WHITE PAPER

Clearway Health

Towards Eliminating Hepatitis C as a Public Health Threat in the United States

The Role of Health System Specialty Pharmacies

Background

Hepatitis C is an inflammation of the liver caused by the hepatitis C virus (HCV). HCV infection is the most common blood borne infection in the United States with approximately 1% of adults (2.4 million) living with HCV between 2013-2016.[1]

The most common mode of transmission of HCV is through contaminated blood products via sharing needles, syringes, or other drug-injection tools, vertical transmission from mother to baby during pregnancy or at birth, and rarely through sexual contact.

While some with HCV infections will have a spontaneous resolution within six months (acute HCV infection), the majority (80%) of individuals will progress into developing persistent viremia (chronic infection).[2] Chronic hepatitis C infection is a major cause of liver cirrhosis, hepatocellular carcinoma and death.[3,4] This is, in part, due to the fact that chronic HCV infection often remains asymptomatic for decades (silent infection) and when symptoms appear, they often are a sign of advanced liver damage.

A recent study shows 1 in 3 adults in the United States are not aware of their potentially life-threatening infection.[5] At the time of diagnosis, around 20% of patients will already have serious liver damage, cirrhosis and/or end-stage liver disease.[6] This highlights the need for a comprehensive screening program for early diagnosis and linkage to care.

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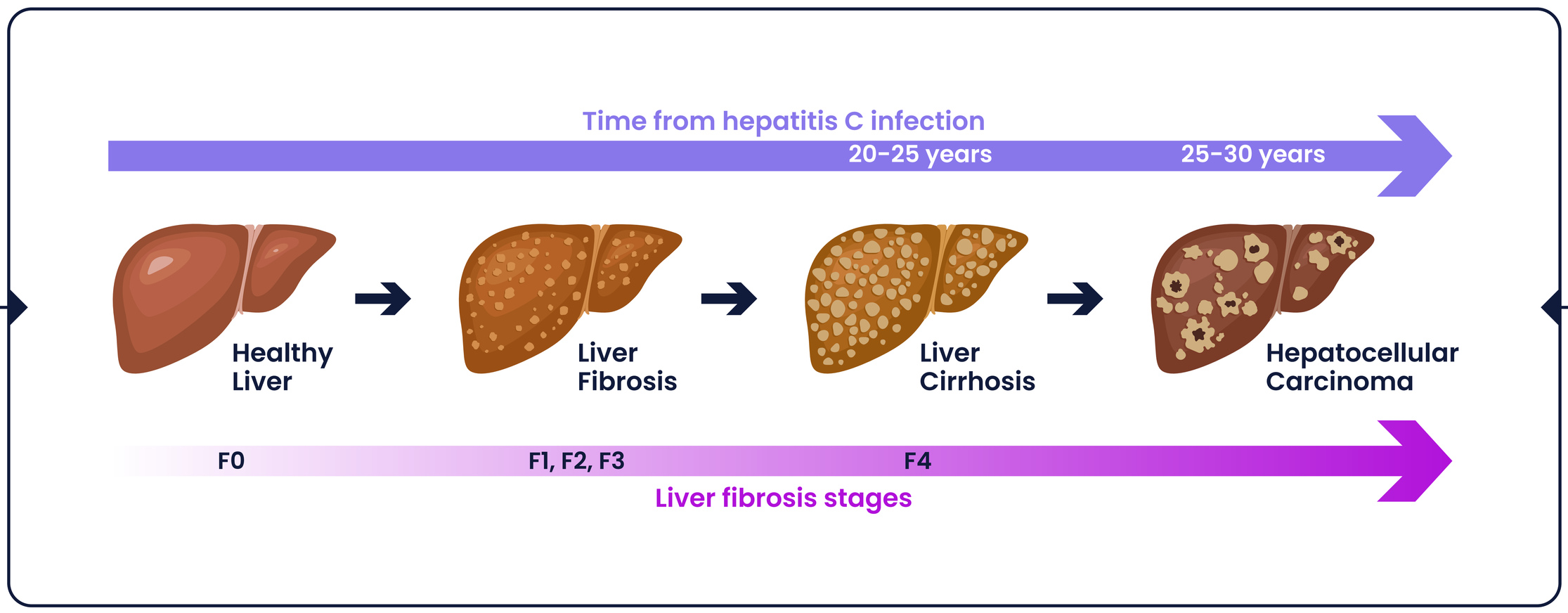
Stages of liver damage[7]



- Without hepatitis C treatment, viral insult to the liver damage continues and results in liver fibrosis, cirrhosis and ultimately hepatocellular carcinoma (HCC).
- Successful hepatitis C treatment eliminates the constant viral insult to the liver and allows the liver to regenerate. Treating patients with moderate liver fibrosis (F1, F2, & F3) may lead to complete or partial liver regeneration. While advanced liver fibrosis (F4) and cirrhosis is not completely reversible, successful hepatitis C treatment slows down disease progression to HCC and other complications.

