

Find The **Missing** Millions.

How Patients Lived Experiences Can Inform Viral Hepatitis Screening & Care Efforts

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August 5, 2019

Australasian Viral Hepatitis Elimination Conference



ELIMINATE ~~HEPATITIS~~



ELIMINATION

will not be achieved without involving
PEOPLE WHO ARE AFFECTED
by viral hepatitis



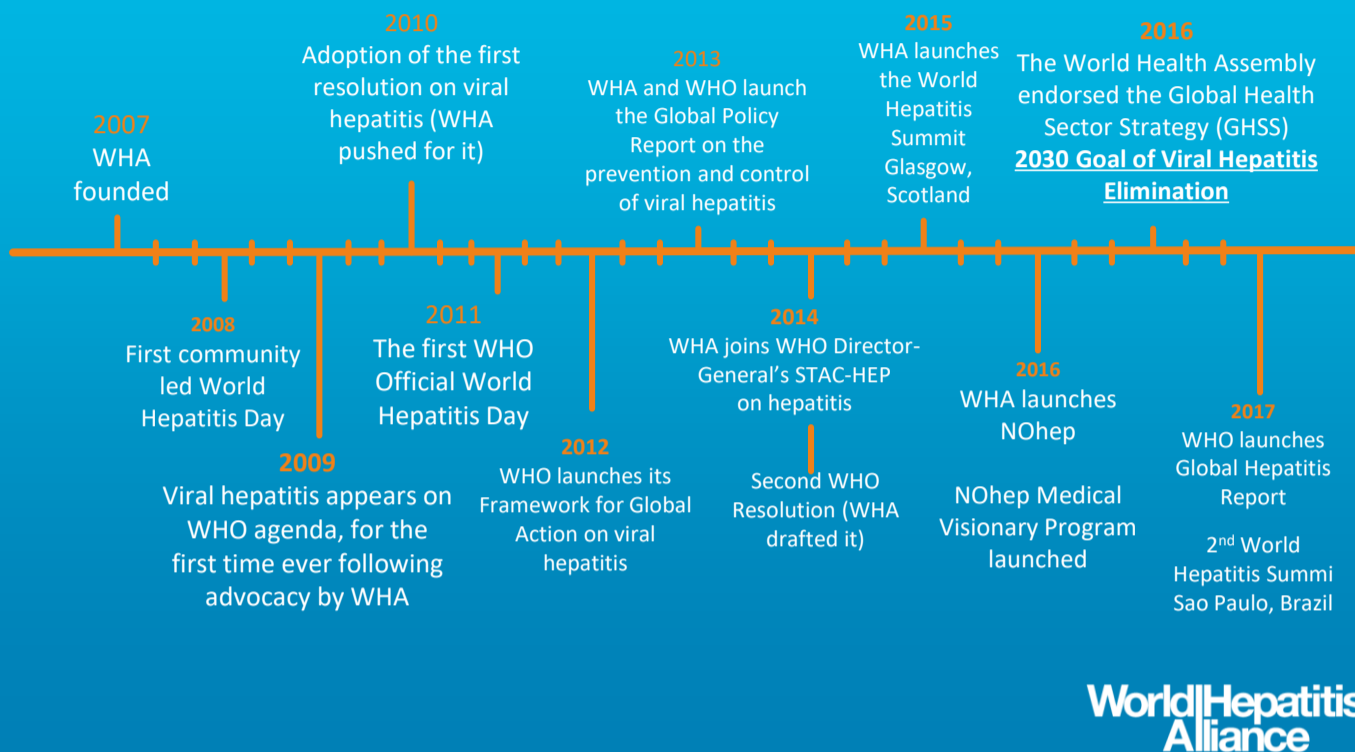


OUR MISSION

Harness the power of people living with viral hepatitis to achieve its elimination.



World Hepatitis Alliance: Our first 10 years



Living with Hep B...

"I am embarrassed and paranoid about sharing my status with family and friends - even HCPs. During my first appointment, my GI doctor said to me "you should have known better" when I shared how I contracted hep B.."

"Africa looks towards the Western World in finding permanent cure for Heptatis Virus. As of now, many will continue to die, infected and get isolated due to lack of timely medical interventions and stigma due to economy and poor health infrastructures

"Honestly, there is too much discrimination in my own country about this HBV. I feel down about this, all my dreams seem to be eliminated my this disease."

"I just got diagnosed of chronic hepatitis b, and to be honest, I feel like committing suicide. I'm just 23 and I've had only one partner my whole life."

I am positive hepatitis B since a year now, pls sir I really need help I have try type of drugs but still same pls help me sir,I cannot even afford for all test needed,pls help me, its like I will die soon plss

Slide courtesy of Maureen Kamischke, Hepatitis B Foundation



ELIMINATE HEPATITIS

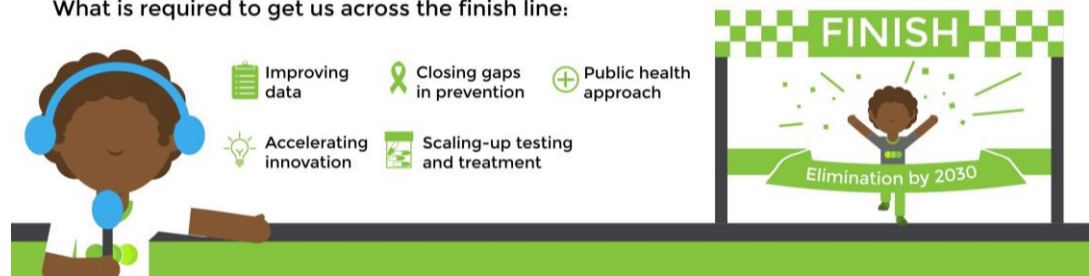


The race to elimination by 2030



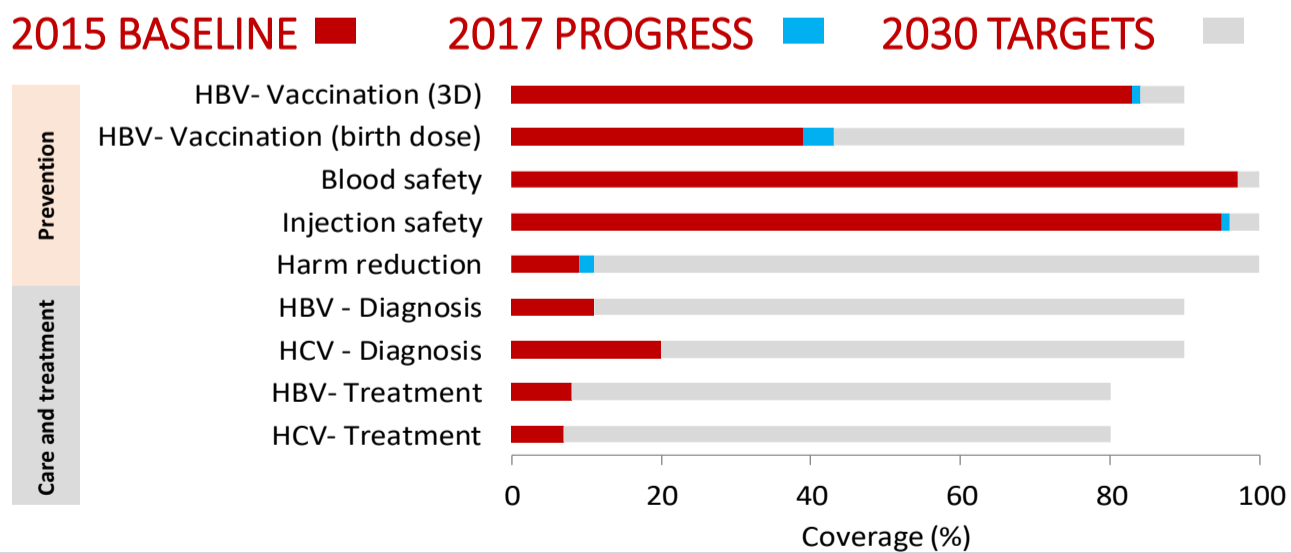
Commentary and Analysis

What is required to get us across the finish line:



Global Elimination Strategy:

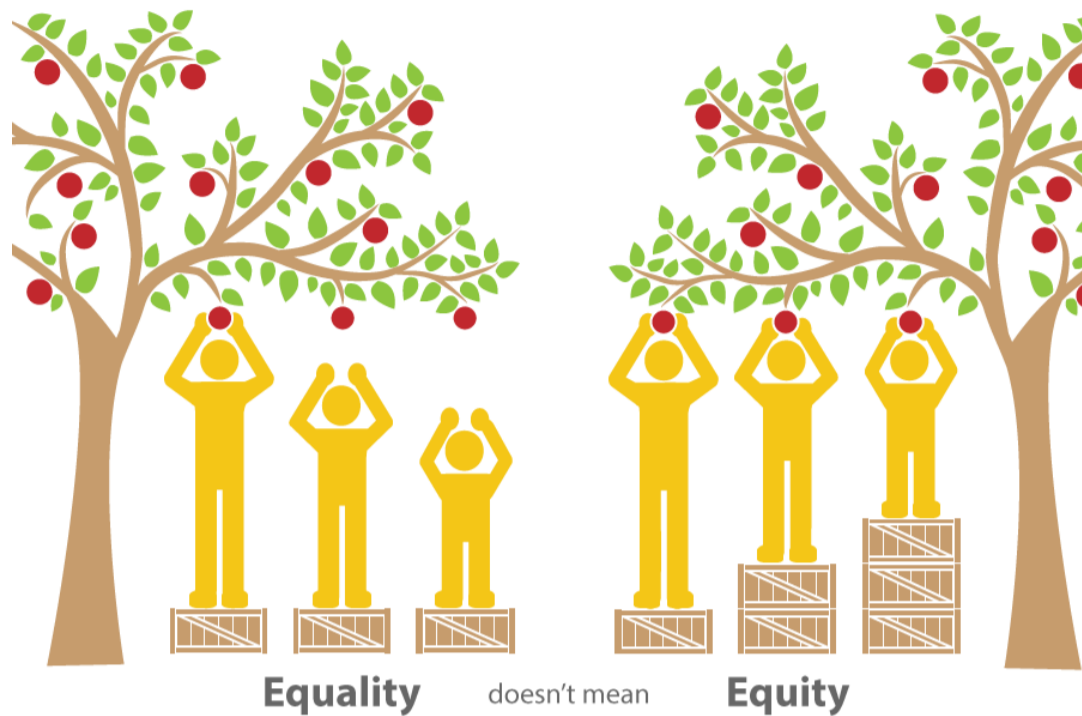
Core interventions with sufficient coverage would lead to elimination



Major gaps in HBV birth dose, harm reduction, testing and treatment



We won't achieve viral hepatitis elimination without addressing health equity



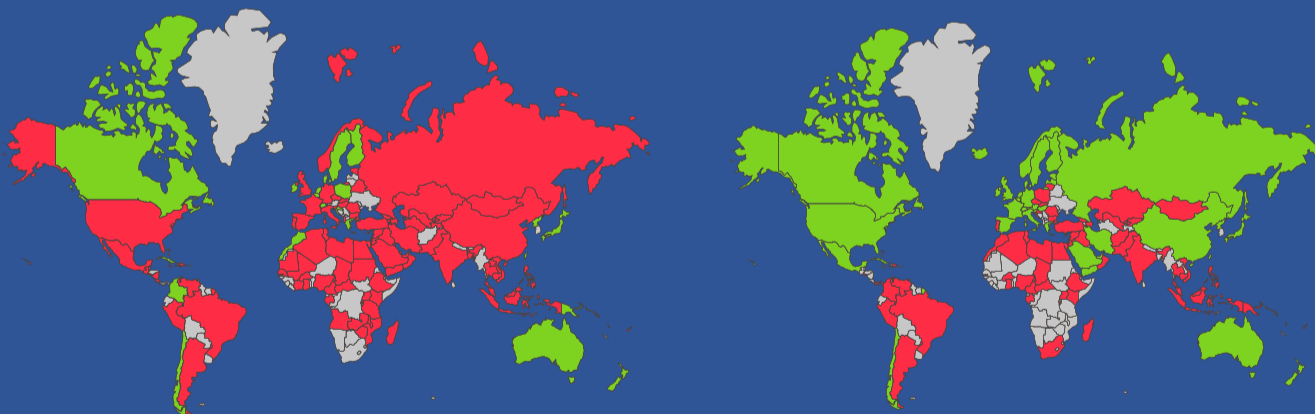
We have the tools.

We can screen, vaccinate, and treat hepatitis with medication & cures.
But the people most at-risk don't have access.

Global Diagnosis Rates are Low

Global HBV Dx Rates

Global HCV Dx Rates



- Countries on target to reach WHO's interim target of 30% by 2020
- Countries not on target to reach WHO's interim target of 30% by 2020
- Data not available

Find The **Missing** Millions.

Overcoming the barriers to diagnosis: The Role of Civil Society and the Affected Community in the viral hepatitis response.

The Importance of Involving Civil Society and the Affected Community in the Response

People living with viral hepatitis and the affected community should be at the heart of every effort to eliminate viral hepatitis. Aside from fulfilling the need for trusted entities that consistently disseminate reliable information, civil society organisations bring fundamentally important perspectives and experiences which greatly enhance the effectiveness of strategies and programmes.



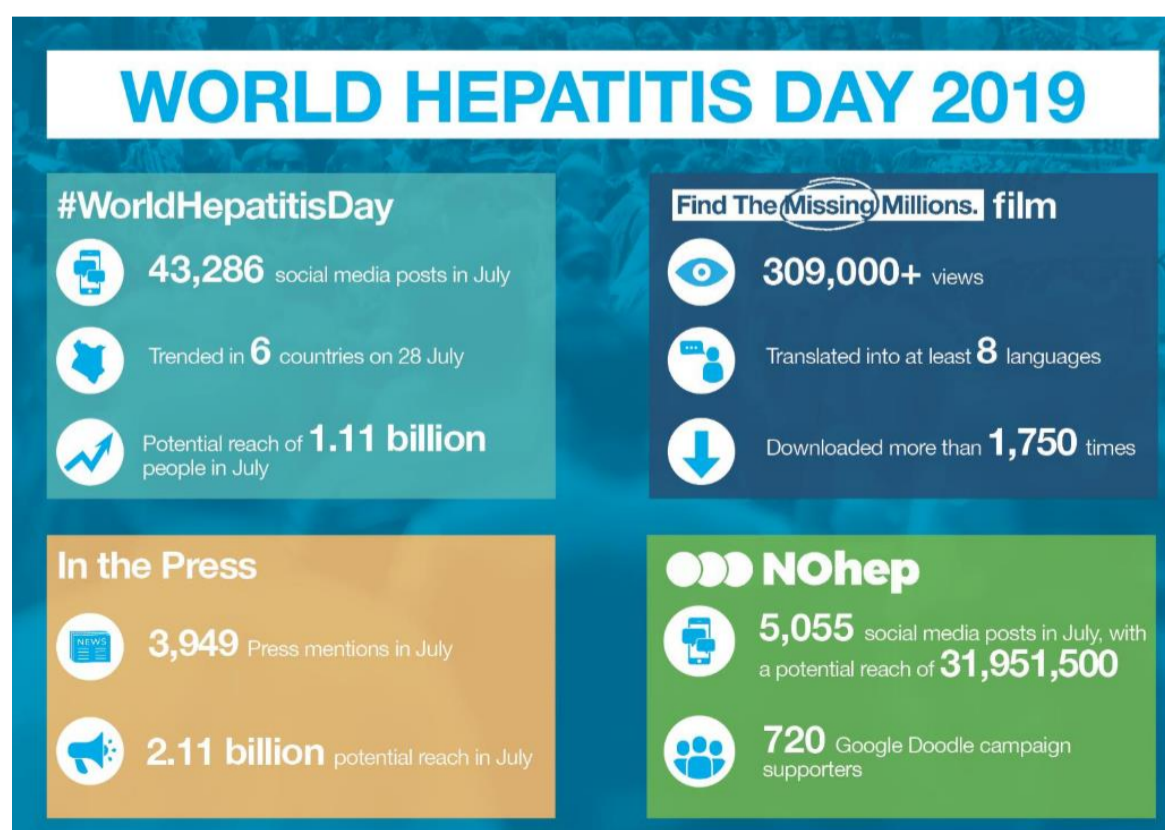
Five main barriers to HBV/HCV testing (2018 global survey)

