# What further actions to take to achieve HCV elimination?

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## **Disclosures**

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# The 20 Countries HCV Map

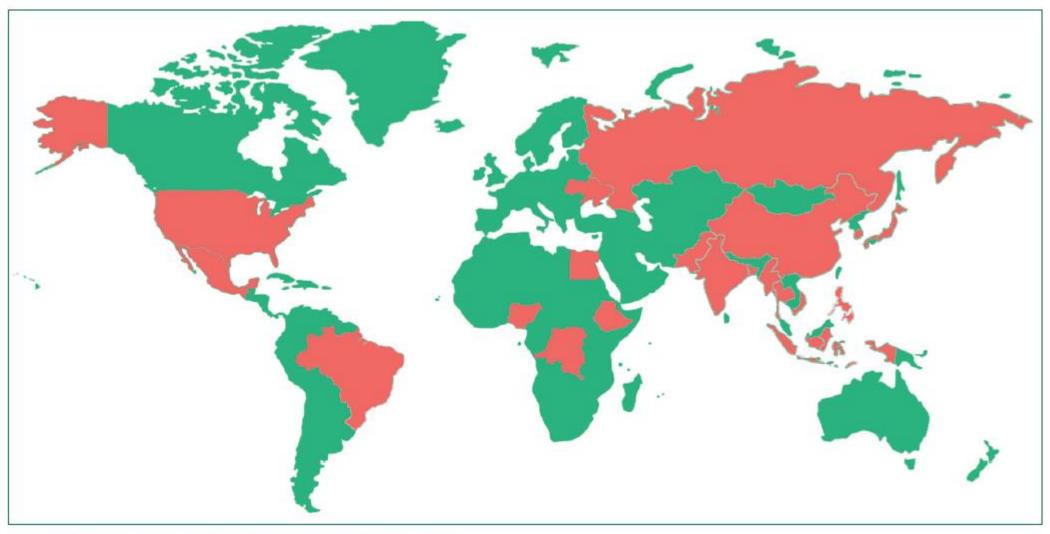


Figure 1: The 20 countries most heavily burdened with viral hepatitis

Shown in red are the 20 countries with the highest burden of viral hepatitis on the basis of The Lancet Gastroenterology & Hepatology 2019 Commission on accelerating the elimination of viral hepatitis.<sup>1</sup>

## **Continental Efforts! Africa**

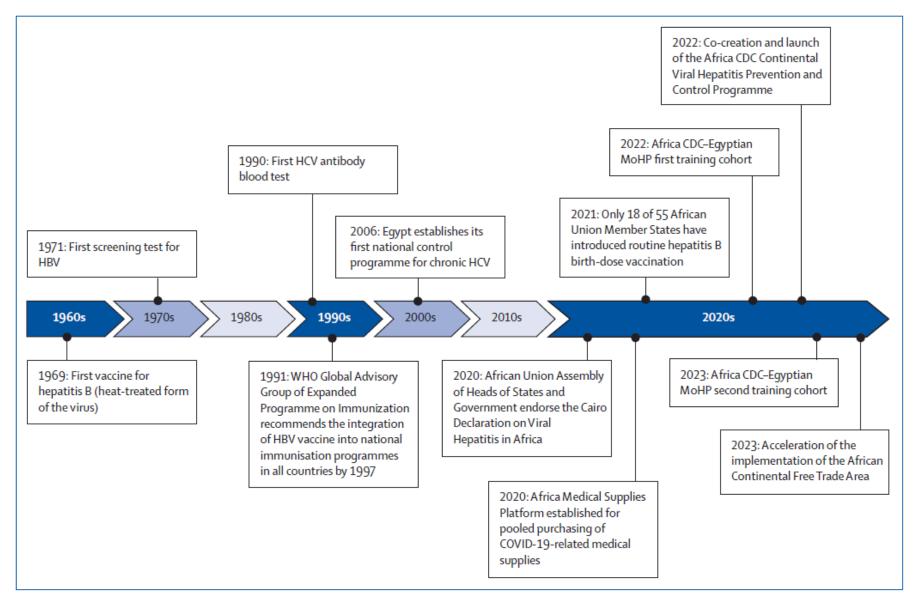


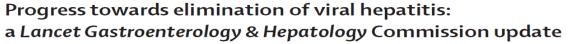
Figure: Major hepatitis-related milestones on the African continent

Africa CDC=Africa Centres of Diseases Control and Prevention. HBV=hepatitis B virus. HCV=hepatitis C virus. MoHP=Ministry of Health and Population.

