-initiated, facility-based HBV and HCV testing in settings that have electronic records or analogous reminder systems (<i>Conditional recommendation, very low quality of evidence</i>). ○ Use of PoC viral load testing ○ Reflex HCV viral load testing in those with a positive HCV antibody test result* ○ Dried blood spots for serological and virological testing

*This can be achieved either through laboratory-based reflex VL testing using a sample already held in lab, or in clinic-based reflex testing in a health facility through immediate sample collection following a positive RDT HCV antibody test.

Systematic review: Lab-based and clinic based reflex VL (Tang et al. 2021)

PoC vs lab VL assay arms – BY POPULATION GROUP (Trickey et al, 2021)

Within-study comparisons of HCV RNA testing uptake and treatment uptake

HCV RNA testing uptake (N=4 studies)

Population:	RR (95% CI)	N studies
Overall	1.11 (0.89-1.38)	4
PWID/homeless	2.11 (1.47-3.03)	1
Gen-pop	1.08 (1.06-1.09)	1
Prisoners	0.91 (0.82-1.01)	2

Treatment uptake (N=10 studies)

Population:	RR (95% CI)	N studies
Overall	1.32 (1.06-1.64)	10
PWID/homeless	1.38 (0.70-2.71)	5
Gen-pop	0.79 (0.67-0.92)	2
Prisoners	3.47 (2.56-4.71)	3

Relative risks (95% confidence intervals) – larger RRs mean greater uptake with PoC VL assays

Summary of results:

HCV RNA testing uptake

- Evidence of increased RNA testing uptake with PoC assays in PWID/homeless populations + general population
- No clear difference in RNA testing uptake with PoC assays among prisoners

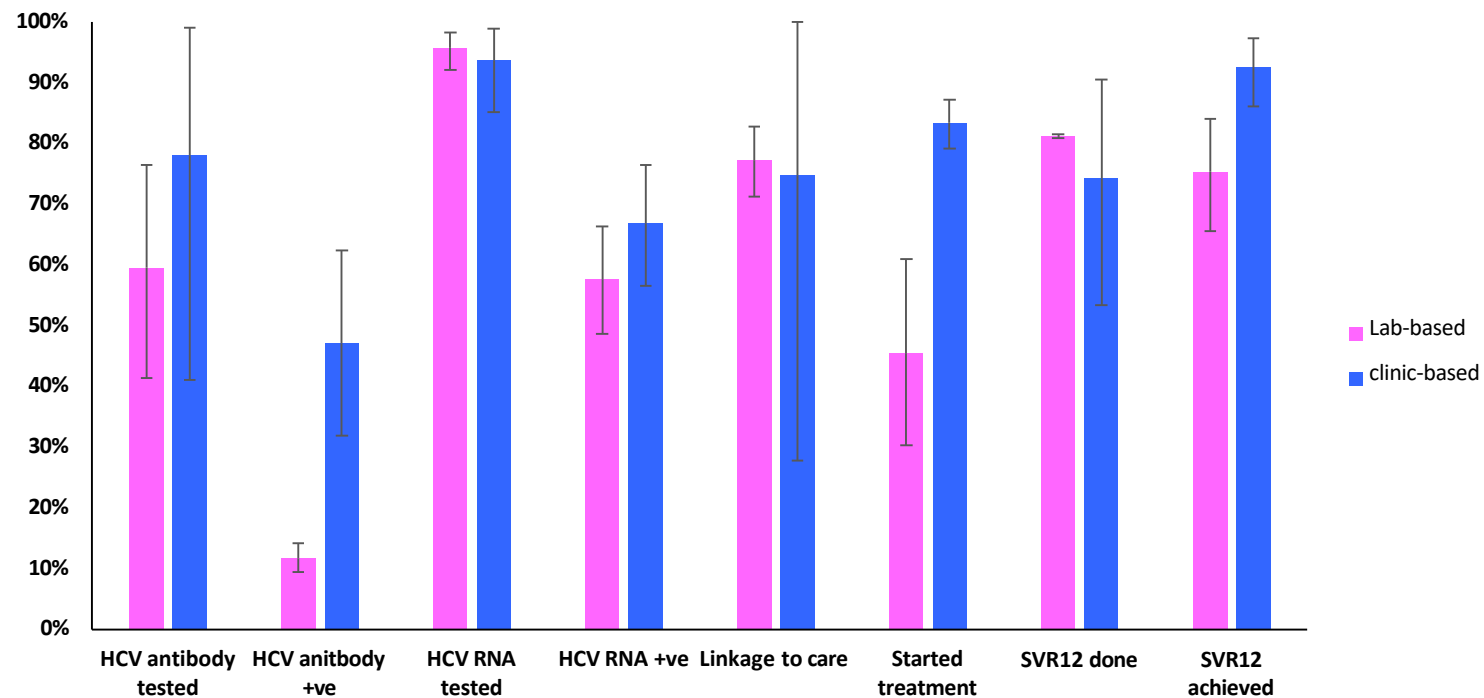
Treatment uptake

- Some evidence of increased treatment uptake with PoC assays among prisoners
- No clear difference in treatment uptake with PoC assays among PWID/homeless populations
- Some evidence of decreased treatment uptake with non-PoC assays among the general population – affected by issues with historical comparators

Systematic review: Lab-based and clinic based reflex VL (Tang et al. 2021)

Results:

Pooled estimates (and 95% CIs) for HCV cascade of care percentages, stratified by lab-based or clinic-based reflex testing.