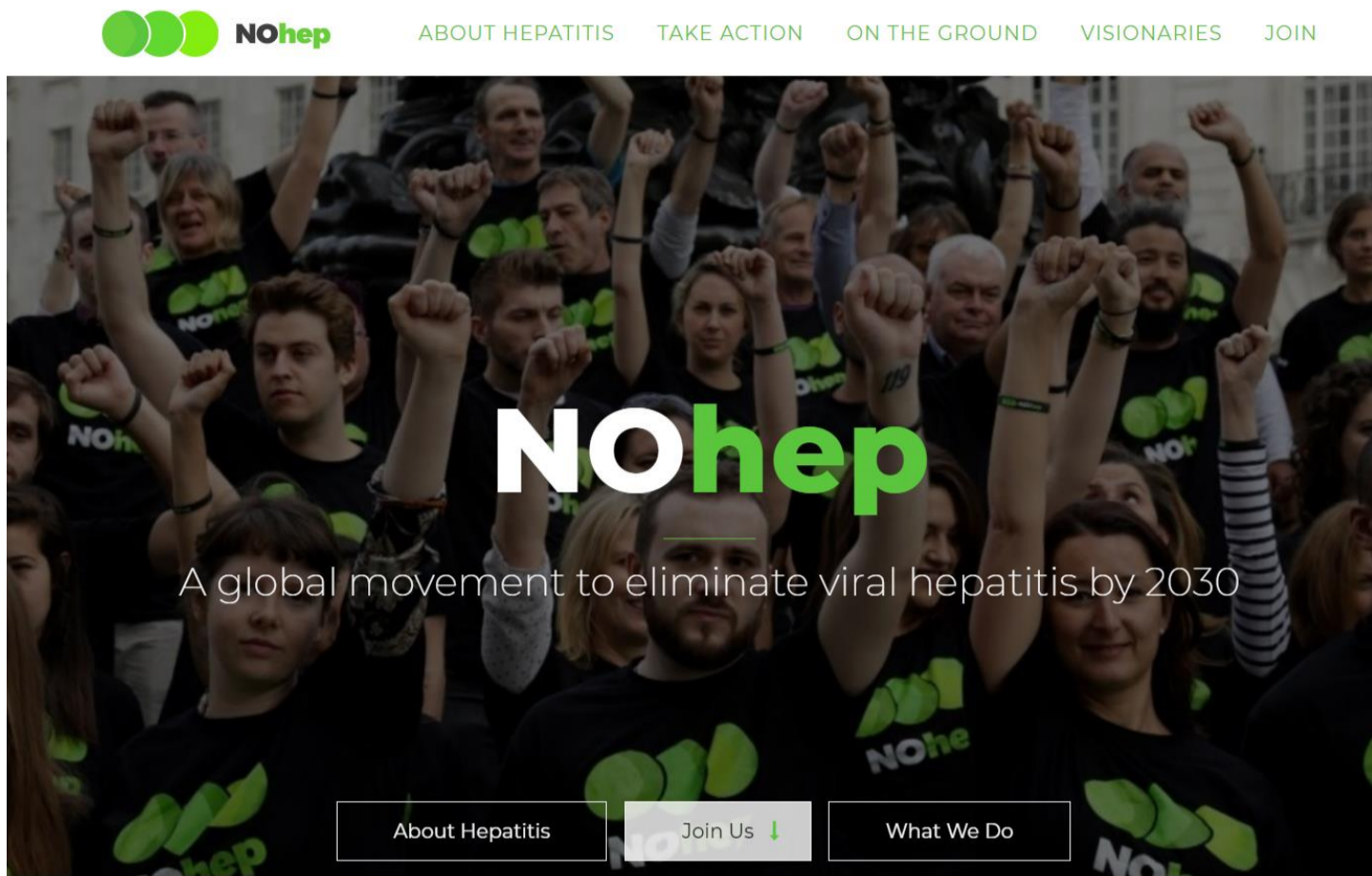
- 1 Lack of public knowledge of the disease
- 2 Lack of knowledge among healthcare professionals
- 3 Lack of easily accessible testing
- 4 Stigma and discrimination
- 5 Out-of-pocket costs for the population



Overcoming the Barriers to Finding the Missing Millions: The Role of Civil Society and the Affected Community White Paper, World Hepatitis Alliance 2019

1 Lack of public knowledge of the disease

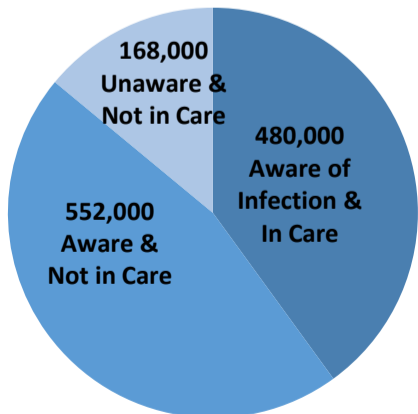




2 Lack of knowledge among healthcare professionals

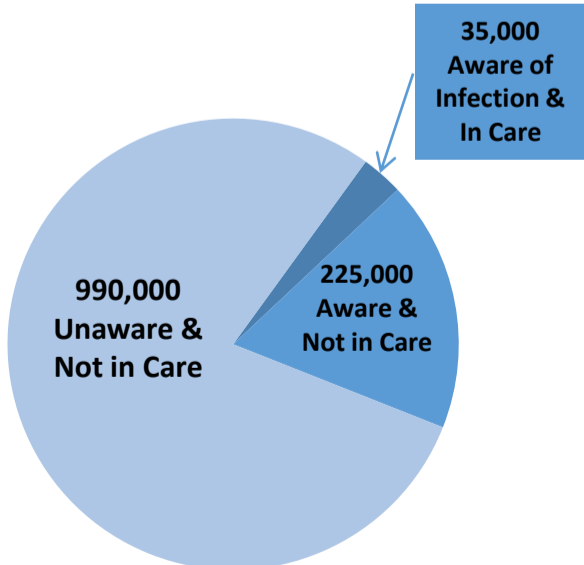
1,200,000
in US with HIV

Routine Screening
One time for all adults, as of 2006



1,250,000
in US with Chronic HBV


Risk-Based Screening



HIV – CDC HIV Surveillance System & Monitoring Project, 2011 <https://www.cdc.gov/vitalsigns/hiv-aids-medical-care/>
 HBV - Cohen, C. (2011) Is chronic hepatitis B being undertreated in the United States?. Journal of Viral Hepatitis, 18: 377–383

THE NOhep GUIDE FOR MEDICAL PROFESSIONALS

5 PRINCIPLES FOR TAKING ACTION TO ELIMINATE VIRAL HEPATITIS



BECOMING A NOhep MEDICAL VISIONARY

This section provides YOU with a practical guide for delivering progress and change – using the 5 Principles of a NOhep Medical Visionary. These principles provide guidance and actionable steps that you can take TODAY to work towards the elimination of viral hepatitis.


