
Public health impact of a population-based approach to HCV treatment in New Mexico

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation's Polaris Observatory, in collaboration with ASTHO, CDC, New Mexico Project ECHO, the New Mexico Department of Public Health, and the University of New Mexico

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Executive Summary and Key Recommendations

Hepatitis C virus (HCV) is a blood borne infectious disease that causes substantial liver related morbidity and an increased risk of liver cancer and liver-related death.¹ HCV is often known as a “silent disease”, as there are few noticeable symptoms, especially in early stage infection.² Because of this, many infected individuals are unaware of their HCV status until more serious, late stage complications arise. Treatment is available for HCV, with success measured by the sustained viral response (SVR) rate at 12-24 weeks post treatment. Prior to 2014, an average of 48-70% of patients achieved SVR with the available therapies; however, recent therapeutic advances mean that SVR rates in 2018 have increased to more than 95%.³ Achieving SVR can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or hepatocellular carcinoma (HCC).^{4,5} This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.⁶ Transmission of HCV can be prevented by avoiding direct exposure to contaminated blood or blood products, including objects that may have come in contact with contaminated blood, such as needles and syringes.

Over the last 14 years, the HCV epidemic has drastically changed in the US. Originally a disease affecting “baby boomers” (people born between 1945 and 1965), HCV has reemerged as a syndemic with opioid misuse, overdose and HIV.⁷ In 2010, approximately 3.5 million Americans were infected with chronic HCV⁸ and, according to CDC data; HCV now kills more Americans than any other infectious disease.⁹ Additionally, HCV is the leading cause of cirrhosis and liver cancer, and the most common reason for liver transplantation in the US.¹⁰ In 2013, HCV-related deaths surpassed the total combined numbers of deaths from 60 other infectious diseases reported to the CDC, including HIV and tuberculosis; and in 2014, HCV-related deaths reached an all-time high with more than 19,600 deaths reported.¹¹ At the same time, there has been a marked simultaneous increase in the number of new cases of HCV across the US, particularly among people with a history of injection drug use.¹² Increases in acute HCV and hospital admissions for opioid injection were seen between 2004 and 2014, with new cases of HCV more than doubling between 2010 and 2014.¹³

National-level programs to control the burden of HCV have focused primarily on the older cohort of previously infected individuals. These programs include screening for HCV in the baby boomer birth cohort (1945-1965) as well as programs through the Veteran’s Administration (VA) to diagnose and cure all veterans infected with HCV. Despite these efforts, barriers to treatment still exist at the state Medicaid level, as evidenced in many states by fibrosis requirements that preclude treatment for patients with early stage liver disease.¹⁴ Universal procedures exist to prevent HCV transmission in medical settings across the US (though localized outbreaks may still occur when procedures fail). However, the recent opioid crisis presents a new challenge for HCV prevention efforts. At present, policies to prevent transmission among drug users are entirely state-specific, and in many states these policies are non-existent.¹⁵

This report presents the outcomes of a multi-stakeholder collaboration to assess the HCV disease burden in the state of New Mexico. This work follows a standard methodology (modified Delphi process) developed and facilitated by the CDA Foundation’s Polaris Observatory staff. It engages local stakeholders, including the New Mexico Department of Health, Researchers from the University of New Mexico, and Project ECHO (Extension for Community Healthcare Outcomes) staff to ensure the data used in the analysis represent the best available and to develop momentum and consensus toward a common goal. The tool used in this work is a Microsoft Excel based Markov model, populated with consensus estimates, which can answer the basic questions needed for HCV policy development.

Key Insights and Recommendations

Who is affected?

- At the beginning of 2017, there were 53,100 HCV-RNA+ (viremic) infections in New Mexico. Approximately 77% of infections were diagnosed prior to or during 2017 (n= 41,000) with 5,500 infections diagnosed annually, and 2% of persons infected (n=1,300) were initiated on treatment annually. There were an estimated 1,100 new infections annually, an incidence rate of 52.2 per 100,000 in 2017.
 - 45% of total infections were in the 1945 to 1965 birth cohort*
 - 17% of total infections were among people who inject drugs*
 - 15% of total infections were among women of child bearing age*
 - 6% of total infections were in prisons*
 - The percent of the HCV infected population on Medicaid was unknown
- *Percentages do not sum to 100% because overlap exists across groups and not all subpopulations are considered here

What is the impact of current policies?

- If currently policies continue and there is no change to the HCV treatment paradigm in New Mexico, the total number of HCV infections will decline 25% by 2030; but liver related deaths, HCC, and cirrhosis will increase 20-30% as the infected population ages.