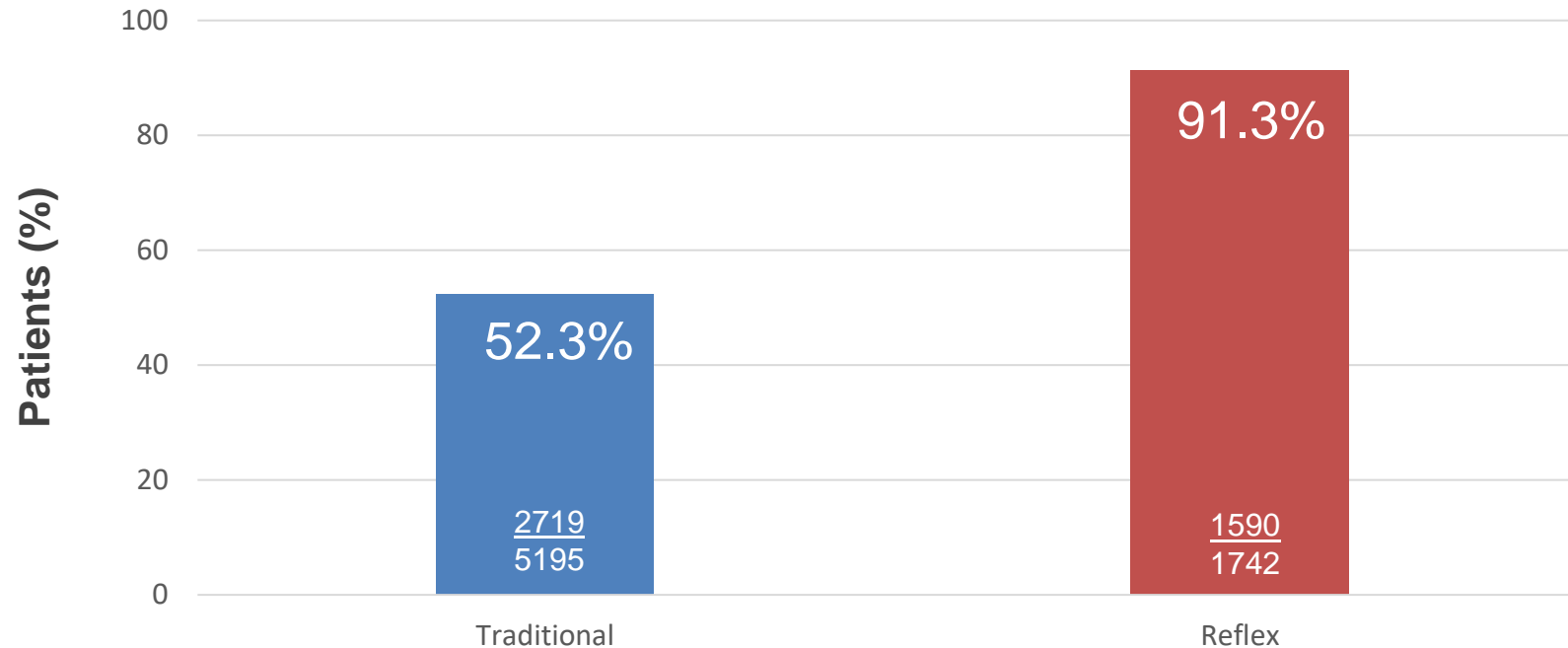
	HCV antibody tested	HCV antibody +ve	HCV RNA tested	HCV RNA +ve	Linkage to care	Started treatment	SVR12 done	SVR12 achieved
Lab-based	59.6% (41.4-76.5%)	11.7% (9.4-14.1%)	95.7% (92.1-98.3%)	57.7% (48.7-66.4%)	77.3% (71.3-82.8%)	45.5% (30.3-61.0%)	81.2% (80.9-81.6%)	75.4% (65.6-84.1%)
Clinic-based	78.1% (41.0-99.1%)	47.0% (31.9-62.4%)	93.7% (85.1-99.0%)	66.9% (56.6-76.4%)	74.8% (27.7-100.0%)	83.4% (79.2-87.2%)	74.3% (53.4-90.6%)	91.0% (87.5-94.5%)
Total	62.0% (45.1-77.6%)	21.2% (18.1-24.5%)	95.2% (91.9-97.7%)	60.9% (54.2-67.4%)	77.5% (70.9-83.4%)	61.1% (53.5-68.4%)	71.3% (52.9-86.6%)	84.1% (77.0-90.1%)

Anti-HCV Reflex to HCV RNA: Impact on Testing

HCV RNA reflex testing of anti-HCV positive patients in Barcelona, Spain, 2015-2018

Analysis of diagnostic tests performed by a central laboratory before and after implementing a reflex testing protocol

Percentage of anti-HCV positive patients screened for HCV RNA



Implementation of viral load reflex testing significantly increases the diagnostic effectiveness and allows for the identification of underdiagnosed cases

Baseline questionnaire to labs on HCV testing

- Rapid Snap Survey of current HCV testing practices in UK NHS laboratories
- Labs recruited through the UK Clinical Virology Network (N=26) in October 2021
- 7 questions completed on-line or emailed responses

1. For any sample found to be anti-HCV positive, does your laboratory undertake a reflex HCV RNA test (whether in-house or referred to another lab)? Yes/No
2. For any sample found to be anti-HCV positive, does your laboratory undertake a reflex HCV antigen test (whether in-house or referred to another lab)? Yes/No
3. Please describe details of any barriers (e.g. contractual, financial, etc.) to undertaking reflex testing for HCV RNA or antigen.
4. Does your laboratory use HCV RNA and/or HCV core antigen as a first line test (i.e. without testing for anti-HCV)? Yes - HCV RNA/Yes - core Ag/Yes - both/No
5. Does your laboratory have the platforms to implement HCV core antigen testing? Yes/No
6. If your laboratory undertakes HCV diagnostic testing on dried blood spots (DBS), do you undertake a reflex HCV RNA test on any DBS found to be anti-HCV positive (whether in-house or referred to another lab)? Yes/No
7. Does your laboratory add a commentary to an HCV RNA or HCV core antigen positive result indicating the need for referral to specialist services for treatment? Yes/No

Investigating reflex testing using surveillance data

Reflex testing defined as RNA or Ag test within 1 week of anti-HCV

Between 2015 and 2020, 2.2% (60,949 / 2,711,153) of individuals tested for anti-HCV were positive (19 labs)

- 69.5% (42,389) were reflex tested
- 8.0% (4,853) were RNA tested between one week and six months
- 1.5% (894) between six and 12 months and
- 21.0% (12,813) had no RNA test within 12 months.

The proportion reflex testing rose from 66.9% in 2015 to 83.9% in 2020

Previous analysis between 2008 and 2013, reflex testing was 52.7%

Median time to treatment following anti-HCV positive result

Persons reflex tested: 183 days

Persons non reflex tested (between one week and six months): 214 days

Cost comparison of reflex and non-reflex pathway for persons diagnosed in 2019 England and reported to SSBBV

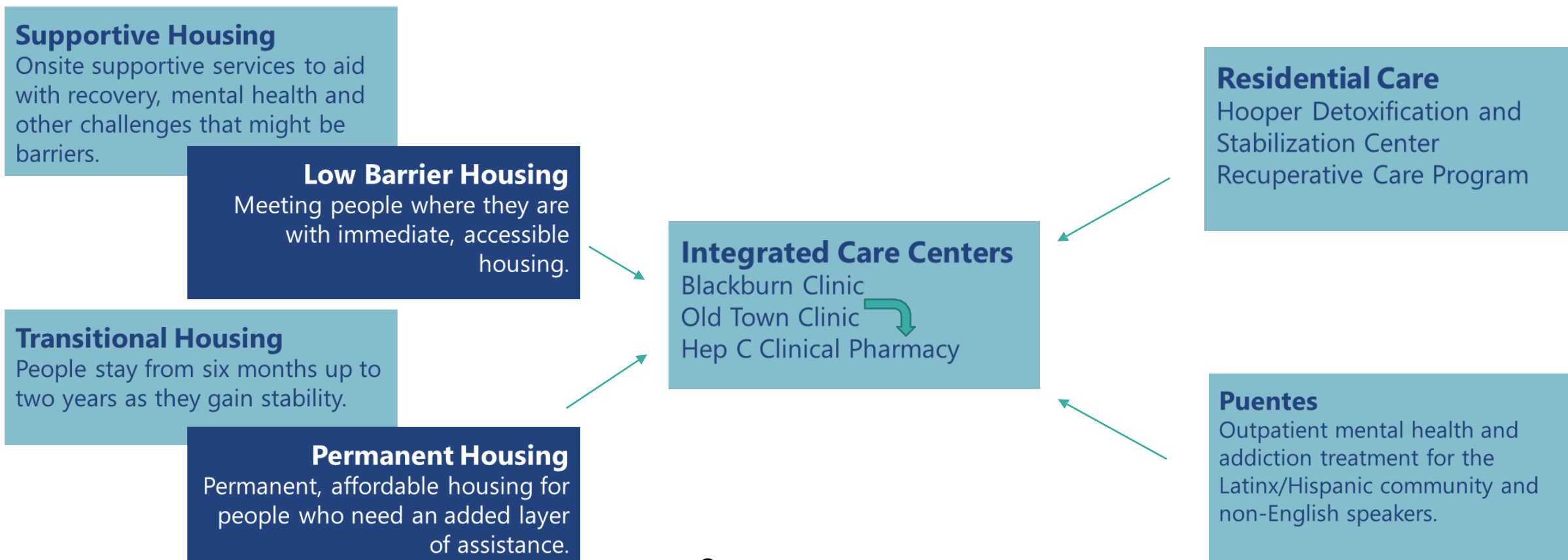
	Unit cost (£)	Number of persons	Total Cost (£)
Non-reflex pathway			
Anti-HCV test	7.4	529,553	3,918,692
Referral of Anti-HCV positives			
Phlebotomy for additional bloods	5		63,920
General Practitioner appointment and additional bloods	35	12,784	447,440
Outpatient appointment and additional bloods	125		1,598,000
HCV-RNA test	64	12,784	818,176
Referral of HCV-RNA positives	75	5,500	412,500
Total			5,213,288 - 6,747,368
Reflex pathway			
Anti-HCV test	7.4	529,553	3,918,692
HCV-RNA test on Anti-HCV positives	64	12,784	818,176
Referral of HCV-RNA positives	75	5,500	412,500
Total			5,149,368