Global initiative for hepatitis C eradication

The past decade marked the emergence of several highly effective and safe direct-acting antiviral (DAA) therapies with high (95-99%) cure rate within 8-12 weeks.[8] This, coupled with comprehensive screening programs and prevention strategies offers a unique opportunity to eradicate hepatitis C as a public health threat globally and in the United States.

In 2016, the World Health Organization (WHO) presented an action plan for global elimination of hepatitis C as a public health threat by 2030.[10]

WHO hepatitis C elimination targets are defined as:

90% reduction in hepatitis C infection

65% reduction in morbidity & mortality

90% increase in hepatitis C diagnosis

The United States National Strategic Plan:
A roadmap to hepatitis C elimination

At time of this report, new cases of hepatitis C were on the rise, a 71% increase from 2014 to 2018.[11] This posed a challenge as achieving the strategic goal requires reversing the trajectory of acute infection rate and making aggressive incremental gains in a short period of time.

This led to establishment of a two-phase approach to reduce hepatitis C infection and mortality in the general population by 20% and 25% respectively from baseline (2017) by the year 2025; while maintaining the 2030 goal as set forth by the WHO; a 90% decrease in new hepatitis C infections and 65% reduction in hepatitis C related morbidity and mortality rate.[12]

To achieve these goals, the national strategic plan focuses on five key areas:

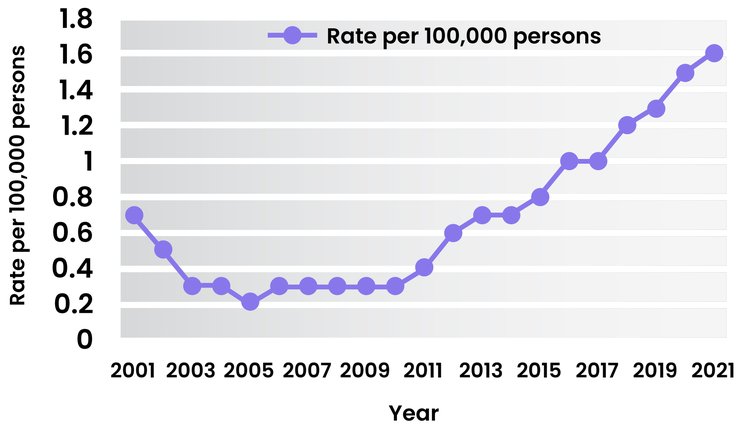
- **Increase public awareness**
- **Expand testing services**
- **Improve access to treatment**
- **Render follow-up visits**
- **Long-term health outcome**

The 2023 National Progress Report[13]:
Acute hepatitis C: Case count rising

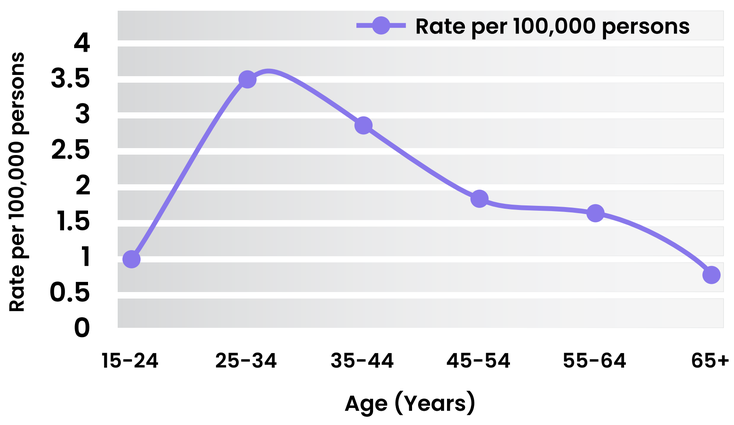
In 2021, a total of 5,023 acute hepatitis C cases were reported by 42 states, corresponding to 69,800 infections.[9]

60% increase from 2017 (baseline)

7% increase from 2020



Rates of acute hepatitis C were highest among males, aged 20–39 years, non-Hispanic American Indian/Alaska Native (AI/AN) persons.