What needs to be done to eliminate HCV in New Mexico?

- In order to eliminate HCV (defined as a 90% reduction in prevalent cases) by 2030 in New Mexico, fibrosis restrictions need to be removed by 2019. Between 2018 and 2030, 43,600 total treatments are needed, an average of 3,400 patients annually.
 - This elimination plan will result in a decrease in the number of HCV related liver related deaths, as well as end stage liver disease. Ultimately, more than 2,400 lives can be saved under this scenario.
- Additionally, prevention efforts need to increase, to lower the incidence rate from 52.2 per 100,000 cases in 2017 to around 2.1 per 100,000 by 2030.
 - Strategies such as expanding coverage of Medication Assisted Treatment (MAT) services, providing access to clean needles and syringes, and treating active drug users for their HCV could all contribute to this prevention effort.

Background

HCV globally

Today, an estimated 71 million individuals globally are infected with Hepatitis C, a curable disease that can lead to cirrhosis, liver cancer, and liver related death. Approximately 400,000 people die each year from causes related to HCV, which can be eliminated through coordinated efforts for prevention and treatment. Unfortunately, as of 2017, only 20% of those infected patients have ever been diagnosed, and, currently, only 2% of total infected patients are being treated for the disease annually.

The CDA Foundation and the Polaris Observatory

The CDA Foundation (CDAF) is a non-profit organization that specializes in the study of complex and poorly-understood diseases in order to provide countries and states with the data and information to create and implement successful elimination strategies. The Polaris Observatory, an initiative of CDAF, provides epidemiological data, modeling tools, and decision analytics to support eliminating Hepatitis B and C globally by 2030. The observatory offers the most up-to-date estimates for the HCV, hepatitis B virus disease burden and economic impact, and offers strategies for elimination of each virus, along with financing options. An independent advisory board with representatives from global health organizations, academia, civil societies and donors oversees the activities of the observatory. The Polaris Observatory's teams of epidemiologists work directly with stakeholders in over 100 countries to assess the current – and future – disease burden of hepatitis, model economic impact, and develop strategies that can achieve country or state-defined targets to eliminate it. By developing partnerships at country and regional levels, the observatory collects and analyzes data for its platform and publishes key findings to enable policies around hepatitis elimination.

How this model has been used globally

This work has resulted in the adoption of national hepatitis elimination strategies in countries such as Egypt and Mongolia. In Egypt, this included an economic analysis that accounted for both direct costs (healthcare, screening, diagnostic and antiviral therapy costs) and indirect costs (costs based on disability-adjusted life years). The analysis showed that it would cost Egypt US\$90 billion over a 15-year period if the government kept the status quo. A plan of action was then developed beginning in 2014 with a goal of treating 300,000 patients annually, including cost subsidies for four years. After seeing successes, the plan continued each year. In 2016, Egypt treated 577,000 patients and the plan expanded to include patients at all stages of disease, even those without any HCV-related consequences.

In Mongolia, CDAF and its Polaris Observatory team worked with the World Health Organization's Regional Office for the Western Pacific (WPRO) to first design an economic analysis and understand the disease burden. Working with partners including WPRO, the president of the Mongolian Association on Study of Liver Diseases, a physician professor and a group of other researchers, the team developed the co-payment method based on income level. The Mongolian government subsidized part of drug treatment and as prices declined, treatment became even less expensive for patients. CDAF also worked with the WPRO to develop a national screening program in urban and rural areas after reaching the conclusion that, even if the prevalence of HCV goes down in the next decade, there will still be more cases and deaths unless there is an increase in screening and diagnosis.

How this model has been used in the United States

In 2014, this work expanded to include state-based analyses within the US. Through collaborations with a combination of state health departments, the CDC Foundation, Association of State and Territorial Health Officials (ASTHO) and state collaborators this model has been used to encourage the removal of Medicaid fibrosis restrictions (Colorado), to publish the HCV epidemiology and an elimination scenario (Rhode Island) and to inform the development of state elimination strategies (District of Columbia and New York, *in progress*). Additionally, the results for five states (California, Colorado, Louisiana, Rhode Island and Washington) are included on the Polaris Observatory Website (<http://cdafound.org/polaris-hepC-dashboard/>). Ongoing analyses include collaborations with ASTHO, CDC and state partners to identify the disease burden and associated elimination strategies in Georgia, Iowa, Maryland, New Mexico, Pennsylvania, and Tennessee.