Summary

- Variations in reflex testing commissioning and provision across England
- Barriers include sample volume and inappropriate samples to conduct RNA, testing being requested by external services.
- Proportion of tests reflex tested have increased over time
- Reflex testing is associated with earlier treatment
- Efficiencies are gained by moving to reflex testing, by preventing unnecessary appointments and multiple positive anti-HCV tests
- There is a need for the co-commissioning of testing, treatment and care based on an HCV diagnosis rather than component test result

Background: Central City Concern

CCC is a homelessness services organization serving 14,000 Portlanders



Andrew Seaman, MD
Assistant Professor of Medicine, Oregon Health & Sciences University
Director of Hepatitis and HIV Services, Central City Concern



Background: Central City Concern

CCC is a houselessness services organization serving 14,000 Portlanders

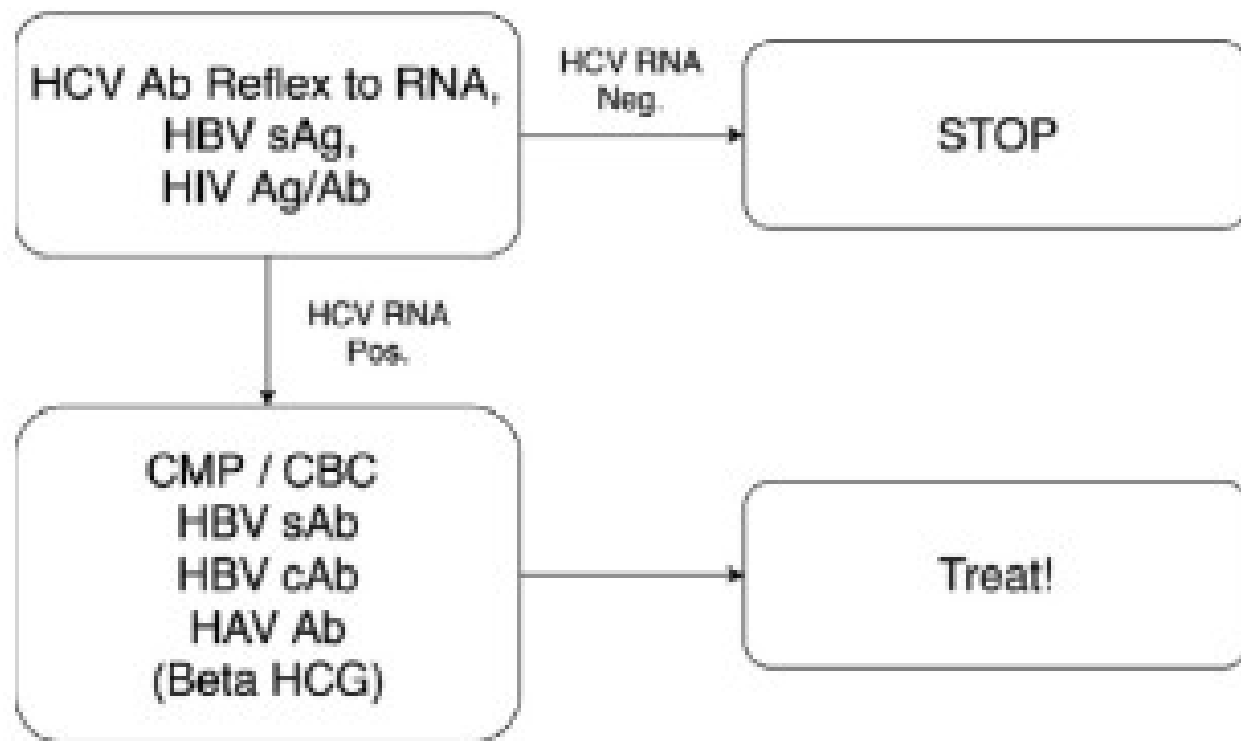
HCV RNA prevalence
26%

Andrew Seaman, MD
Assistant Professor of Medicine, Oregon Health & Sciences University
Director of Hepatitis and HIV Services, Central City Concern

Solving for pre-treatment loss to follow up

- HCV Ab reflex RNA available since 2016
- But: challenges completing full treatment evaluation!
- Collaborated with Labcorp to link pre-treatment eval to HCV screening 2018 -> Implemented 2019

Screening-to-Treatment Lab Bundle*



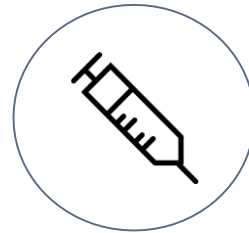
*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.

Health Setting Reflexive Screening Process

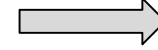
- Labs ordered by intake staff, universal opt-out
- Patients proceed to internal lab
- 100-300 tests / month
- Labs result in HCV provider inbox
- Provider reviews, orders DAA, insurance Prior Auth approval
- Start treatment Visit #2

Visit #1

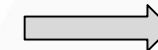
Labs Ordered -> Lab
(Intake Staff)



Phlebotomy
(Phlebotomist)



Medication
Review
(Provider)



Visit #2

Treatment Initiation
(Provider or Pharmacist)