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#### The Lancet Gastroenterology & Hepatology Commission





Graham S Cooke, Barnaby Flower, Evan Cunningham, Alison D Marshall, Jeffrey V Lazarus, Adam Palayew, Jidong Jia, Rakesh Aggarwal, Mamum Al-Mahtab, Yashuito Tanaka, Sook-Hyang Jeong, Kittiyod Poovorawan, Imam Waked, Lindsey Hiebert, Pham M Khue, Jason Grebely, Diana Alcantara-Payawal, Juan F Sanchez-Avila, Charles Mbendi, David H Muljono, Olufunmilayo Lesi, Hailemichael Desalegn, Saeed Hamid, Alexandre de Araujo, Hugo Cheinquer, Charles A Onyekwere, Ruslan Malyuta, Iryna Ivanchuk, David L Thomas, Nikolay Pimenov, Vladimir Chulanov, Mae Ashworth Dirac, Hannah Han, John W Ward

	Actions required	Exemplars of progress
Simplification of care	Validation and roll out of simplified strategies for hepatitis B: minimising monitoring, simplifying investigations, reducing clinical visits, and decentralising care; long-acting injectable treatments	Validation of minimal monitoring approaches; <sup>153</sup> incorporation of simplified treatment strategies into guidelines <sup>154,155</sup>
Improved diagnostics	Investment in simplified diagnostics; innovation with novel or existing diagnostics <sup>156-158</sup>	Evaluation of rapid diagnostic tests and point-of-care tests,7,156,159 incorporation into guidelines6,154,160
Financing	Global investment; domestic prioritisation; innovative financing of HBV and HCV care; incorporation into existing services	New funding sources;161,162 market analysis and transparency;10,163 success stories164,165
Lessons from the COVID-19 pandemic	Responding to setbacks; telemedicine and decentralisation of care; improving surveillance	Greater acceptance of self-testing; incorporation of remote care into guidelines <sup>155,166</sup>
BV=hepatitis B virus. HCV=hep	•	remote care into goldenies

#### Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2017–2020





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SCHOOL OF PUBLIC HEALTH

#### BACKGROUND

- Hepatitis C virus (HCV) infection is the most common bloodborne illness in the United States, but disease burden is challenging to measure. Accurate estimates of the disease burden are the first step in monitoring and evaluating progress toward hepatitis C elimination.
- A report from the most recent National Health and Nutrition Examination Survey (NHANES) estimated 2.2 million adults had current HCV infection during 2017-March 2020.<sup>1</sup>
- However, NHANES underestimates true prevalence of HCV infection because it excludes or underrepresents some populations with high prevalence.<sup>2</sup>

	Estimated Adult	HC	/ Antibo	ody	HCV RNA			
	Population Size	Prevalence		Prevalence				
Population	N (95% CI)	%	95%	C	%	95	% CI	Source
Non-institutionalized	249,177,857	2.04	1.36	3.06	0.89	0.55	1.45	NHANES
Unsheltered, unhoused	212,090	22.04	10.53	40,44	11.10	5.94	19.78	Meta-analysis
Incarcerated	2,086,600	19.60	14.98	25.23	9.72	7.10	13.18	Meta-analysis
Active-duty military	1,326,200	0.22	0.19	0.26	0.02	0.01	0.03	Meta-analysis
Nursing home residents	1,404,421	1.47	0.94	2.01	0.57	0.30	0.85	NHANES
Persons who inject drugs	3,694,500	53.5	47.0	59.9	43.7	40.7	46.7	Degenhardt 2023
	(1,872,700-7,273,300)							

Note: Prevalence estimates for the nursing home resident population are age-adjusted.

#### CONCLUSIONS

- Using the NHANES+ model, we estimated that approximately 2.4 million US adults had current HCV infection during 2017–2020. Using an expanded methodology that aimed to better account for increased HCV prevalence among PWID, we estimated there were over 4.0 million adults that had current HCV infection during 2017–2020.
- When accounting for increased injection drug use in the United States, estimated prevalence of hepatitis C is substantially higher than previously reported.
- Despite years of an effective cure, prevalence of HCV in 2017–2020 remains unchanged from 2013–2016 when using comparable methodology.
- National action is urgently needed to expand testing, increase access to treatment, and improve surveillance among medically underserved populations to support hepatitis C elimination goals.

# Biden Administration Viral Hepatitis Elimination Program: A focus on HCV

Modeling of the National Hepatitis C Elimination Program shows that within 5 years of implementation:

92.5% of all persons with HCV will be diagnosed and 89.6% of those with HCV infection will be cured.

Over 10 years, compared with the status quo, this **initiative will avert 20,000 cases of** 

#### **HCC**

49,100 cases of diabetes 25,000 cases of chronic kidney disease

With this disease prevention, the initiative will avert 24,000 deaths adding 220,000 life-years.