Over the following pages, you will find information, ideas and tools to help you implement these principles and play your part in a powerful global effort to eliminate viral hepatitis.

NOhep Medical Visionaries are medical professionals committed to the elimination of viral hepatitis by 2030.

- They maximise the role of medical professionals in improving hepatitis diagnosis, linkage-to-care, treatment and chronic care;
- They make a real difference to elimination efforts through bold and innovative actions (be that at a local, regional, national or international level) that advance progress and bring about change; and
- They actively engage peers, other medical professionals, budget holders, patients, the public and political decision-makers to advocate for change.

PRINCIPLE 4 CASE STUDY

DR SAEED HAMID, IBNE SINA PROFESSOR AND CHAIRMAN, DEPARTMENT OF MEDICINE THE AGA KHAN UNIVERSITY, KARACHI, PAKISTAN



Working with communities to increase capacity

10% of the global hepatitis C burden lies in Pakistan, with 71 million people living with the disease. According to a recent WHO report, 90% of cases are not diagnosed and less than 160,000 people were treated in 2016. National efforts towards eliminating the virus have been minimal with the bulk of efforts being carried out by NGOs on the ground.

Recognising the pivotal role healthcare practitioners play in raising awareness of the disease and scaling-up diagnosis and treatment, Dr Saeed Hamid, Ibne Sina Professor and Chairman of Department of Medicine at The Aga Khan University, Karachi, Pakistan, embarked on a series of activities to engage them in the fight against viral hepatitis.

Dr Hamid has used his role as a medical professional to interact with the community and healthcare workers. One of the key projects he is currently working on is The Echo Community Project titled "Extension of Hepatitis C Screening, Diagnosis and Treatment into the Community: A Low Cost, One Window, Test-and-Treat Model for Pakistan."

The project goes into communities to educate general practitioners on viral hepatitis and screening. Over the course of 4 weeks, with the help of online modules and face-to-face workshops, general practitioners are educated in community screening using rapid tests in high prevalence peri-urban areas of Karachi.

This is supported by co-diagnosis using Genie for hepatitis C and linking patients to care. Initially, general practitioners were hesitant about treating people living with hepatitis C, having experienced low success rates with interferon treatments. Once educated on the advancements of the DAA treatment and the positive patient outcomes, they became confident and willing to treat patients through the programme. To date, more than 3811 people have been diagnosed and 54 treated.

4. PRINCIPLES OF A NOhep MEDICAL PROFESSIONAL

"I think there has been a consistent effort to raise awareness and that is now being evidenced. Many people are now aware and are very engaged in the effort. National stats are not just known, they have seen friends and relatives die of this disease"



The NEW ENGLAND JOURNAL of MEDICINE
May 23, 2019

Global Elimination of Chronic Hepatitis

David L. Thomas, M.D., M.P.H.



International journal of science

The silent epidemic killing more people than HIV, malaria or TB

Viral hepatitis B is on the rise. Tackling hepatitis B in Africa is key to fighting back.

NEWS FEATURE • 05 DECEMBER 2018 •




FORGOTTEN NO MORE

A long-overlooked scourge of millions, hepatitis B is in the crosshairs at last

By Jon Cohen

In the quest to cure hepatitis B, an infectious disease that affects as many as 250 million people worldwide, a small laboratory in a hazy part of the Rocky Mountains of Idaho plays an outsize role. The lab, two nondescript buildings that abut a forest of a dirt road, houses 400 woodchucks, also known as groundhogs. These large rodents are a natural host for a cousin of the hepatitis B virus (HBV), making them a favorite research model for studying the disease. The owner, Anne Whipple, both traps pregnant females in the wild and breeds woodchucks in the colony. These days, he says, "it's a job keeping up with the demand."

In woodchucks, as in people, the virus is a shape-shifter. It can be slow, tacking itself away in liver cells and giving few signs of its presence. It can establish a chronic infection, churning out new viruses but doing little harm. Or it can rage, triggering liver damage that can develop into HIV-related cirrhosis or cancer which kills nearly 900,000 people around the world each year. Whipple's woodchucks, which let lab interns with the virus to study its life cycle and assess

THE LANCET GASTROENTEROLOGY & HEPATOLOGY COMMISSION | VOLUME 4, ISSUE 2, P135-184, FEBRUARY 01, 2019

Accelerating the elimination of viral hepatitis: a *Lancet Gastroenterology & Hepatology* Commission

HEALTH POLICY | VOLUME 4, ISSUE 7, P545-558, JULY 01, 2019

A global scientific strategy to cure hepatitis B

3

Lack of easily accessible testing

- Barriers of healthcare infrastructure
 - Provider initiated screening
 - Coverage of screening
- Limited uptake of point-of-care testing

Simple/Rapid Assay (Company)	Report No ^a	Price/test ^b (US\$ (year))	Sensitivity ^c (%) ^e	Specificity ^d (%) ^e	In
ADVANCED QUALITY [®] One Step HBsAg Test (Bionike Inc.)	1	0.75 (1999)	99.0 (94.5 – 100.0)	95.5 (91.3 – 98.0)	
Determine [®] HBsAg (Abbott Laboratories)	1	1.20 (1999)	99.0 (94.5 – 100.0)	99.4 (96.9 – 100.0)	
Doublecheck HBs Antigen (Organics)	1	1.00 (1999)	99.0 (94.5 – 100.0)	96.1 (92.1 – 98.4)	
Genelabs Diagnostics Rapid HBsAg Test (Genelabs Diagnostics Pte Ltd.)	1	0.63 (1999)	99.0 (94.5 – 100.0)	97.8 (94.3 – 99.4)	

https://www.who.int/diagnostics_laboratory/evaluations/en/hep_B_rep1.pdf?ua=1



Novel Screening Coupon: Patient Initiated at Outpatient Labs

**If you or your parents are from ONE OF THESE COUNTRIES...
You are at risk for Hepatitis B!**

Hepatitis B is the world's leading cause of liver cancer

**Do you know your status?
Get tested for free!
2 out of 3 with Hepatitis B are not aware.
Get tested at one of the locations on the back.
LiverBWell.com**

Get Your Free Test — Visit One of Our Hepatitis B Screening Sites Today!
Building Bridges to Liver Health: A Northern New Jersey & New York City Hepatitis B Collaborative Program
LiverBWell.com

NORTHERN NEW JERSEY — You Must Bring This Coupon

CENTER FOR ASIAN HEALTH Call for appointment
Phone: 973.322.6888
Hours: M-F 9:00 AM – 5:00 PM
101 Old Short Hills Road, Suite 408, West Orange, NJ 07052

**NEW YORK CITY
CHARLES B. WANG COMMUNITY HEALTH CENTER** Call for Appointment

- Manhattan:
268 Canal Street, New York, NY 10013
Phone: 212.379.6998
- Queens:
136-26 37th Avenue, Flushing, NY 11354
Phone: 718.866.1212