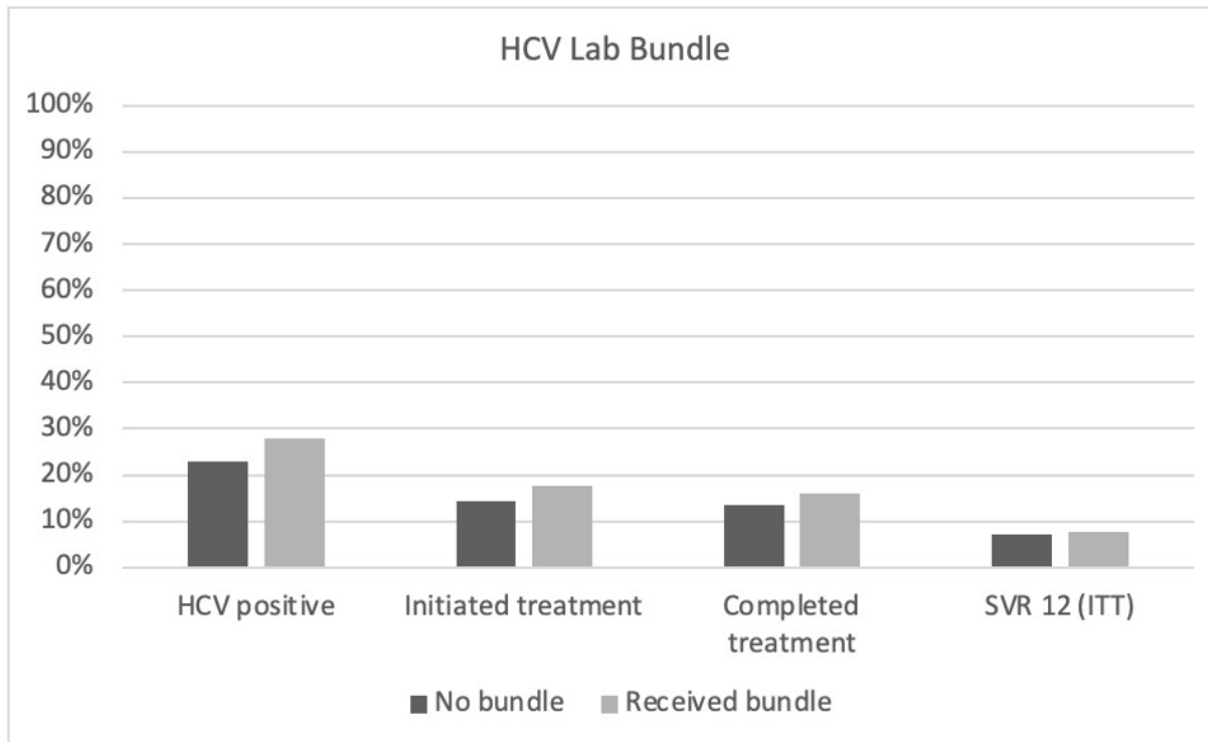


Modified graphic courtesy of Jason Grebely, Kirby Institute

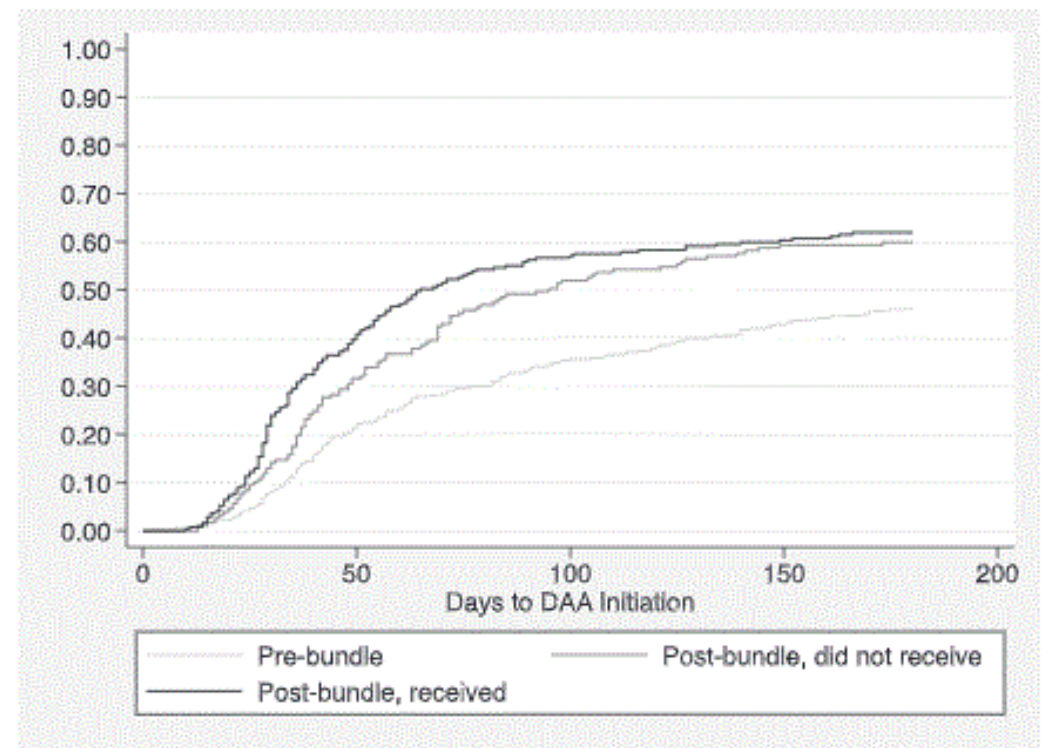


Lab bundle decreases time-to-treatment*

Multinomial logistic regression adjusted prediction of care cascade progression*



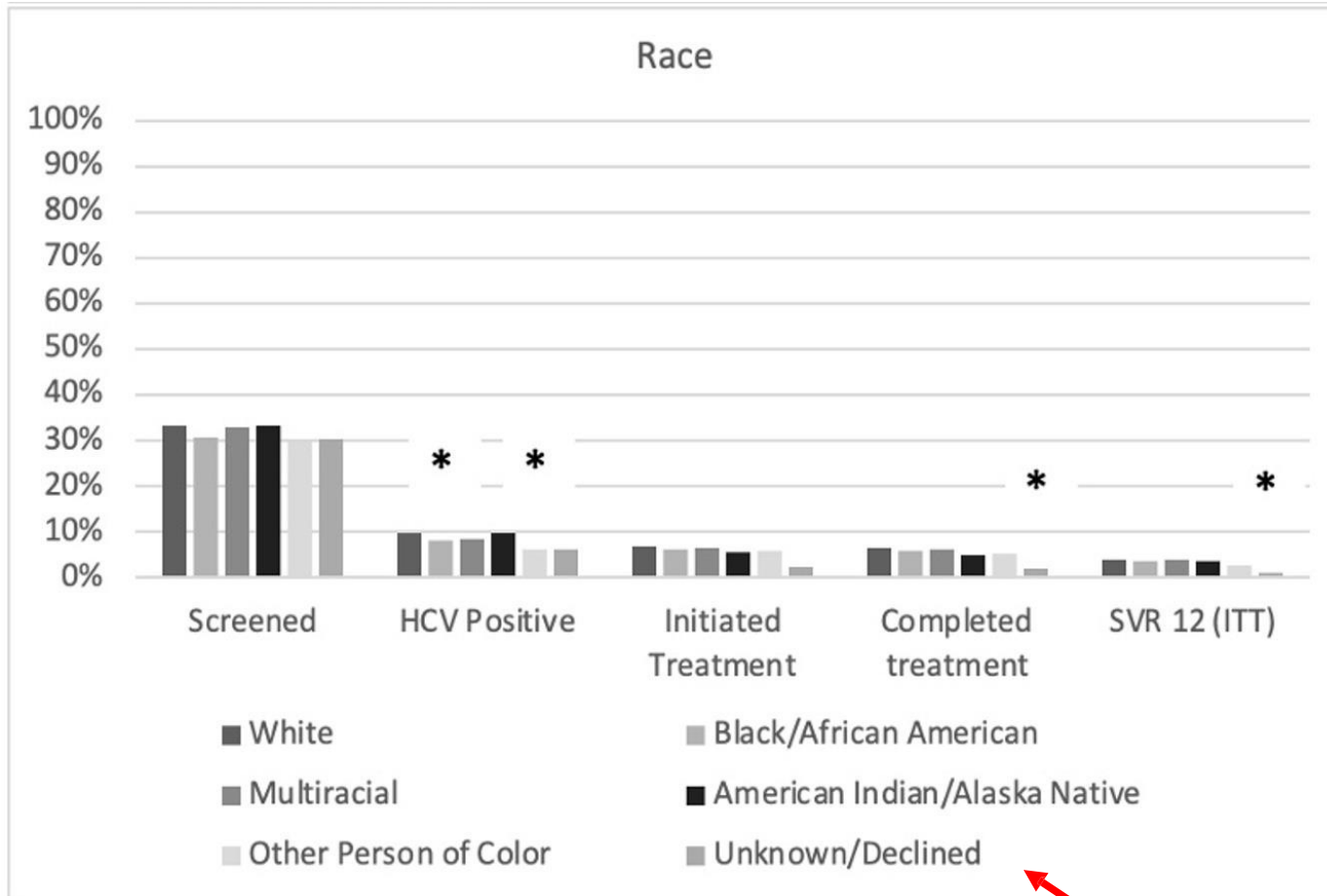
Lab bundle decreases time-to-treatment*
Adjusted Kaplan-Meier Curve, receipt of treatment



*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.



