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NEWS

We have a cure for hepatitis C. Why are hundreds of New Englanders still dying every year?

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Harriet Callahan was caught completely by surprise.

While visiting a doctor for arthritis a few years ago, a routine blood test revealed she had hepatitis C, one of the deadliest infectious diseases in the United States. Callahan, in her 70s, was told it was likely the viral infection had been living silently in her bloodstream for decades.

She doesn't know where she contracted it. Was it in her teens when she received several blood transfusions after a car accident? Or from occasional drug use during her "hippie" days?

All these years later, it didn't really matter. The retired medical and legal secretary living in Hingham, Massachusetts was shocked — she'd shown no symptoms of the infection, which can lead to liver cancer and cirrhosis and contributed to upwards of 14,000 deaths in the U.S. in 2020.

"It was hard to deal with," said Callahan, 74, "knowing all these years I had it."

After two rounds of direct-acting antiviral treatment through the Brockton Neighborhood Health Center, Callahan was considered cured. Today she is "100% pleased" to be rid of it.

But even before taking her first pill, Callahan — on a Medicare prescription drug plan — said she was "ready to go home and live with it" when she saw the price tag — up to $30,000 per treatment round for the most common direct-acting antivirals. And she had two.

Callahan received a grant from the Patient Access Network Foundation to help cover the costs not paid for by insurance. And while she was cured, her story offers a daunting glimpse of the red tape that keeps people with hepatitis C from getting healthy.

When revolutionary direct-acting antivirals started to debut on the market between 2011 and 2014 and were later proven to cure hepatitis C 90% of the time, they sported a list price around $94,500, or $1,000 a day in some cases. States didn't want to dole out the money, concerned about the chunk of Medicaid funding hepatitis C treatment would take up alone.

So state Medicaid programs implemented restrictions such as prior authorization, constraints around substance use and special pharmacy/physician requirements — barriers to treatment that did years of damage, experts say. For years in which low-income people could have been cured of hepatitis C, they were instead faced with administrative roadblocks and labyrinthine regulations.

Dr. Francis Collins, former director of the National Institutes of Health and currently acting science adviser to President Joe Biden, said direct-acting antivirals — the most common being Harvoni, Epclusa and Maverik — are some of the most exciting medical developments of the last decade. The drugs have the ability to cure the most common bloodborne disease, and one of the most deadly, with 8-12 weeks of pills.

Despite a proven treatment, people are still dying.

According to the Centers for Disease Control and Prevention, between 2016 and 2020, the U.S. saw more than 80,000 deaths with hepatitis C listed as a cause. That data doesn't include undocumented immigrant or fetal deaths.

In the year 2020 alone, across all six New England states, approximately 467 people died with hepatitis C named on their death certificate.

An analysis by the USA TODAY Network found that hepatitis C treatment rates vary significantly across New England's state Medicaid programs and have actually fallen since 2018 and 2019 in all states except Maine, the last in the region to expand Medicaid in 2019.

The region's death rates vary dramatically, too. Federal and state data shows Rhode Island and Vermont had the highest death rates related to hepatitis C in New England between 2016 and 2020 and most years both states were higher than the national average. Maine and Connecticut had the lowest death rates in the region.

Officials have attributed the recent decline in treatment largely to the COVID pandemic which interrupted pathways to health care, though people with hepatitis C have faced challenges in accessing the cure long before the public health crisis.

The numbers paint a revealing picture that the region, and more broadly the country, isn't making the necessary progress to eliminate hepatitis C as a public health problem by the World Health Organization's 2030 goal.

CDC study shows: Fewer than a third of insured Americans with hepatitis C receive timely treatment

What is hepatitis C and how is it spread?

Hepatitis C is a viral infection spread primarily through contact with blood and blood products. Symptoms can include bleeding and bruising easily, fatigue, nausea, poor appetite, jaundice and dark-colored urine. Some people never show symptoms and can ultimately clear the virus.

But in the chronic phase, hepatitis C can cause cirrhosis, liver cancer and liver failure. According to the CDC, more than half of people who become infected with hepatitis C experience a long-term, chronic infection.

Before doctors were able to screen and test for hepatitis C, blood transfusions were one of the most common ways to spread the virus — one of the complex reasons so many "Baby Boomers'" are infected with it. Boomers, defined as people born between 1946 to 1964, make up three-quarters of Americans chronically infected with the virus, according to the CDC.

In the early 1990s, developments in testing nearly eliminated transfusion-related infections. Today, injection drug users are most commonly at risk for contracting hepatitis C, specifically through repetitive use of needles and other drug-related materials. It's estimated more than 50% of people who inject drugs have the viral infection.

Pregnant women with hepatitis C can also pass it to their baby. Other less-frequent ways of contracting the virus include illicit tattooing, needle-stick injuries in health care settings, and sometimes sexual activity in higher-risk populations.