SAINT BARNABAS MEDICAL CENTER OUTPATIENT LABS Walk-In

- 94 Old Short Hills Road, Livingston, NJ 07039 (Saint Barnabas Medical Center)
Hours: **M – Th:** 6 am – 6 pm
F: 6 am – 4 pm **S:** 6 am – 1 pm
- 200 South Orange Avenue, Suite 105, Livingston, NJ 07039 (Ambulatory Care Center)
Hours: **M, W, F:** 6 am – 5 pm
T, Th: 6 am – 6 pm **S:** 6 am – 2 pm
- 189 Eagle Rock Avenue, Roseland, NJ 07068
Hours: **M – F:** 6:30 am – 5 pm
- 560 Springfield Avenue, Suite 104, Westfield, NJ 07090
Hours: **M – F:** 8 am – 4 pm
- 382 Bloomfield Avenue, Caldwell, NJ 07006
Hours: **M – F:** 7 am – 5 pm
Th: 7 am – 7 pm **S:** 7 am – 3 pm

This is a lab requisition for:
Please fill out your name) First Name _____ Last Name _____
For NJ Lab Personnel:

- Patient must complete consent form (Lab results will be sent by mail, so patient must fill in correct address)
- Patient must complete survey
- Please fax both consent form and survey to 973.322.6886 (For any questions, please call 973-322-6777)

Ordering physician: Dr. Su Wang (ph 973.322.6888 fax 973.322.6886) **Plan Code:** G32 (no insurance info needed)
3 Lab Tests: Hepatitis B Surface Ag & Hepatitis B Surface Ab & Hepatitis B Core Ab IgG

Screening in the ED

New Jersey

Population 9 million, densest state

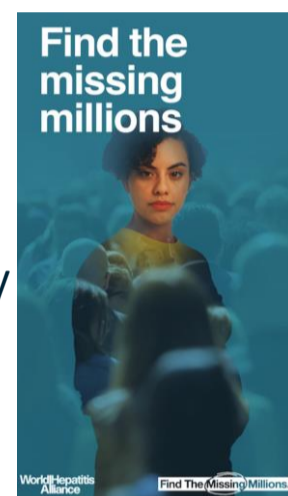
~160,000 living w HCV, ~50,000 with HBV

3rd highest % of foreign-born in US (Asia, Caribbean, Africa)



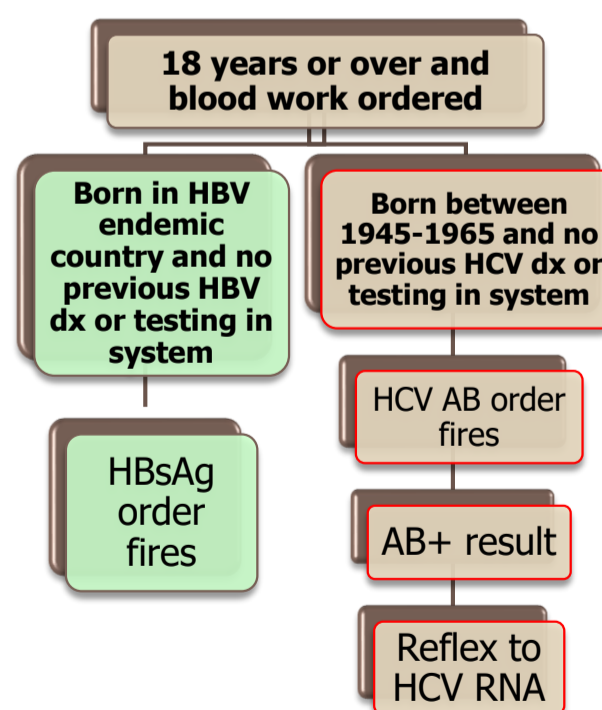
- **Saint Barnabas Medical Center**

- Suburban, community teaching hospital in NJ
 - ED with 100,000 visits a year
 - 30% HCC cases presenting in stage IV (13% nationally)
- Automated screening via Electronic Health Record
- Linkage-to-care to Primary Care
- Patient navigator educates, counsels and can directly shedule pts via EMR



Automated Algorithm

- **HCV- Date of birth (DOB)** to identify HCV at-risk (born 1945-1965, “baby boomer” cohort)
- **HBV- Country of birth (COB)** to identify HBV at-risk, added as drop-down menu & auto-fill function in registration, programmed HBV-endemic countries
- IF eligibility met, blood work ordered & no previous testing done → blood test automatically ordered



Collecting Country of Birth at Registration

```

Quick ER                               Patient Information    02/13/18  0734
                                     F                               Pt #:
Atn Dr: EMA PHYSICIANS                 EMERG
Adm Dt:                                Isol:                               Mr #:
-----
Last Name: GILEAD                       First: QUICKREG
Mid Name:                               Name Sfx:
Registrar Init: GW_                     Birth Date: 01 / 01 / 1990
Sex: F                                   Financial Cls: -
Marital Sts: S                           SSN#: - - - -
Clinic Code: EMERG                       Hosp Svc: ---
Country of Birth: AW ARUBA              Atn Dr Name: EMA PHYSICIANS
Atn Dr No: 08002                          Diagnosis: screen prints country birth
Mode of Transport: wa                     Arrival Date/Time: 02 / 13 / 18  07 : 34
Reg Date/Time: - / - / - : -
Med Rec No:                               Leave fields blank for
Pt No:                                     automatic number generation
-----
! PF13 Master Menu
! PF14 Submenu
                                     &Comments: Y/N      & Enter
  
```

Field is a drop down menu & searchable

March 2018 Launch

Program introduced to ED staff via daily huddles (nursing, registration) & provider meetings, public signage placed

Saint Barnabas Medical Center
Provides
Hepatitis B & C Testing



This facility performs **HBV** and **HCV** testing as part of our routine health care, as recommended by the U.S Centers for Disease Control and Prevention (CDC). Chronic hepatitis is the leading cause of liver cancer.

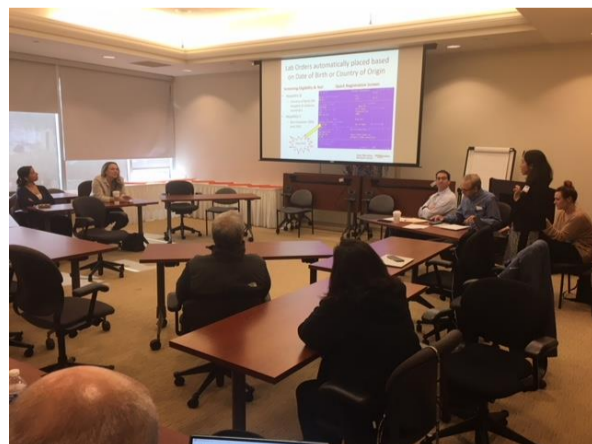
Your healthcare provider may order these tests if you have not been tested within the past year in our network and you are considered at-risk:

- **Hepatitis C** -- If you were born between 1945-1965
- **Hepatitis B** -- If you were born in a country where HBV is endemic