57% of persons with acute hepatitis C reported injection drug use as a risk factor

The 2023 National Progress Report[13]:
Chronic hepatitis C

A total of 107,300 newly identified chronic hepatitis C cases were reported in 2021, corresponding to 39.8 chronic hepatitis C cases per 100,000 people.

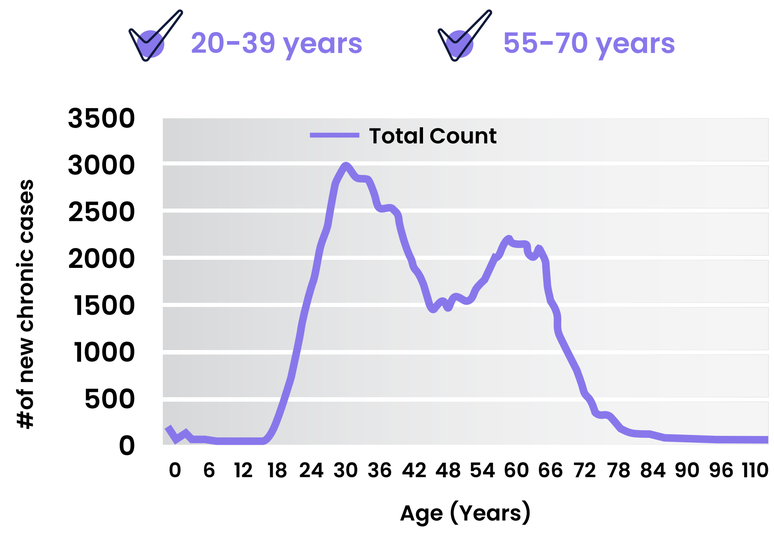
- **65%** of the newly reported chronic hepatitis C cases were men
- **23%** reduction in age adjusted hepatitis C associated death rate from baseline (2017)

However, disparity exists among racial and ethnic groups. In comparison to non-Hispanic white persons; hepatitis C related death rate was:

- **3.4 times** higher in non-Hispanic American Indian/Alaska Native
- **1.7 times** higher in non-Hispanic Black

Shifting Epidemiological Trends

Chronic hepatitis C affects multiple generations with infections highest among two age groups:



Proportion of cure rate

Proportion of hepatitis C virus-infected persons with evidence of viral clearance is lowest in the 20-39 years age group across all payer types.

Health system specialty pharmacy role in hepatitis C elimination

Since health system specialty pharmacies have access to and work inside an integrated Electronic Medical Record (EMR), they have a unique opportunity to contribute towards achieving the national goals of eliminating hepatitis C as a threat to public health through:

Patient Education
Patient education and engagement to increase public awareness on the need for hepatitis C screening and current treatment options

Testing Services
Expanding testing services and making them easily available to high risk communities

Treatment Plan
Streamlining hepatitis C treatment cascade for a seamless transition from diagnosis to linkage to care path

Patient Support
Developing patient support programs to make hepatitis C treatment readily accessible and affordable

Treatment Completion
Maximizing treatment completion and cure rates though patient engagement and providing medication adherence and adverse effect management services via telemedicine

Provider Partnership
Partnering with primary care physician offices to make sure patients follow through their cure confirmation laboratory studies

The Clearway Health Approach

Clearway Health partners with hospitals and health systems to accelerate their specialty pharmacy programs and operationalize clinical programs like hepatitis C screening and treatment. We have developed a clinical pharmacist-led hepatitis C program that eliminates barriers to testing services, medication access and affordability, and minimizes the attrition from initial diagnosis to linkage to care through:

Making hepatitis C screening service accessible and convenient by:

- Developing systemwide screening programs within our hospital partners:
  - ✓ Building best practice reminders into EMR
  - ✓ Screening opt-out option at patient visits, such as Emergency Department (ED) and Primary Care Providers (PCP) offices
- Targeting high-risk populations at our hospital partner sites through unique collaborations with:
  - ✓ Community health centers
  - ✓ Substance use treatment centers