"The whole human family all over the world is touched by hepatitis C," said Dr. Lynn Taylor, a Rhode Island expert in hepatitis C prevention and treatment and director of the RI Defeats Hepatitis C program. "We need to treat people with dignity and respect. When we get people cured, the relief of that stigma and that shame can be profound."

Taylor said everybody knows someone with hepatitis C, whether they know it or not. A loved one, co-worker, neighbor. Between 2013 and 2016, an estimated 2.4 million people in the U.S.

were living with hepatitis C, but the true number could be much higher since many people go untested.

Public health officials in March and April of 2020 issued significant updates to hepatitis C screening recommendations, but the announcement was largely lost in the COVID frenzy. The CDC now recommends universal hepatitis C screening at least once in a lifetime for all adults 18 years and older and for all pregnant people during each pregnancy.

The Biden administration is working on unveiling a comprehensive national hepatitis C plan, one that would include the CDC, Substance Abuse and Mental Health Services Administration, the Indian Health Service, Food and Drug Administration and the Federal Bureau of Prisons.

"The only way we can treat our way out of the hepatitis C epidemic in the U.S., driven by injection drug use, is diminish the infectivity of the transmitting population," said Taylor. "We need to prioritize and target people who inject drugs."

Why hasn't New England made more gains in hepatitis C treatment?

Tracking by the Center for Health Law and Policy Innovation at Harvard Law School and National Viral Hepatitis Roundtable shows that Medicaid restrictions for hepatitis C treatment remain across much of the country today.

Seventy-three percent of states currently require prior authorization before Medicaid beneficiaries can access treatment, and 36% still put restrictions in place for those actively using drugs, despite drug users being at disproportionate risk for contracting the virus, according to the 2022 State of Hep C Report.

More: States make secret deals with drugmakers to fight hepatitis C – and taxpayers pick up the tab

The federal Centers for Medicare and Medicaid Services has previously told states that some of those restrictions violate federal law, and yet they persist. CMS has not released any updated guidance for states since 2015.

Dr. Arthur Kim, director of the Viral Hepatitis Clinic in the Division of Infectious Diseases at Massachusetts General Hospital, said populations that acquire and live with hepatitis C are more likely to be on Medicaid than private insurance, making Medicaid a good barometer of how the country as a whole is making progress, or not, against the virus.

Treatment roadblocks in state Medicaid programs pose extremely large barriers to eliminating hepatitis C completely, experts say, because the lion's share of those infected have insurance through them.

In New England, the region is split. Massachusetts, Rhode Island and New Hampshire have since lifted nearly all Medicaid restrictions, while Vermont, Maine and Connecticut maintain prior authorization requirements and other various stipulations.

It's too soon to tell if lifting some of the major restrictions will increase the number of people taking direct-acting antivirals in New England, though other studies have found that hepatitis C treatment improves with such policy changes. Massachusetts and New Hampshire, for example, just lifted prior authorization in 2022, and Rhode Island in 2021.

New England as a region has made progress in recent years on the Medicaid front, perhaps more so than other areas of the U.S., but it hasn't always been that way. Kim said despite being a "fairly liberal place compared to the rest of the country," for a long time, New England states saw hepatitis C as "something not to treat widely because of the cost."

"Many payers were not willing to pay for everyone they were covering all at once," said Kim. "They saw very large dollar signs and said, 'We need to restrict this....' It really limited the impact of these highly promising agents."

"Hepatitis C: State of Medicaid Access," a tracking effort by the Center for Health Law and Policy Innovation of Harvard Law School and National Viral Hepatitis Roundtable, shows how New England's approach has changed over the last five years. In 2017, Maine, New Hampshire and Rhode Island all had substance use and sobriety restrictions in place, for example. In Maine, someone had to be six months sober before becoming eligible for treatment, while New Hampshire and Rhode Island required someone undergo substance use screening and counseling.

All of New England has since eliminated Medicaid restrictions for substance users.

Vermont and Rhode Island once both reserved Medicaid coverage of hepatitis C treatment only for people with F2 and F3 stages of fibrosis, respectively, designations that signal severity of liver scarring. Both states dropped those restrictions by 2018.

Kim said states started to see a drop in numbers on their liver transplant lists as Medicaid restrictions were shelved.

Suzanne Davies, clinical fellow at the Center for Health Law and Policy Innovation, said a "huge improvement" in New England is the recent removal of prior authorization in Massachusetts (2022), Rhode Island (2021) and New Hampshire (2022). That administrative process, she said, can be a significant barrier to tapping into direct-acting antivirals.

"Now in those states, it's as simple as the doctor prescribing whatever the medication is and the person going to the pharmacy," said Davies. "But because it's such a recent change, one thing I've heard many times from providers and advocates is it's not enough to just remove a restriction. In the wake of a state Medicaid program making a really big change to their program, it's important they make sure all of the providers are aware of the change and what they should be doing now."