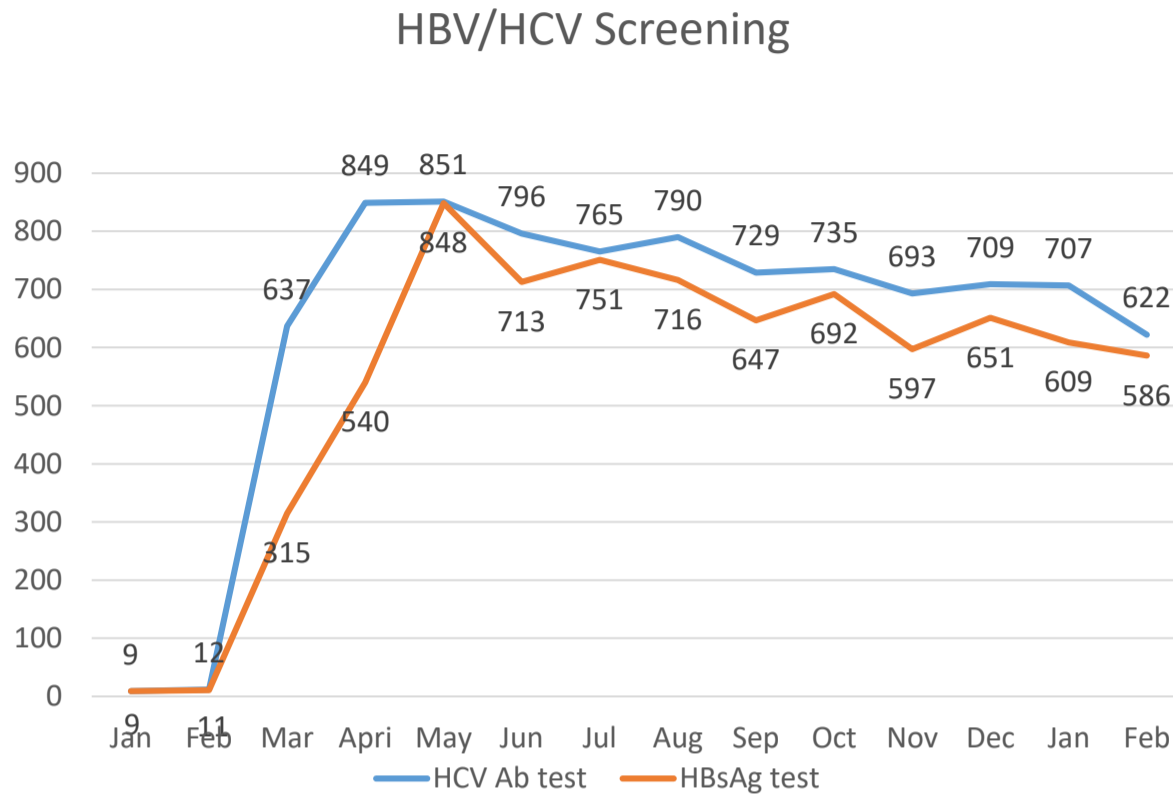
Incorporating hepatitis testing into routine care helps to diagnose patients and offer them care and treatment before the disease progresses.

If you test positive, you will be contacted for further follow-up.

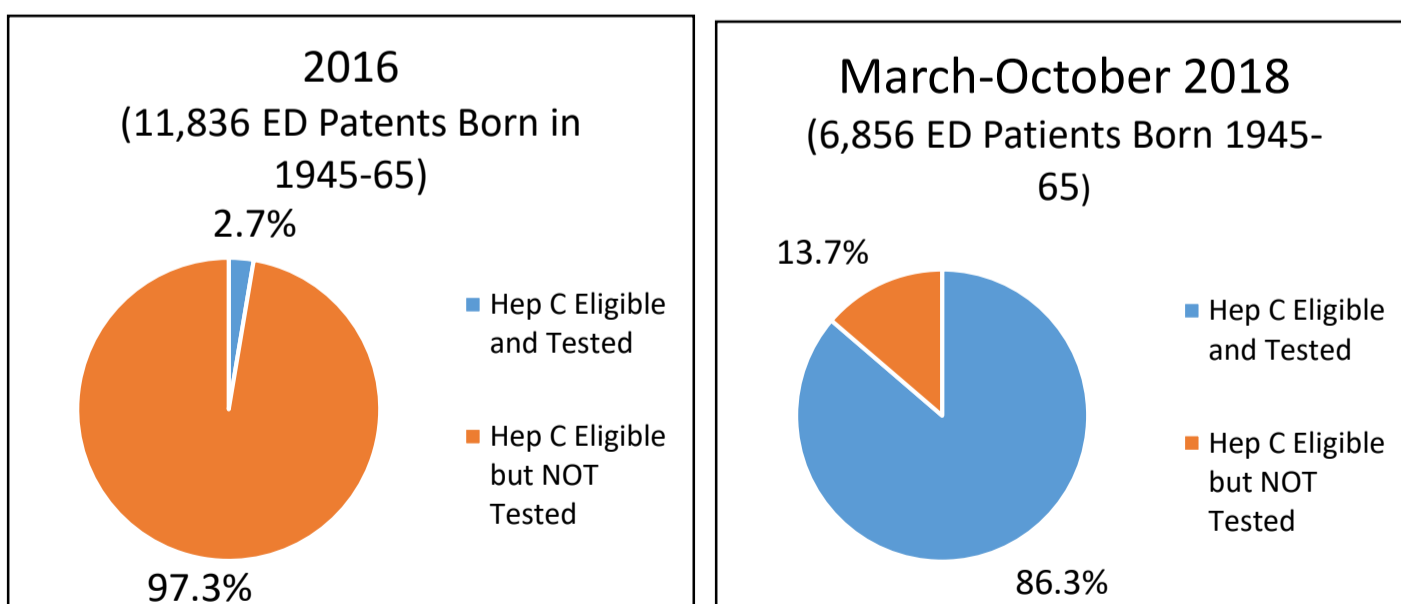
*I understand that notification is contingent on providing accurate contact information.



Results: Uptick in screening



Proportion of Baby Boomer Cohort Screened for HCV



→ HCV Screening increased from 2.7% to 86.3%

HCV Screening and Linkage-to-Care

	# Tested	# HCV Ab Positive (%)	# HCV RNA Detected (Current Infxn) (%)	# New Diagnosis (%)	# Linkage to care (%)	# Linked to Our Center	% Adjusted LTC
HCV	10182	283 (3.3%)	95 (1.1%)	53 (55.8%)	62 (65.3%)	29	89.0%

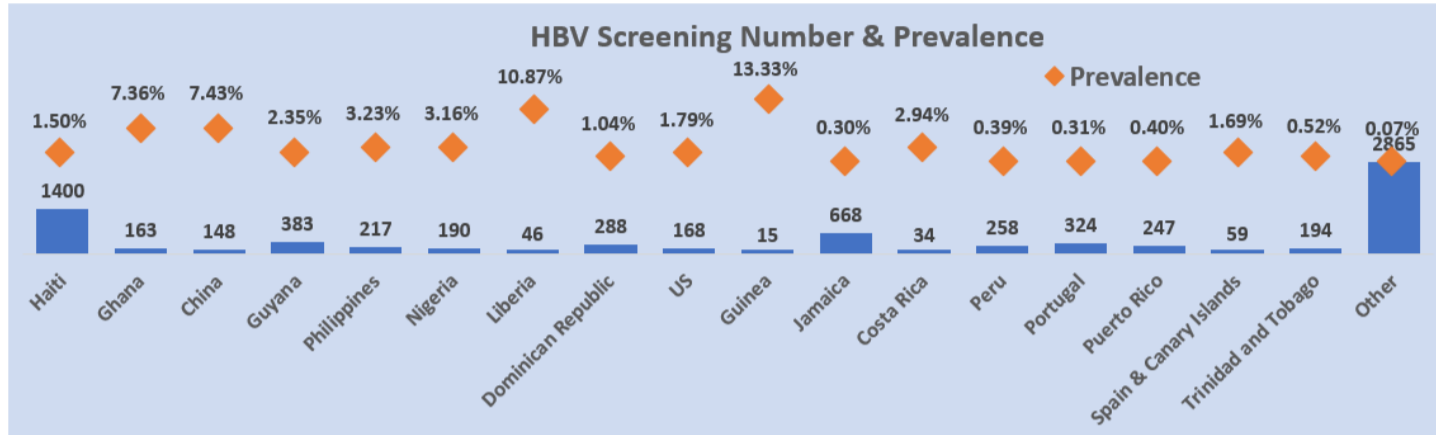
- **19** patients initiated HCV cure therapy in the liver center
- **11** cured, sustained virologic response(SVR) confirmed at 12 weeks
- **5** with undetectable HCV RNA at week 4 (preliminary cure), now awaiting 12 week labs (final cure results)
- **3** currently in treatment.