Equity Assessment: Race

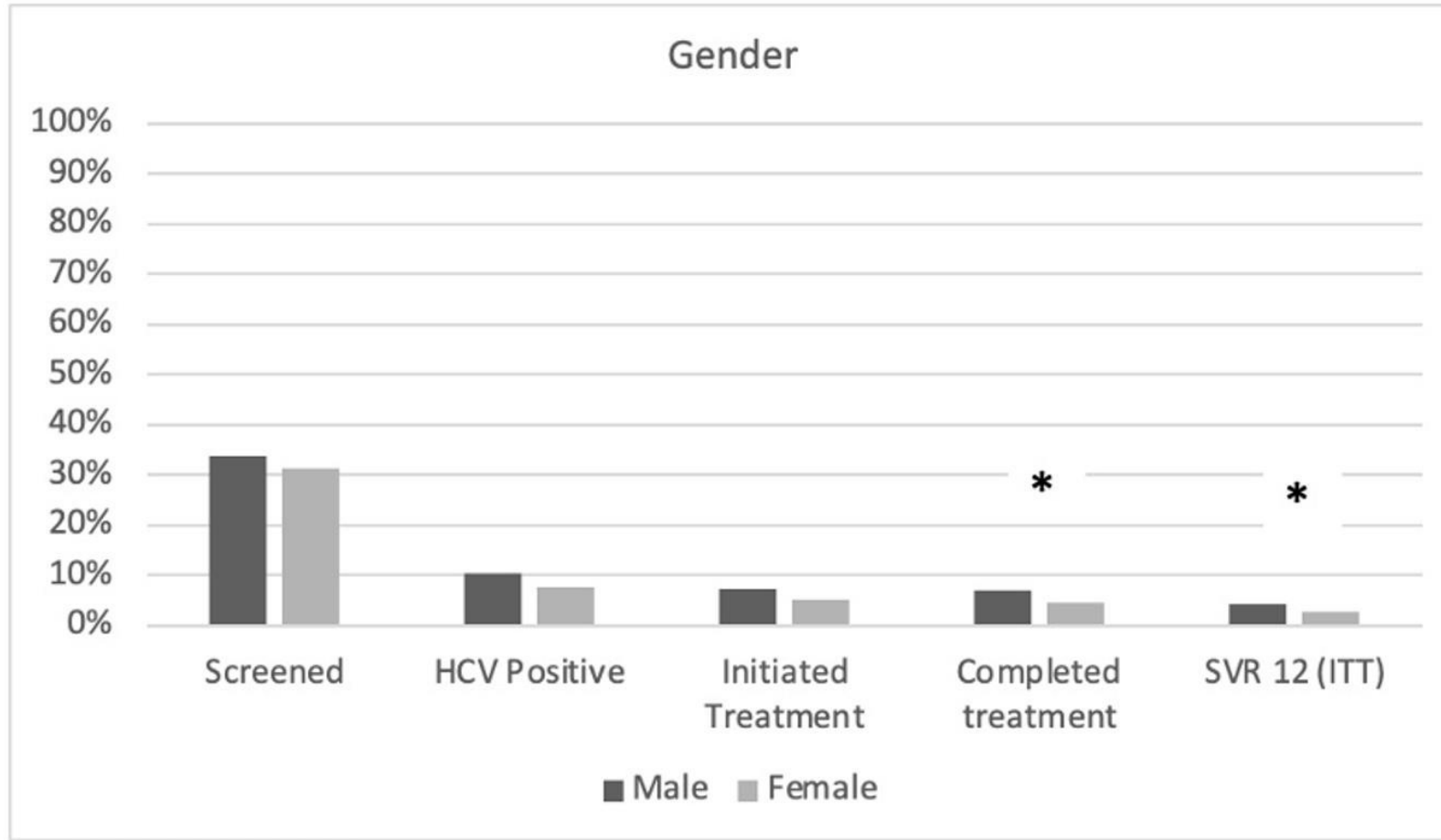


- No difference in screening / Tx across ALL groups
 - Less equity in Tx completion/SVR12
- ➔ Culturally specific case management

Mostly Latinx, Pacific Islander

*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.

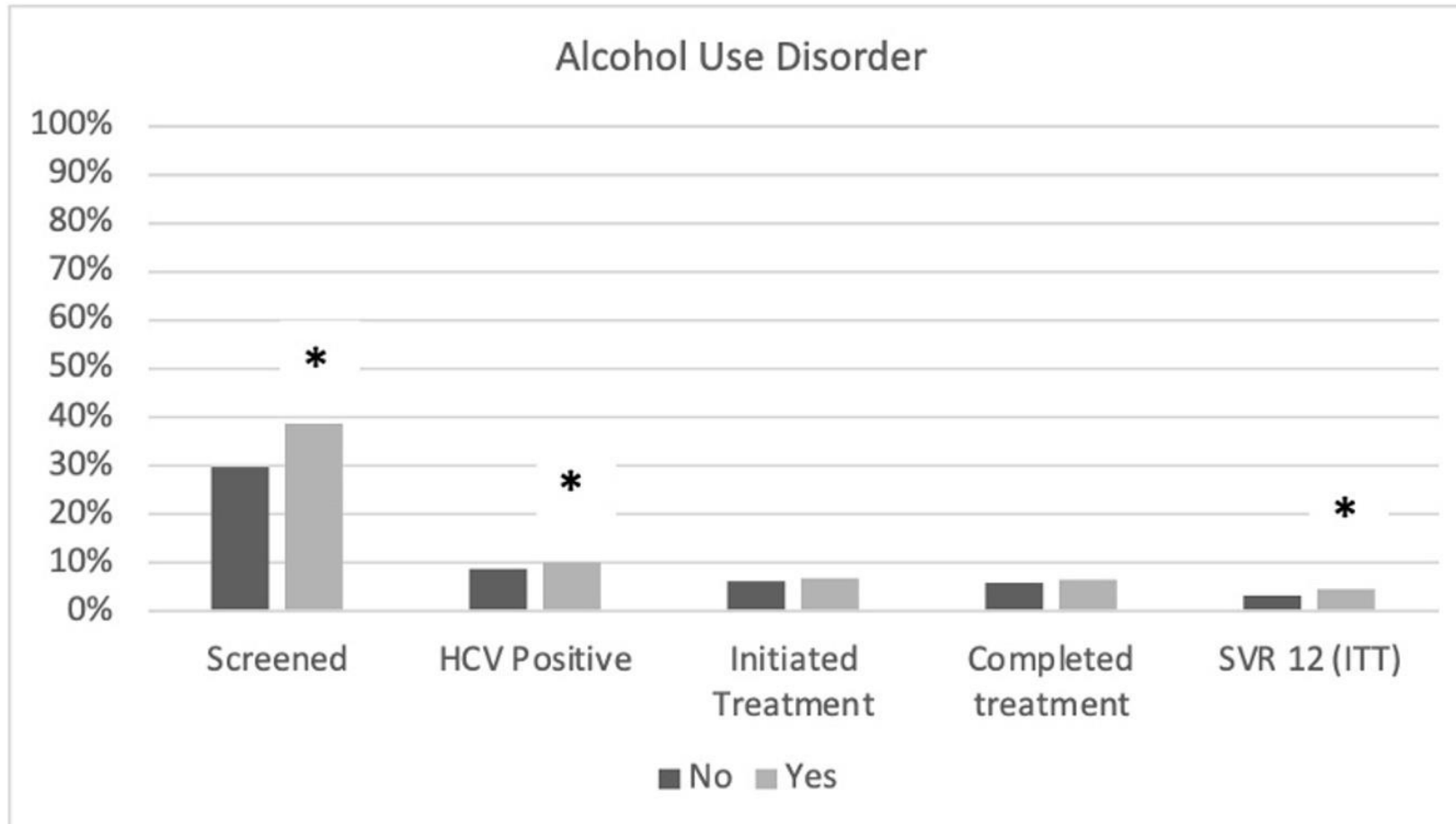
Equity Assessment: Gender



- Female-identifying less likely to complete Tx / SVR12
- Due to competing demands?