These benefits in improved health will save \$18.1 billion in direct health care spending, of which \$13.3 billion would accrue to the federal government. Over 20 years, the health benefits would increase by more than 2-fold and cost savings by 3-fold.

#### **Patient Education**

- Provide education on HCV prevention, testing, and treatment of the target and general population
- Utilize current online resources (e.g., AASLD website) to link persons with HCV to treatment nationwide

#### Capacity Building and Provider Education

- Educate PCPs, non-HCV specialists, and non-physician prescribers (i.e. APPs, pharmacists, nurses) on how to treated HCV
- Promote telemedicine initiatives on HCV care to support training for physician and non-physician providers
- Encourage mentorship programs to expand provider capacity

#### Diagnostics

- Wide implementation of point-of-care antibody testing
- Serve as screening champions in their facilities
- Working with local administrators and other healthcare providers on universal HCV screening strategies for all patients using electronic medical records (medical chart reminders)

# HCV Elimination in the U.S.

#### **Patient Care**

- Encourage patient navigation programs to improve care access
- Expand traditional and nontraditional strategies to reach and treat patients
- Simplify HCV care
- Implement innovative models of care for special and vulnerable populations
- Manage patients with severe hepatic or extrahepatic manifestations of HCV

#### Research

- Vaccine development
- · Long-acting injectable treatment
- Validation studies on new diagnostics
- Implementation and dissemination of successful models on HCV care with lessons learned from COVID-19 and states (e.g. Louisiana, Washington)

#### Advocacy

- Convene a coalition of organizations. committed to eliminating HCV in U.S.
- Help draft legislation for the National Hepatitis C Elimination Program
- Work with coalition partners to call on Congress to embrace the National Hepatitis C Elimination Program
- Collaborate to prioritize recommendations for the National Hepatitis C Elimination Program
- Work with stakeholders to obtain nationwide reimbursement for HCVrelated telehealth services

# **Conclusions From the US Veterans Medical System**

- 80% of Veterans with HCV currently in care have been treated
- SVR > 90%
- Birth sex, race, or ethnicity not associated with adverse impact to HCV care continuum
- Younger Veterans less likely to initiate treatment or achieve SVR; more likely to have repeat viremia
- Neither alcohol nor opioid use associated with decreased likelihood of achieving SVR.
  - Veterans with opioid use less likely to be treated
- Repeat viremia rare and associated with younger age, unstable housing, opioid and stimulant use
- Stimulant use and unstable housing negatively associated with each step of the HCV care continuum

## Now let's go to a US state-based model

- Promotion of public awareness about HCV screening via outreach campaigns, focus groups, and community involvement to formulate best practices for patient engagement, communication strategies, understanding stigma, and service delivery.
- Expansion of HCV screening by partnering with the Centers for Medicare & Medicaid Services, departments of corrections, opioid treatment programs, syringe services programs, and primary care providers.
- 3. Enhancement of HCV surveillance by upgrading technology, automating reporting, and developing task forces. Both states mandate manual and laboratory reporting of acute and chronic cases, positive and negative antibody and RNA results to track cases, spontaneous clearance, and curative treatment; they define a case as a positive HCV RNA test or a documented negative HCV antibody test, followed by seroconversion within 12 months. 11–13
- 4. Promotion of harm reduction by expanding opioid treatment programs and syringe services programs statewide as well as utilizing patient navigators for linkage to care.

#### Implications for Policy & Practice

- Screening and surveillance systems are cornerstones to address rising HCV incidence.
- Recommended screening activities include:
  - Destigmatizing HCV screening,
  - Performance measures, and
  - Targeted screening in high-yield settings.
- Recommended surveillance activities include:
  - Linking and merging external data sources and registries,
  - Automating laboratory real-time reporting of positive and negative test results with universal reporting requirements and clear case definitions,
  - Monitoring screening performance and detecting screening-deficit sites for corrective action, and
  - Identifying outbreaks and transmission networks, reporting treatment outcomes, and evaluating program metrics.
- Recommended implementation activities include:
  - Establishing treatment- and outbreak-focused task forces and
  - Promoting HCV education and harm reduction.
- Screening and surveillance systems implemented by Louisiana and Washington could be adapted and modified by other HCV elimination programs.
- The White House HCV elimination plan proposes to:
  - Expand screening, testing, treatment, prevention, and realtime monitoring,
- Focus on high-risk populations,
- Support universal screening,
- Diversify and expedite test-and-treat services through mobile treatment, telehealth, primary care, community sites, and case managers, and
- Promote awareness campaigns in affected communities, include leadership and collaboration between federal agencies addressing HCV.