And yet, noted Davies, there's still another layer of complication. Many state Medicaid programs contract with managed care organizations, which each have their own set of requirements. While prior authorization has been dropped in Massachusetts and New Hampshire, she said, not all of the states' managed care organizations have made the change themselves.

Taylor pointed to what she perceives as "administrative waste" associated with hepatitis C treatment restrictions.

"How much time do we spend on these bureaucratic tasks rather than the patients?" she said. "We have to simplify and streamline the pathway. We have a very arduous pathway. We put people through a lot."

How well are New England states treating hepatitis C patients on Medicaid?

The USA TODAY Network submitted information requests to each New England state Medicaid program to track direct-acting antiviral treatment for hepatitis C patients over the last five years.

The data provided reflected a national problem with gathering uniform numbers on hepatitis C.

An October report released by HepVu and the National Alliance of State and Territorial AIDS Directors found that one-third of U.S. jurisdictions in 2021 did not have a full-time viral hepatitis surveillance employee, and only 55% of jurisdictions could produce an annual surveillance summary.

In New England, state Medicaid programs offered different definitions of treatment, for example. Some provided numbers of prescriptions per year, while others provided the number of unique individuals treated per year. Some states struggled to calculate the total number of Medicaid beneficiaries with a hepatitis C diagnosis.

In its response, MassHealth – Massachusetts' Medicaid program – noted the data doesn't necessarily reflect someone being cured of hepatitis C, but rather simply their use of direct-acting antivirals. "Some members may require longer treatment durations, and completing a course of therapy does not indicate a clinical cure (whichneeds to be confirmed via lab tests)," the state's response said.

In 2020: Two Americans, British scientist win Nobel medicine award for hepatitis C virus discovery

Comparing the states' treatment rates proved difficult, but the USA TODAY Network was able to identify overall trends in each state between 2017-2021. While the number of Medicaid beneficiaries in New England with a hepatitis C diagnosis has declined, data shows, so has the rate at which states have been treating people.

Generally speaking, New England states saw their biggest treating years in 2017, 2018 and 2019, but nearly all have fallen off since. According to the American Association of the Study of Liver Disease, the nation saw an overall decline in the number of patients with hepatitis C who initiated treatment between 2015 and 2020.

Massachusetts, for example, went from treating 3,763 hepatitis C patients in 2017 to 1,708 in 2021. Connecticut went from treating 1,588 patients in 2018 to treating 726 in 2021.

Though 2022 isn't finalized, preliminary data shows Massachusetts, Rhode Island and Connecticut are all on track to treat the fewest number of patients in six years.

"Our team thinks we may be seeing a combination of incomplete 2022 data, claims submission lag and the need for patients to catch up on many areas of routine medical care that may have lapsed during the pandemic," said Kerri White, spokeswoman for Rhode Island Medicaid. "We are ramping up our (2023-2027) Hepatitis Elimination Plan. The next step of our plan is direct conversations with providers, to remind them of who to test and how to test. We also will be offering presentations to hospitals, group practices and medical staff meetings, as well as print materials for providers and patients."

New Hampshire and Vermont saw the least fluctuation in the number of people treated each year since 2017. And Maine actually saw a large increase that proved steady through COVID,

despite still having several Medicaid coverage restrictions in place such as prior authorization, required consultation with a specialist and prohibition of retreatment if someone is infected more than once.

In 2017 and 2018, Maine was treating 205 and 234 people per year, respectively, and in 2019, jumped to treating 495 people. The state has since consistently treated more than 450 people each year.

That's because 2019 was the year Maine expanded Medicaid, the last state in New England to do so.

Jackie Farwell, spokesperson for MaineCare, the state's Medicaid program, said, "Many MaineCare members who enrolled early on through the expansion had multiple chronic conditions, including hepatitis C, and were able to access treatment with their coverage."

In 2020, Maine also saw the nation’s highest new hepatitis C case rate, according to the CDC.

CDC data from 2016 to 2020 shows people with hepatitis C living in Vermont and Rhode Island are dying at higher rates than the rest of New England. During 2017-2019, Rhode Island consistently saw the highest death rate in the region, while Vermont had the highest in 2020.

'The business of medicine out-ruled public health'

Despite the resources and wealth at its disposal, the U.S. remains leaps and bounds away from a society where hepatitis C is eradicated, said Taylor. She pointed to countries such as Nigeria, Egypt, Switzerland and Portugal that are on their way to eliminating the virus.

"We're now years into this therapeutic revolution (with direct-acting antivirals), and that should have been a transformative moment where we really came together and said, 'We're going to cure everyone,'" said Taylor. "Unfortunately the first thing that happened, the business of medicine out-ruled public health."