Hepatitis C related disease burden – New Mexico

New Mexico is a geographically large, populous state in the Southwestern region of the US. According to the recent HCV epidemiological profile of New Mexico, in addition to provider and funding deficits to cure HCV, stigma continues to be a barrier to receiving care and treatment, particularly amongst drug users.¹⁶

The analysis presented here represents the work of stakeholders from the New Mexico Department of Health (NMDOH), the University of New Mexico (UNM), Project ECHO (Extension for Community Healthcare Outcomes), ASTHO, CDC and CDAF. The primary objectives were to quantify the current and future disease burden of HCV in New Mexico and identify the level of effort necessary to eliminate HCV in the state.

Based on National Health and Nutritional Examination Survey (NHANES) adjustments conducted by Dr. Kimberly Page, it was estimated that 2.5% (1.7%-3.3%) of the population of New Mexico was chronically infected (RNA positive) with HCV in 2016.¹⁷ This equates to approximately 53,100 (36,700 – 69,500) infected individuals in 2016.¹⁸ These estimates are also supported by the New Mexico Department of Health prevalence calculations.

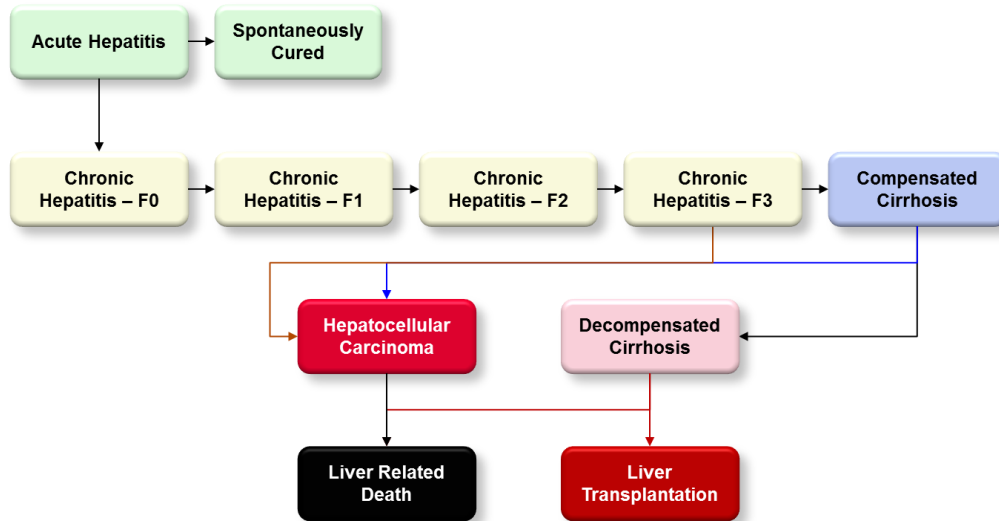
Achieving a sustained virologic response (SVR) to HCV treatment can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or HCC.^{19,20} This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.²¹ Direct acting antivirals (DAA) can achieve SVR in >95% of HCV cases.

Similar to the United States a whole, in New Mexico, almost 70% of individuals infected have genotype 1.^{22,23} Though previously genotype 1 chronic infection was the most difficult to treat, DAAs have become the standard of care and are safe for the treatment of genotype 1 patients. For this modeling exercise, we assumed a conservative SVR rate of 90% for all genotypes.

The model

The mathematical model is an Excel based disease progression model which was calibrated using reported, state-specific, epidemiologic data. The progression is as follows (Figure 1):

Figure 1.



The details of the model have been described previously in Blach 2017.²⁴ Briefly, a Markov disease progression model grounded in population, mortality, and state-specific HCV data was developed. The model was then used to forecast the disease burden by HCV-sequelae, including fibrosis, cirrhosis, decompensated cirrhosis, hepatocellular carcinoma (HCC), and liver related death from 1950-2030. The model follows the annual acute infections that progress to chronic infection, accounting for spontaneous clearance. Additionally, the model captures the progression of new cases by age and sex starting in 1950, accounting for mortality and cure. The age and sex distribution of new infections was back-calculated to match the reported prevalence.

Input data

The following epidemiologic data were input into the model (Table 1):

Table 1.