# Finally the Federal System in the US: FQHC example San Diego, CA takes care of > 40 M people in the US: uninsured, underinsured, Medicaid federal and state

Table 4. Differences in Eventual Treatment

Characteristic	No treatment	Received treatment	P value
Age, years $\pm$ SD (n = 278)	N = 116	N = 162	
Average age	$51.9 \pm 1.4$	$51.4 \pm 1.1$	0.775
Sex, n (%) (n = 278)	N = 116	N = 162	
Female	45 (38.8)	62 (38.3)	0.93
Male	71 (61.2)	100 (61.7)	
Race, n (%) (n = 278)	N = 116	N = 162	
American Indian	4 (3.5)	0 (0)	0.20
Asian	5 (4.3)	7 (4.3)	
Black/African American	11 (9.5)	18 (11.1)	
More than one race	1 (0.9)	0 (0)	
Other Pacific Islander	1 (0.9)	2 (1.2)	
White	94 (81.0)	135 (83.3)	
Ethnicity, n (%) (n = 278)	N = 116	N = 162	
Hispanic or Latino	38 (32.8)	73 (45.1)	0.075
Not Hispanic or Latino	78 (67.2)	88 (54.3)	
Unknown	0 (0)	1 (0.6)	
Language, n (%) (n = 278)	N = 116	N = 162	
Non-English	17 (14.7)	47 (29.0)	0.017
English	99 (85.3)	115 (71.9)	
Income, annual $\pm$ SD (n = 274) <sup>a</sup>	N = 113	N = 161	
Average income	$6,299.61 \pm 2,181.38$	$7,703.93 \pm 908.15$	0.509
nsurance, n (%) <sup>a</sup>			
Managed care (n = 278)	N = 116	N = 162	
	94 (81.0)	140 (86.42)	0.225
Out-of-pocket (n = 277)	N = 116	N = 161	
	22 (19.0)	22 (13.7)	0.234
Inability to pay (n = 278)	N = 116	N = 162	
	2 (1.7)	16 (9.9)	0.006
Denials (n = 278)	N = 116	N = 162	
	6 (5.2)	54 (33.3)	< 0.001
Gilead Services (n = 269)	N = 115	N = 154	
	0 (0)	11 (7.1)	0.003
Risk factors, n (%)a			
History of incarceration (n = 183)	N = 95	N = 88	
	34 (35.8)	31 (35.2)	0.937
History of blood transfusion (n = 172)	N = 95	N = 77	
	4 (4.2)	4 (5.2)	0.761
History of alcohol use disorder (n = 277)	N = 116	N = 161	
	24 (20.7)	37 (23.0)	0.65
Current alcohol use disorder (n = 277)	N = 116	N = 161	
	13 (11.2)	11 (6.8)	0.202
History of IV drug use (n = 264)	N = 108	N = 156	
, (,	53 (49.1)	67 (43.0)	0.326

#### Original Article

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Barriers to Hepatitis C Virus Care and How Federally
Qualified Health Centers Can Improve Patient
Access to Treatment

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279 patients were HCV RNA+

162 started on treatment

138 completed a full treatment course > 90% compliance

Key differences in access to care/treatment:

- ☐ Insurance barriers p=0.001
- ☐ Non-English language as first language p=0.017
- ☐ Cash pay patients (not qualified for any insurance) p=0.0006

## **HCV Elimination**

- Successes have been achieved that have greatly reduced disease burden (blood safety, infection control)
- The toolbox is ample to reduce prevalence and mortality- reliable tests, low-cost curative treatments and strategies for access.
- The ultimate goal of HCV elimination is health equity- key marginalized populations – PWID, incarcerated, the displaced, pregnant women, LMICs

## **HCV Elimination**

- Model countries have put in place the essential components of effective HCV elimination programs demonstrating feasibility
- The key ingredient for success –national commitment put tools into action, often missing
  - Seeking to build commitment- UN Group of Friends
  - US initiative
- Operational research can accelerate progress- LA DAA; POC testing; HCV vaccine, treatment of pregnant women, improved strategic information

# HCV vaccination development program is proposed to include induce HCV infection for up to 24 weeks:

# Conclusion: No detectable long-term hepatic or non-hepatic consequence of < 24 weeks of HCV infection

- Cirrhosis, ESLD, HCC, lymphoma, vasculitis, diabetes, cardiovascular
- Spontaneous clearance vs persistence
- DAA treatment vs none
- Cannot exclude low risks (as with other CHIM paradigms)
- Safety supported by abundance of data, biological and medical plausibility supports safety

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