HBV: Diagnosis and Linkage to Care

	# Tested	# HBsAg Positive (%)	# Newly Diagnosed (%)	# Linkage to care (%)	# Linkage to Liver Center	% Adjusted LTC
8096	7207 (89.0%)	89 (1.2%)	39 (43.8%)	50 (56.2%)	24	86.9%

- 89 diagnosed, 24 seen at our outpatient site
- 1 started on treatment, 1 HIV/HBV co-infected

HBV Screening Numbers & Prevalence by Different Countries



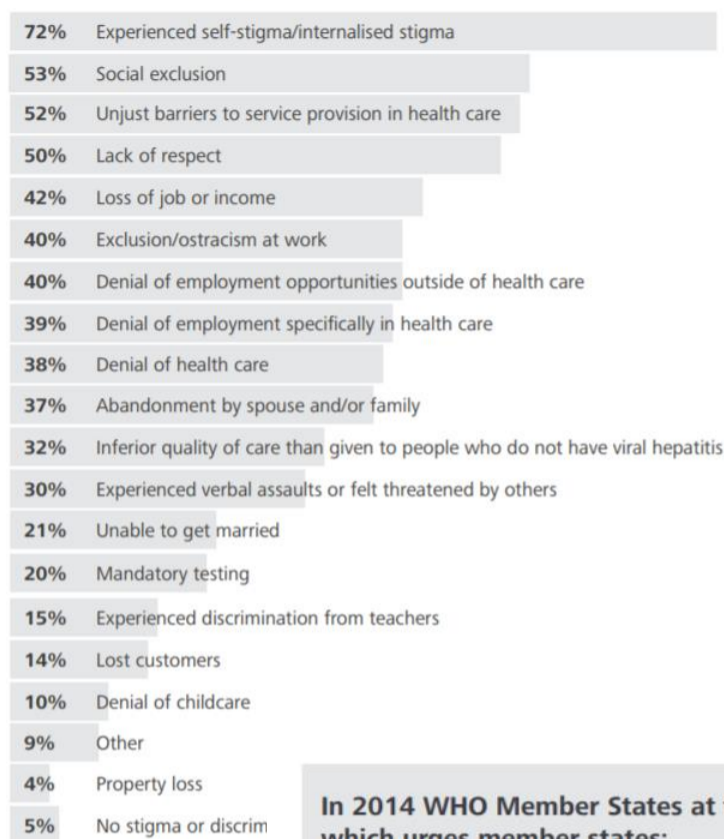
4 Stigma and discrimination

World Hepatitis Alliance Civil Society Survey
Global Findings Report



Holding governments accountable: World Hepatitis Alliance civil society survey global findings report.
World Hepatitis Alliance, London; 2017
http://www.worldhepatitisalliance.org/sites/default/files/resources/documents/holding_governments_accountable_-_civil_society_survey_report.pdf

Form of stigma/discrimination (Percentage of respondents who gave this answer)



Holding governments accountable:
World Hepatitis Alliance civil society
survey global findings report.



In 2014 WHO Member States at the World Health Assembly adopted resolution 67.6 which urges member states:

(16) to review, as appropriate, policies, procedures and practices associated with stigmatisation and discrimination, including the denial of employment, training and education, as well as travel restrictions, against people living with and affected by viral hepatitis, or impairing their full enjoyment of the highest attainable standard of health;

Student & Healthcare worker discrimination in the US

- 2011 Two medical students lose acceptances over HBV diagnosis, DOJ brought in
- 2012 CDC updates guidelines for health care students & professionals with hepatitis B
- 2013- People w hepatitis B officially protected under the American Disabilities Act
- 2013- Letter sent from DOJ, Dept of Education, Health & Human Services to healthcare schools



Justice Department Settles with the University of Medicine and Dentistry of New Jersey Over Discrimination Against People with Hepatitis B

Yet, the Hepatitis B Foundation has received 20-30 cases/year of students or professionals facing discrimination

Nurses, physicians, x-ray technicians, physical therapists, dentists, ultrasonographers

5

Out-of-pocket costs for the population

- Procurement/production costs of vaccine, tests, treatments are different from end-user costs
 - Low cost to country or purchaser \neq low cost to patient
- Insure hepatitis services are part of preventative services or essential benefits
- Negotiate volume purchasing of diagnostics and treatments or other innovative financing

Hep Community: Be Alert and Ready to Act!

Cary James @caryjameslondon · Jul 12
The UN #UHC political declaration is being discussed as I tweet, @Hep_Alliance and others have reached out to the co-facilitators @kahaimnadze and @ThailandUN to urge the inclusion of viral hepatitis in the declaration. We need to ensure that #HealthForAll includes #NOhep

Raquel Peck @RaqPeck · Jul 12
#NOhep community: the political declaration on #UHC was supposed to be free of any mention of specific diseases, yet, its latest version has references to HIV, TB & Malaria. No #viralhepatitis, even though it will kill more than these 3 diseases combined by 2040 if...

Su Wang @swang8
This is ridiculous!! We know global deaths from #ViralHepatitis have exceeded #HIV, #Malaria and #TB. Yet #HBV #HCV were totally omitted from this #UHC Universal Health Coverage declaration!! It's time to speak up #Hepatitis community! #NOhep #DiseaseDiscrimination #SilentNoMore

Raquel Peck @RaqPeck
#NOhep community: the political declaration on #UHC was supposed to be free of any mention of specific diseases, yet, its latest version has references to HIV, TB & Malaria. No #viralhepatitis, even though it will kill more than these 3 diseases combined by...

9:55 AM - 12 Jul 2019

23 Retweets 42 Likes

**Political Declaration
of the High-level Meeting on Universal Health Coverage
“Universal health coverage: moving together to build a healthier world”**

11. Recognize that action to achieve universal health coverage by 2030 is inadequate and that the level of progress and investment to date is insufficient to meet target 3.8 of the Sustainable Development Goals, and that the world has yet to fulfil its promise of implementing, at all levels, measures to address the health needs of all, noting that:
- c. despite major health gains over the past decades, including increased life expectancy, the reduction of maternal and under-5 mortality rates, and successful campaigns against major diseases, challenges remain with regard to emerging and re-emerging diseases, non-communicable diseases, mental disorders and other mental health conditions as well as neurological disorders, communicable diseases including HIV/AIDS, Tuberculosis and malaria, antimicrobial resistance, noting that non-communicable diseases account for over 70% of all deaths in the age group 30-69;
32. Strengthen efforts to address communicable diseases, including HIV/AIDS, tuberculosis, malaria and hepatitis as part of universal health coverage and to ensure that the fragile gains are sustained and expanded by advancing comprehensive approaches and integrated service delivery and ensuring that no one is left behind;

<https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/07/FINAL-draft-UHC-Political-Declaration.pdf>

We have evidence-based guidelines But who's following them?