Historical Input	Estimate (Range)	Estimate Year	Source	Source Description
HCV-RNA+ Infections	53,100 (36,700-69,500)	2016	²⁵	Page 2016, Adjustments from NHANES data
RNA+ HCV Prevalence by Age and Sex	See Figure 1	2006	^{26,27,28}	Denniston 2014
RNA+ HCV Prevalence by Age and Sex	See Figure 2	2016	^{29,30,31}	Denniston 2014, scaled to the NM prevalent population (Page 2016) and aged through the model accounting for new cases of HCV in the under 30 population, reported through NMDOH notification data
HCV Genotype	See Table 2	2014-2017	^{32,33}	Managed Care Organization data provided in Scrase et al., (in press) and Project ECHO data
Total Diagnosed (RNA +)	38,840	2016	³⁴	Notification data provided by the New Mexico Department of Health
RNA+ Annual Newly Diagnosed	6,030	2016	³⁵	Notification data provided by the New Mexico Department of Health
Annual Number Treated	1,500	2016	³⁶	Managed Care Organization data provided in Scrase et al., (in press)

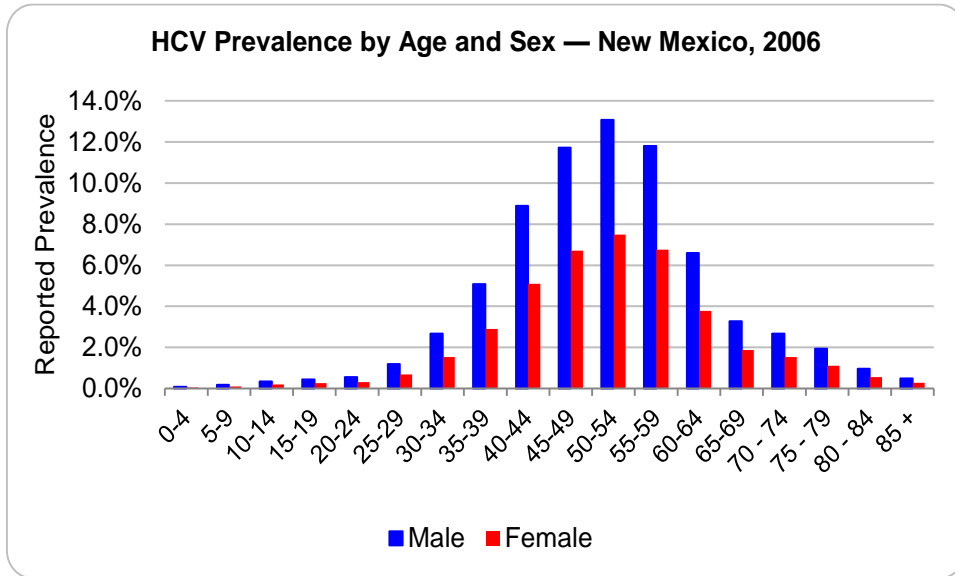
HCV Prevalence

Prevalence of HCV in New Mexico was estimated for 2016 by Dr. Kimberly Page from the University of New Mexico. Dr. Page adjusted values from the NHANES data, including estimates in prison, people who inject drugs (PWID), homeless, and hospitalized populations. Based on these adjustments, it was estimated that 2.5% (1.7%-3.3%), or approximately 53,100 (36,700-69,500) individuals were chronically infected with HCV in 2016.³⁷ The New Mexico Department of Health also estimates a similar prevalence range.