*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.

Equity Assessment: AUD

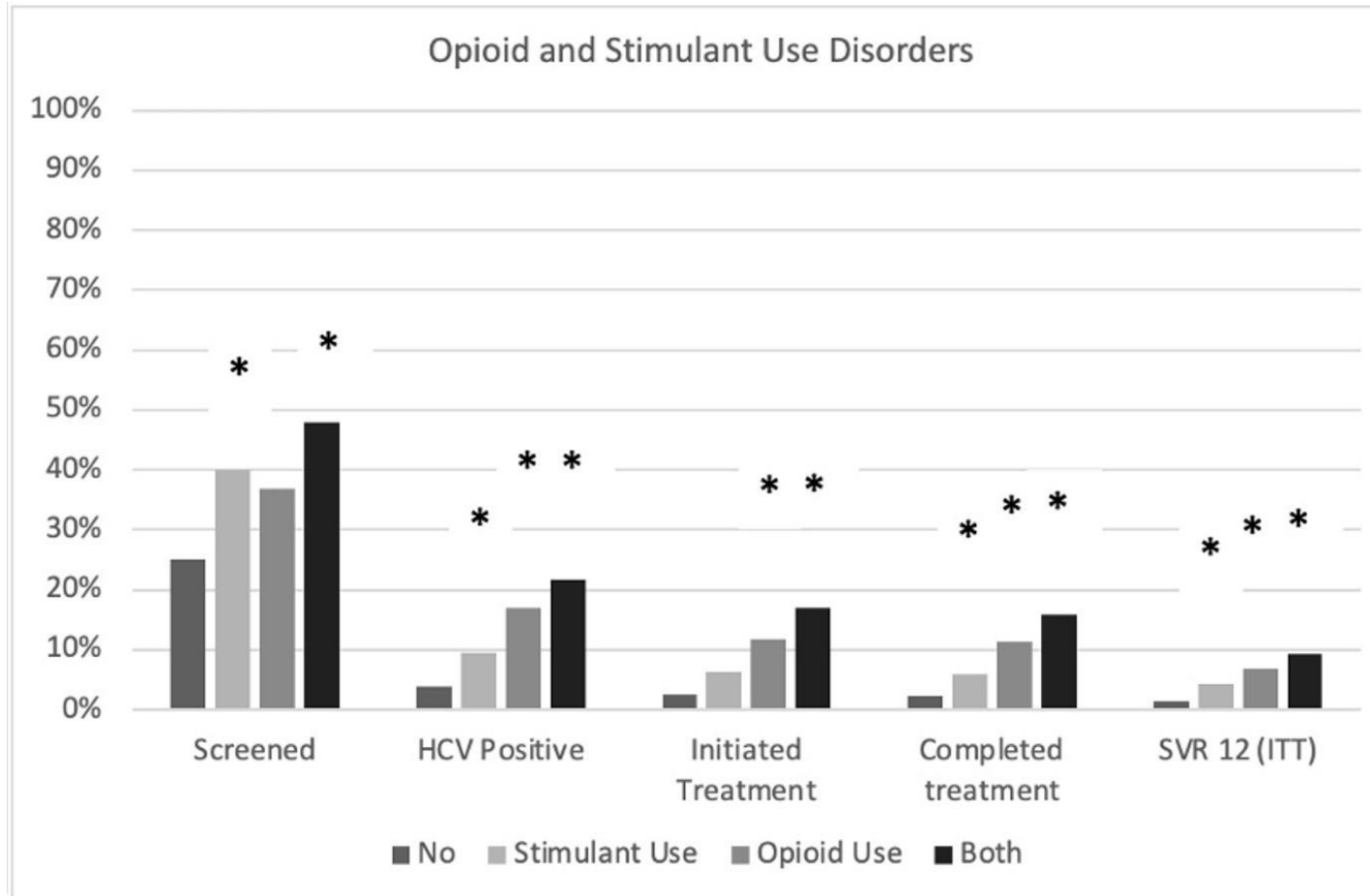


*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.



THE TASK FORCE FOR GLOBAL HEALTH

Equity Assessment: Opioid and Stimulant Use



*Source: Seaman A, King CA et al. Int J Drug Policy. 2021 Jul 26:103359.

Operational considerations / Challenges

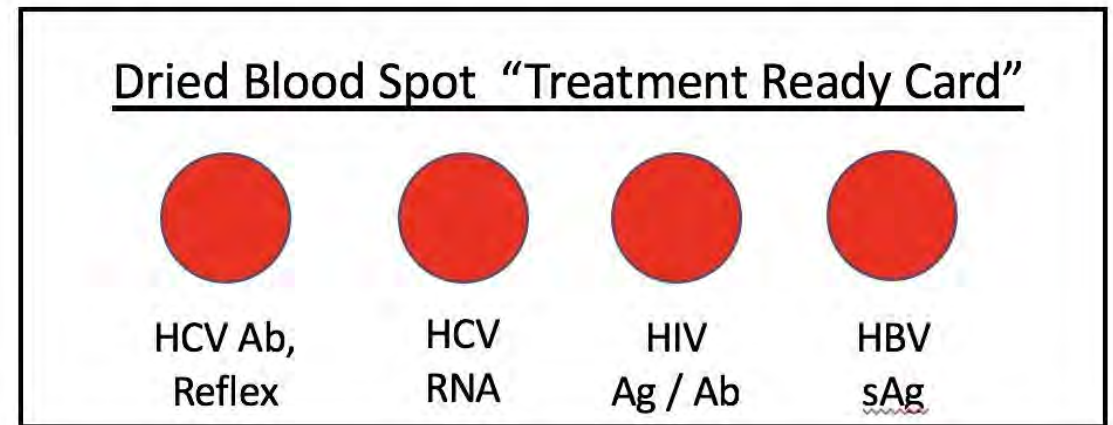
- High volume of blood:
 - HCV reflex testing, HBV: 1 SST (HCV Ab) + 2 SSTs (PCR) + 1 SST (HBV)
 - HIV: dedicated SST
 - CMP/Serologies: 1 SST
 - Platelets: 1 K2-EDTA
- Requires skilled phlebotomists in PWID population
- Primary lab-based challenge → designing sample storage systems for multiple reflex tests

Economic considerations

- Reflex testing cost dependent on what is completed:
 - If HCV Ab is non-reactive, charge payers for HCV Ab, HIV Ag/Ab, HBV sAg alone
 - If HCV Ab reactive, charge for all pre-treatment eval labs

Solving for confirmatory testing in outreach settings, or pts with difficult venous access

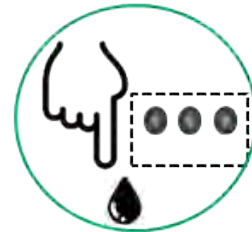
- Phlebotomy challenging in outreach settings / in PWIDs
- HCV RNA available on Dried Blood Spot outside US, not validated yet here
- Partnered with Molecular Testing Labs to validate HCV RNA w/ reflex