Taylor called the country's hepatitis C response "the posterchild for health care disparities," one in which minorities, Indigenous people, the homeless, incarcerated and substance users are disproportionately hurt.

"We've had a patchwork response and instead of saying this is an opportunity in the long-run to save money, even if you don't care about health and wellness and suffering, Medicaid

responded by saying, 'We're going to ration treatment and make up rules. We're going to decide who's worthy and who's not.'"

Wiping out hepatitis C is going to take a multi-pronged approach. Experts cite dropping insurance barriers, harm reduction, opioid agonist therapy, and co-locating treatment in easy-to-access places as all critical to the fight against the infection. But instead, said Taylor, the country is addressing it in silos, making someone's likelihood of dying from the virus dependent on socioeconomic status and geographic location.

Hepatitis C doesn't exist in a vacuum, Kim said. Opioid addiction, homelessness and lack of access to health care keep people infected with hepatitis C, despite a widely available cure. By addressing the underlying problems that feed hepatitis C, said Kim, the country will also address the infection itself.

"The idea that you can't treat hepatitis C and cure it in these populations is basically false," Kim said. "But there's still barriers even if you make it easy from an insurance standpoint, including connection to care, competing priorities in life. Getting to an appointment to get your hep c treatment when you're dealing with homelessness or child custody issues. And then COVID came along and has clearly set us back in terms of people moving along the cascade of care."

Experts like Taylor and Kim argue, and are corroborated by data, that rationing Medicaid coverage of hepatitis C treatment means spending more on the back-end: liver cancer, cirrhosis and the many costs associated with substance use. The CDC itself says the average cost of curing people with hepatitis C "is not only cost-effective, but cost-saving to the health care system."

In 2011, the estimated total health care costs associated with hepatitis C infection was $6.5 billion, according to the CDC. Since 2017, one study has found, Medicaid has saved more money each year in long-term health costs by curing hepatitis C than it spent covering direct-acting antivirals themselves.

On the front lines of curing hepatitis C in New England

Testing for and treating hepatitis C in rural areas is a different challenge. In New Hampshire and Vermont, researchers are taking a mobile approach as part of the second-phase of the Rural New England Health Study focusing on injection drug users.

A joint effort between Better Life Partners, Baystate Health and Tufts University School of Medicine, a van offering hepatitis C testing, treatment and syringe services connects with people in rural communities in the Connecticut River Valley – setting up in parking lots of community-based agencies people are already frequenting.

People who test positive for hepatitis C on the van are either referred to Dartmouth Medical Center or the University of Vermont Medical Center, or, participate in a trial to receive treatment directly on the van – a way to measure effectiveness of mobile treatment.

Dr. Peter Freidmann, chief research officer at Baystate Health, said the availability of services in rural areas is "very limited," and researchers wanted to focus on risk factors for injection drug users in communities as such. Whether people would respond positively to an unmarked van offering hepatitis C services was a big question.

"We did a number of surveys with 600-plus people who use drugs, the lion's share of whom inject drugs," said Thomas Stopka, associate professor of public health and community medicine at Tufts University. "Some of the qualitative data really caught our attention because people talked about repetitive use of syringes. Access to harm reduction in Boston is much easier, for example."

Mobile treatment: Health care providers take a van to rural Vermont to curb hepatitis C

Stopka said the van allows researchers and medical staff to "get into nooks and crannies of the community that otherwise won't be reached or will have to go to great lengths to access services."

They've received widely positive feedback. "Wow, your staff on the van really get it, they listen to us," said Stopka, paraphrasing patients. "They are kind and are interesting in helping us."

Farther south, 25 miles outside of Boston, Dr. Shrien Saini looks proudly at the board of ribbons representing each patient the Brockton Neighborhood Health Center has cured of hepatitis C. Somewhere on the board is Harriet Callahan's ribbon from a few years back.

In March, Saini took over the center's hepatitis C clinic, which takes places every Thursday overseen by two providers. In 2022, they've cured nine patients — each person documented to be clear of the virus via a lab test three months post-treatment.

"When patients come to know about their cure, they are relieved," said Saini. "I believe they get a sense of encouragement that they have turned the corner and are another step closer to being healthy."

Saini recognizes the obstacles to care. Patients without working phones or safe places to sleep at night. Fear of bloodwork. Reluctance to attend an initial appointment, and then difficulty following through on subsequent appointments. She knows anecdotally that insurance is a major problem, but said the Brockton Neighborhood Health Center has a dedicated nurse who works on prior authorizations and communicating with various insurers. She calls the center "lucky" in that regard.

Meanwhile, next door in Rhode Island, Taylor often feels it's hard to make a dent in the crisis. She said the country's response to the deadly bloodborne disease is akin to "turning the bathtub water on full force with the drain open." She cures one patient and then diagnoses five new cases.

"I could just sit here and treat, treat, treat, " she said, "cure, cure, cure."