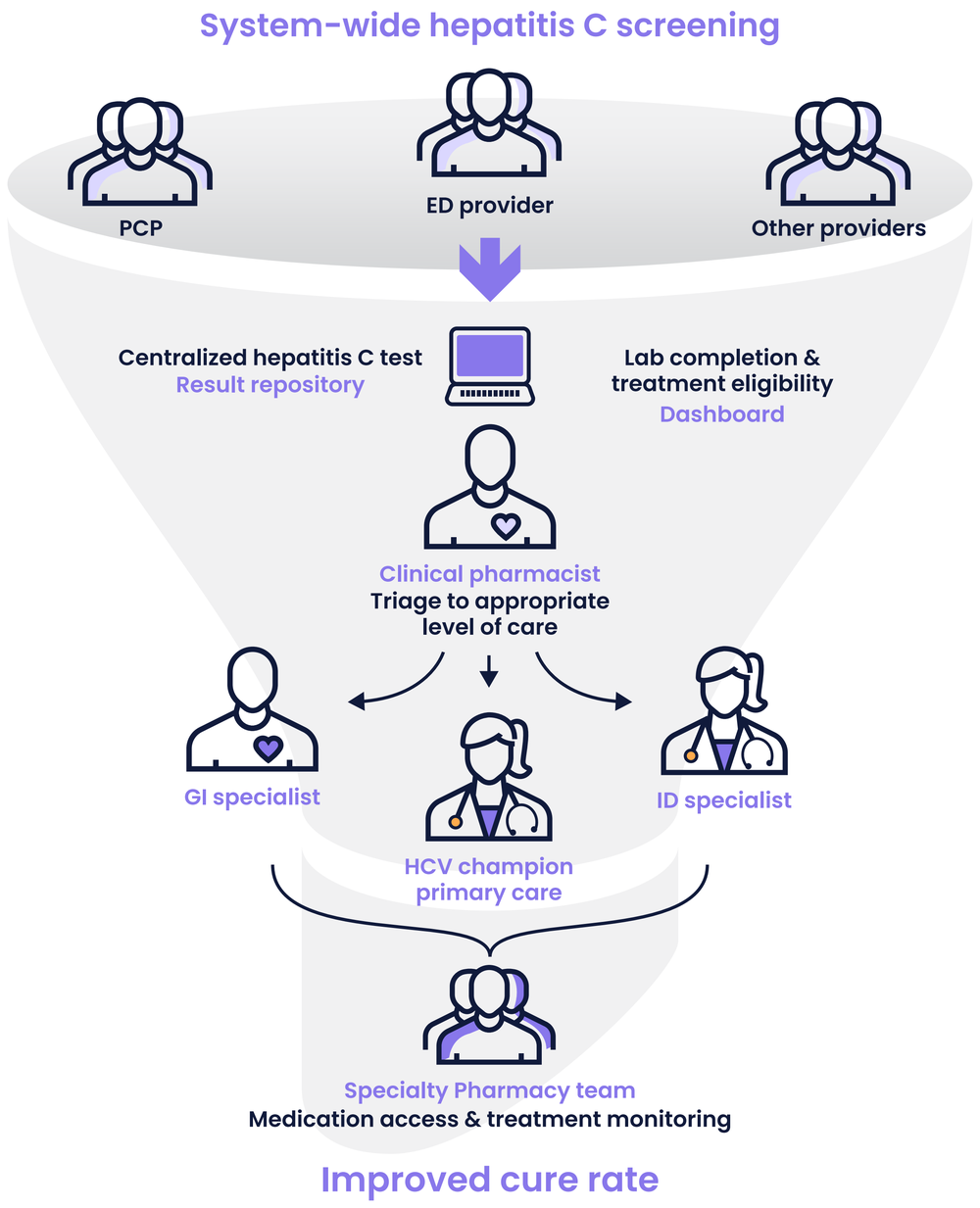
Minimizing attrition in the hepatitis C treatment cascade via:

- Building a reflex lab order procedure to eliminate multiple lab draws prior to starting therapy
- Creating a centralized lab test result repository and dashboard to ensure the a seamless test-to-treat cascade

Increasing hepatitis C medication access and cure rate by:

- Providing medication access support through our embedded pharmacy liaisons and clinical pharmacists
- Offering an in-person and telemedicine follow-up touch points to:
  - ✓ Ensure medication adherence
  - ✓ Provide adverse effect management services
  - ✓ Address clinical and non-clinical barriers to therapy completion
  - ✓ Ensure patients follow through their cure confirmation tests

Clearway Health's hepatitis C test-to-treat funnel



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