Outreach / Opioid Treatment Program Reflexive Screening Process

- Specimens collected by outreach workers on street, in methadone clinics, or self-testing (supported housing)
- Incentive provided at time of results relay
- Automated reflex testing
- 50-80 tests / month

Visit #1



Dried blood
spot sample


Central Lab
→
RNA test
1-2 weeks

Visit #2



Receive diagnosis

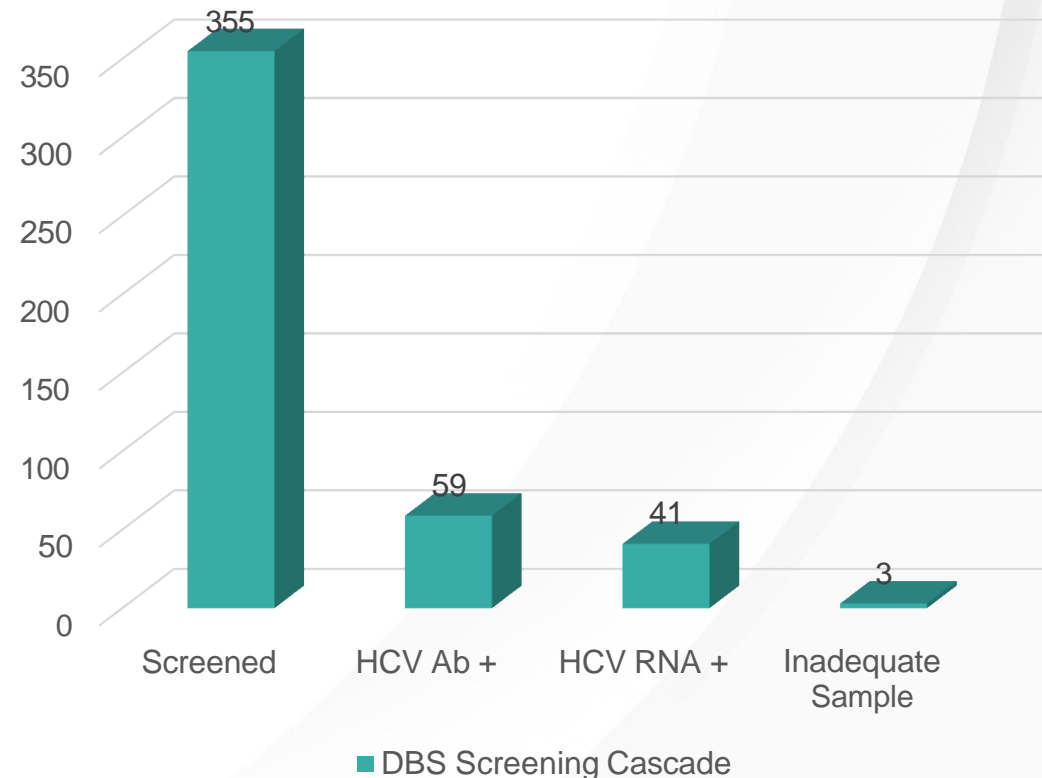
Outreach worker
\$15 incentive!

Impact

- 355 HCV Ab reflex RNA Dried Blood Spot tests done in first 5 months of program; 95% + antibodies successfully completed RNA confirmation
- Turnaround time 3-12 days (shortens as volume increases)
- Treatment / Linkage-To-Care data pending

Andrew Seaman, MD
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Director of Hepatitis and HIV Services, Central City Concern

DBS Screening Cascade



Operational considerations

- Training on optimal card saturation crucial
- RNA requires 8 punches (3-4 circles); 2 full cards for “Tx Ready Panel”
- Hand warmers, patient hydration helpful
- Results relay at 1-2 weeks delay challenging in outreach settings
- Still must complete some liver assessment (FIB-4) prior to treatment → phlebotomy
- Self-testing useful (esp during pandemic!), but requires planning/support to link with payor details

Summary of benefits of reflex testing/Advice to other programs

- Reflex testing is essential; ~no utility of lab-based testing with antibody alone
- Primary operational lift is with the lab; mostly systems design around reflex specimen storage, avoiding specimen contamination, minimizing blood volume
- Recommend minimizing blood volume required by addressing specimen contamination issues, streamlining tube collection
- DBS helpful for outreach / difficult population, but single-draw lab bundle likely more impactful for health settings

What's Working / What's Not Working in HCV Dx

Working

- Excellent assay performance characteristics
- Dual testing claims (qual + quant)
- Auto-reflex to HCV RNA testing for HCV Ab+ specimen
- Medium- (200 – 500 / day) to high-throughput (>500 / day)
- Semi- or fully automated systems
- Batched or random-access testing ability
- Multi-analyte simultaneous testing (integrated HIV-1, HBV, HCV testing)

Not Working

- No Ag assays in U.S. for detection of acute HCV infection
- No FDA-approved / -cleared indication for HCV
- Missed reflex to HCV RNA testing at facilities performing only HCV Ab testing
- U.S. CMS-mandated CPT code to differentiate screening vs diagnostic HCV testing for lab test charge reimbursement
- >72 hrs on HCV RNA results



What are the ideal solutions?

Diagnostic Tools *(medium-to-high throughput laboratories)*

- HCV Ag-Ab combination assays
 - To detect active (acute or chronic) infection
 - Include multiple Ag and Ab targets for good specificity
 - Accept serum plasma, venipuncture & capillary WB, DBS
- Integrated multi-analyte serologic assays (HBV, HCV, HIV, syphilis)
- Low-cost rapid, PoC serologic (USD <\$10) and molecular tests (USD <\$30 / test)



What is needed to get our ideal solutions?

Barriers / Challenges

- CMS-mandated differentiation of HCV Ab screen (CPT code G0472) vs diagnostic testing for test charge reimbursement in U.S.
- Missed reflex to HCV RNA testing for HCV Ab+ specimens
- Separate serum / plasma specimen tubes for initial vs reflex NAT testing to avoid sample-to-sample contamination from automated serologic assay systems
- No NAT as initial testing in current recommended testing algorithm and FDA-approved NAT
- FDA regulatory hurdles for Class 3 devices – future down-classification to Class 2 ?
- Capillary or venipuncture WB, DBS, saliva are not FDA-approved for current lab-based tests
- No standardized DBS collection and processing at PoC for testing at centralized laboratories



What can we do to improve usage of the tools we have?

- Remove CMS-mandated differentiation of HCV Ab screen (CPT code G0472) vs diagnostic testing for test charge reimbursement in U.S.
- Strengthen pre- and post-analytical specimen processing to ensure adequate blood collection and automatic reflex to NAT
- Reduce FDA regulatory burden for IVD industry to submit additional specimen types acceptable for serologic & molecular tests
- Encourage IVD industry to submit NAT as initial testing in those without serologic status
- Update current testing algorithm to include NAT as initial testing option and when suspecting acute HCV
- Changes to agency / institutional policies & operations (screening all, accreditation)



I think one important note to share with them is that many harm reduction programs (and public health departments for that matter) may not be able to bill Medicaid or other insurance providers for services. It is quite hard to get access to free reflex testing to be administered in the field. It is much easier to access free or low cost point of care tests (which of course only gives us an HCV antibody result).

At the Virginia Harm Reduction Coalition we have invested in blood draw tubes and a small centrifuge that we can bring on outreach in our mobile unit as well as a handheld ultrasound machine which helps with blood draws from difficult veins. However, to process a sample is costly and we have to rely on donated services by major laboratories or grant \$, both of which are hard to come by as you know. Partnerships with public health or health systems that allowed us to process claims through insurance providers would be very impactful in states like ours with Medicaid expansion. Many rural health departments rely on donated rapid HCV antibody tests which would be unnecessary if they were set up to bill insurance and do reflex tests.