CDCs Chronic Hepatitis Cohort Study (CHeCS) for Hepatitis B

- **2338 HBV patients, 2006-13**
 - Geisinger Health System (PA)
 - Henry Ford Health System (MI)
 - Kaiser-Permanente- Northwest (OR)
 - Kaiser-Permanente-Honolulu (HI)

Integrated systems of primary/specialty care known for providing high quality patient care
- **ALT testing**
 - 78% had ≥ 1 ALT done per year

Majority of patients access medical care & obtain at least 1 ALT done/year (seeing primary care regularly)
- **HBV DNA testing**
 - Only 37% had ≥ 1 HBV DNA per year f/u
 - 18% **never** had HBV DNA

Majority of HBV Patients not getting an annual HBV done, some had never had it
- **32% prescribed antiviral therapy**
Population had active hepatitis, 1/3 on treatment
- **HBV patients w Cirrhosis**
 - 54% with HBV DNA done annually, 35% less than annually
 - 11% never had HBV DNA done
 - 53% had at least 1 hepatic imaging but only 27% had annual imaging
 - Only 56% prescribed antiviral therapy

Highest-risk population not receiving standard of care treatment

Spradling, PR, et al. "Infrequent Clinical Assessment of Chronic Hepatitis B Patients in United States General Healthcare Settings". Clin Infect Dis. 2016 Nov 1;63(9):1205-1208. Epub 2016 Aug 2.

Many Guidelines for Hepatitis B Treatment: Which to Follow? If we don't simplify, patients will not get treated

Guideline	HBeAg+		HBeAg-	
	HBV DNA IU/mL	ALT U/L	HBV DNA IU/mL	ALT U/L
AASLD 2018	>20,000	>2 x ULN [†] or significant histological disease	>2,000	>2 x ULN [†] or significant histological disease
AATA 2018	>2,000	>ULN	>2,000	>ULN
EASL 2017	≥2000	>ULN and/or at least moderate liver necroinflammation or fibrosis	≥2,000	>ULN and/or at least moderate liver necroinflammation or fibrosis
	≥20,000	>2 x ULN irrespective of fibrosis	≥20,000	>2 x ULN irrespective of fibrosis
JSH 2017	≥2,000	>ULN [^]	≥2,000	>ULN [^]
APASL 2015	≥20,000	Varies	≥2,000	Varies
US Algorithm 2015 [†]	≥2000	>ULN	≥2,000	>ULN

[†] If patients with HBV DNA ≥ 2000 IU/mL and elevated ALT without fibrosis do not undergo treatment, monitor HBV DNA and ALT every 3–6 months.
^{*} Liver biopsy Stages 1–3, Grade 1–3; and/or Risk Impact Score ≥3;
[†] ALT ULN: Males 35 U/L, females 25 U/L ^ ALT ULN: 31 U/L
 AASLD: American Association for the Study of Liver Diseases; AATA: Asian American Treatment Algorithm; ALT: alanine aminotransferase; APASL: Asian Pacific Association for the Study of the Liver; CHB: chronic hepatitis B; EASL: European Association for the Study of the Liver; HBeAg: hepatitis B e antigen; ULN: upper limit of normal; JSH, Japan Society of Hepatology
 Terrault NB et al. Hepatology 2018; Published online February 5, 2018: doi:10.1002/hep.29800
 Tong MJ, Pan CQ, Han SB, et al. An expert consensus for the management of chronic hepatitis B in Asian Americans. Aliment Pharmacol Ther. 2018
 EASL Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol 2017; doi: 10.1016/j.jhep.2017.03.021
 JSH Guidelines for the Management of Hepatitis B Virus Infection. 2017
 Sarin SK, et al. Hepatol Int 2015; doi 10.1007/s12072-015-9675-4; Martin P, et al. Clin Gastroenterol Hepatol 2015;13: 2071–87
 Martin P, et al. Clin Gastroenterol Hepatol 2015; Published online July 15, 2015: http://dx.doi.org/10.1016/j.cgh.2015.07.007

Last Updated July 19, 2019

Hepatitis B Management: Guidance for the Primary Care Provider

Purpose of Guidance: The purpose of this document is to provide simplified, up-to-date, and readily accessible guidance for primary care medical providers related to the prevention, diagnosis, and management of hepatitis B virus (HBV) infection, including hepatocellular carcinoma surveillance.

About the HBV Primary Care Workgroup
 by the Workgroup on Hepatitis B Guidance. This workgroup consists of a multidisciplinary team of experts in the field of viral hepatitis, including renal, infectious diseases, primary care, public health, and epidemiology organizations. The workgroup was organized on Hepatitis B in partnership with the National Campaign and Project ECHO™ and did not receive funding from the CDC.

Collaboration with University of Washington
 These guidelines were produced in collaboration with the University of Washington's National Viral Hepatitis Action Plan. The Washington team will produce and periodically update this guidance on the University of Washington Online website (currently under development) and launch in the fall 2019. The *Hepatitis B Management: Guidance for the Primary Care Provider* is a free educational resource funded by the National Cancer Institute (NCI) and the National Center for Prevention (CDC).

HBV PRIMARY CARE WORK GROUP

HBV GUIDANCE CO-CHAIRS

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Management of the HBsAg(+) Patient[^]

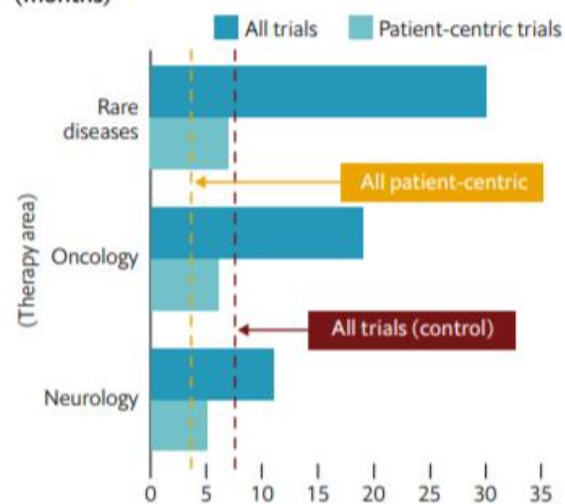
Cirrhosis	HBV DNA (IU/mL)	ALT (U/mL)	Management
Yes	Any	Any	Treat, monitor HBV DNA and ALT every 6 months; Refer to specialist to evaluate for cirrhosis-related complications HCC surveillance (Page 7) All patients with decompensated cirrhosis [#] should be promptly referred to a <u>hepatologist</u> .
No	>2,000	Elevated*	Treat, monitor HBV DNA, ALT, +/- HBeAg** every 6 months
		Normal	Monitor HBV DNA and ALT every 6 months; Liver fibrosis assessment every 2-3 years
	<2,000	Elevated*	Evaluate other etiologies for elevated ALT Monitor HBV DNA and ALT every 6 months
		Normal	Monitor HBV DNA and ALT every 6 months <i>and</i> HBsAg every 1 year for <u>seroclearance</u> .

[^] In contrast to other HBV guidelines have incorporated HBeAg status into treatment initiation decisions for non-cirrhotic HBsAg(+) patients, this guidance for primary care providers uses only HBV DNA and ALT to determine initial treatment indication in non-cirrhotic HBsAg(+) patients.

On the road to HBV Cure, we need patient involvement

- Patient-centric trials involve patients in design & execution
- Designed to improve relevance to patients & encourage participation in trials
- Could impact: inclusion/exclusion criteria, visit burden in trial, patient relevant outcomes
- Patient centered trials more likely to produce drugs that launch (87%) vs standard trials (68%)*

Figure 12: Average time to enroll 100 participants for patient-centric trials vs all trials (months)



*The Innovation Imperative: The Future of Drug Development Part I: Research Methods and Findings, A report by The Economist Intelligence Unit, 2019 https://druginnovation.eiu.com/wp-content/uploads/2019/05/Parexel-innovations-in-drug-development-part-1_V14.pdf

We have the tools, but we need a movement to eliminate viral hepatitis!



World Hepatitis
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