CDC DVH is increasingly interested in time to treatment initiation for HCV. Of course, reflex testing is helpful in speeding up the process but until we have point of care confirmatory tests we cannot achieve same day starts as we do for HIV treatment.

Lauren Canary Advisor NVHR National Viral Hepatitis Round Table

The tables below are from a KY Medicaid Claims data study (2010 to 2019). Though the info are not directly related to reflex testing, they speak volumes on the very poor health comes of those enrolled in Medicaid and diagnosed with chronic HCV.

- From HCV dx to DAA treatment = 8.58 years (mean)
- From HCV dx to death (all causes) and no treatment = 675 days

Credit to KY Medicaid, University of Louisville and Norton Healthcare. Via Michelle Rose (contact information in the notes box below)

- 5.6% HBV+
- 21% Type II diabetes
- 68% opioid use disorder
- 53.1 years – median age at death

Timeline	Days from Hep C Dx to DAA Tx (Median)	Days from Hep C Dx to HCC Dx (Median)	Days from DAA Tx to HCC (Median)	Overall (Median)	HepB	Diabetes II	OPIOID
1. DAA and HCC (n=139)	553	1183	412	8.13 Years	5% (7)	42% (59)	53% (74)
2. HCC Prior to DAA (n=98)	1004	480	(-)131	9.37 Years	3% (3)	43% (42)	62% (61)
3. No DAA with HCC (n=866)	N.A.	296	N.A.	3.65 Years	5.4% (47)	35% (306)	34% (291)
4. HCV no HCC no DAA (n=66,213)	N.A.	N.A.	N.A.	8.58 Years (Mean)	5.6% (3740)	21% (13,672)	68%(44,733)

Timeline	Days from Hep C Dx to Death (Median)	Days from HCC Dx to Death (Median)	Days from DAA to Death (Median)	Age at Death (Median)	Gender Male (%)	LOCATION TYPE Rural (%) Urban (%)
1. DAA and HCC (n=139)	1,616 (n=55)	191 (n=55)	825 (n=55)	56.6	95 (68%)	12 (9%) 32 (23%)
2. HCC Prior to DAA (n=98)	1,595 (n=23)	643 (n=23)	333 (n=23)	57.1	63 (64%)	5 (5%) 17 (17%)
3. No DAA with HCC (n=866)	675 (n=583)	120 (n=583)	N.A.	57.8	670 (77%)	66 (8%) 282 (33%)
4. HCV no HCC no DAA (n=66,213)	675 (n=8,189)	N.A.	N.A.	53.1	33,193 (50%)	8,136 (12%) 28,053 (42%)

3-in-1 Rapid Blood Self-testing for HIV, HBV and HCV: Acceptability and Feasibility

Courtesy of:

Nicolas Salvadori, Jullapong Achalapong, Chonlatorn Boontan,
Surachet Arunothong, Wootichai Khamduang, Phornphimon Moolnoi,
Sakorn Pornprasert, Sumet Ongwandee, Jean Yves Mary, Gonzague Jourdain,
Nicole Ngo-Giang-Huong, for the Napneung Project Team

3-in-1 Rapid Blood Self-testing for HIV, HBV and HCV: Acceptability and Feasibility

METHODS

Setting and population

Client-initiated testing services for HIV, HBV, HCV and syphilis provided free of charge to consenting individuals aged ≥ 15 years in 4 facilities in northern Thailand—3 in Chiang Mai and 1 in Chiang Rai—as part of the ‘Napneung’ research project (NCT04585165)

Self-testing process

- Clients invited to choose between self-testing by fingerprick or blood collection by a HCW using 2 immunochromatographic rapid diagnostic tests that can be used with whole blood:
 - TriQuik™ (Genlantis, San Diego, CA) for the detection of HIV-1/2 antibody, hepatitis B surface antigen and hepatitis C antibody
 - Alere Determine™ Syphilis TP (Abbott Diagnostics, Chiba, Japan) for the detection of antibody to *Treponema pallidum* proteins
- Several clients could simultaneously self-test in separate areas ensuring client privacy
- Through a program on a tablet computer, self-testers:
 - Performed self-sampling as described step by step in a series of short videos
 - 15 minutes later, took a picture of the cassette/strip for immediate remote electronic review by the HCW
 - Reported their interpretation of the results

Statistical analyses

- Satisfaction compared between self-testers and non-self-testers using Wilcoxon rank-sum test
- Sensitivity and specificity of self-tester’s interpretation of test results estimated along with their Clopper-Pearson 95% CI, using HCW’s interpretation as the reference

3-in-1 Rapid Blood Self-testing for HIV, HBV and HCV: Acceptability and Feasibility

RESULTS

Study population

Between October 19, 2020 and September 28, 2021, 2,260 unique clients presented for testing:

- 1,149 (50.8%) born female
- Median age 27 years (IQR, 22 to 34)
- 2,114 (93.5%) born in Thailand
- 1,337 (59.2%) never previously tested for HIV
- 459 (20.3%) belonged to at least one key population
- Supervised by one of 16 HCWs

Uptake and acceptability of multiplex self-testing

- 1,844 (81.6%) clients opted for self-testing
 - Of 1,755 self-testers who reported their satisfaction level on the testing process:
 - 1,637 (93.3%) 'very satisfied'
 - 114 (6.5%) 'satisfied'
 - 3 (0.2%) 'dissatisfied'
 - 1 (0.1%) 'very dissatisfied'
- Similar to
non-self-testers
(p=0.47)

The biggest barrier we face is less about reimbursement and more about total cost of quantitative RNA and reflexive RNA testing. Most patients have access to some type of antibody testing at little to no cost. The state of Missouri, where I practice, has done several initiatives providing rapid test kits to community health centers at no cost. But it is the confirmatory quantitative HCV RNA or the reflexive Ab/RNA tests are both costly to the patient and often patients won't complete it because of the anticipated costs of labs and and lack of non-specialist treatment options. For example, if the provider orders the HCV Antibody with reflex to RNA, it is often \$0.05 if the antibody is negative but ranges \$150-250 (depending on the lab company) if positive and the RNA is calculated. It is an exceptional barrier to treatment.

Also, the rapid antibody test kits cost us around \$17/test. So while we want to include it with opt out HIV testing, that is not always feasible due to cost. I am fortunate enough to practice in an FQHC that has a system of paying for these labs and a sliding scale (up to 100% discount) for visits. So when I provide Hep C treatment, I am able to provide reassurance about cost coverage. But obviously, that is not the case for everyone and cost is a huge barrier to the overall mission of eradicating Hepatitis C.

Happy to help provide anymore information, a provider statement for your presentation, or case examples of barriers if needed.



Rachel Melson

Director Of Provider Engagement

Main: 816-923-5800 | Direct: 816-599-5419

RMelson@swopehealth.org | SwopeHealth.org

3801 Dr. Martin Luther King Jr. Blvd. Kansas City, MO 64130



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Key Takeaways

To reach HCV elimination targets:

We need efficient testing processes

Reflex HCV antibody to PCR testing is key

POC/RDT is an essential step to reach vulnerable populations

HBV testing needs to move to a Class II test from Class III as just happened with HCV testing

Single droplet testing is attractive to clients in multiple settings

Medicaid insurance and all payors need to have payment for serology and NAT testing as automatic

Reflex testing needs to be added to the AASLD guidelines as mandatory to enhance lab uptake and insurance company payments