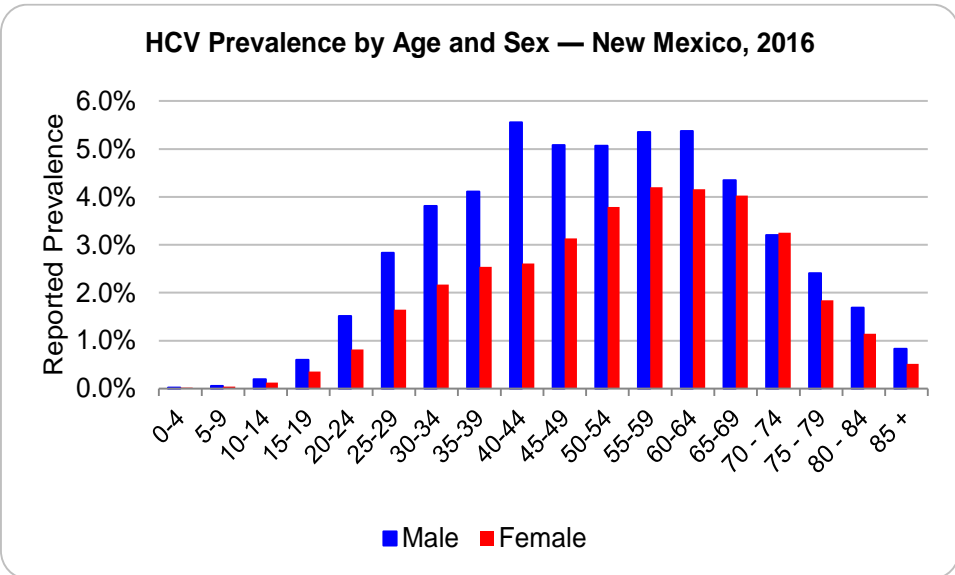
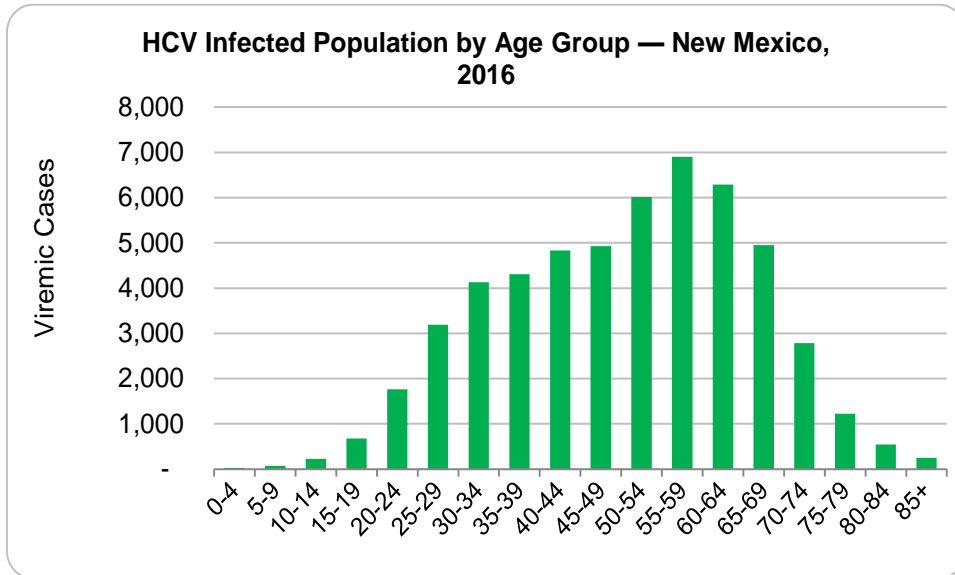
The historical age and sex distribution of the infected population in New Mexico was assumed to be similar to the US as a whole, so data reported from NHANES 2003-2010 were chosen for the baseline prevalence by age and sex in 2006.³⁸ Specifically, published US prevalence by age and sex was multiplied by the New Mexico population by age and sex in 2006, with extrapolations for younger age groups (Figure 2). Next, this distribution was scaled to match the overall number of HCV infections reported by Dr. Page in 2016. The HCV infected population was aged through the model by 10 years to estimate the age and sex distribution of the infected population in 2016. Additionally, the incidence by age from 2010-2016 was adjusted to ensure the age and sex distribution exceeded notified cases (surveillance data provided by the New Mexico Department of Health) for those under 30 years of age.³⁹

The distribution of total viremic cases by age and sex for New Mexico in 2016 can be seen in Figure 3a. As the opioid epidemic grows in the United States, we see an increase in the number of infected individuals between the ages of 25-39. More so, in Figure 3b, we see that males are approximately two-times more likely to be infected than females between the ages of 25-49.

Figure 2.



Figures 3a and 3b.



Genotype

The genotype distribution in New Mexico was calculated using weighted averages from Managed Care Organization (MCO) and Project ECHO (Extension for Community Healthcare Outcomes) databases (Table 2).^{40,41} MCO data represented 4,428 patients with a treatment authorization request between 2014-2017. The data provided by Project ECHO represented 1,738 individuals presenting to Project ECHO clinics, correctional facilities, Indian Health Services, or UNM Specialty Clinics between 2014 and 2017.

Table 2.

Genotype	G1	G2	G3	G4	G5	G6	Mixed/ Other
MCO (Scrase et al., manuscript in preparation)	3,117	401	787	108	6	9	0
Project ECHO	1,184	177	335	29	0	2	11
Weighted Average	69.75%	9.37%	18.20%	2.22%	0.10%	0.18%	0.18%

MCO: Managed care organization; Project ECHO: (Extension for Community Healthcare Outcomes)

Incidence

Incidence was back calculated to fit the total number of infections in 2016 and adjusted to best match notified cases in those aged 30 years and younger. Prior to 2010, the incidence trend in New Mexico was assumed to mirror that of the entire United States.⁴² Acute notification data from the New Mexico Department of Health were not available at the time of the analysis.

Diagnosis

According to notification data provided by the New Mexico Department of Health, 59,169 unique cases of confirmed or probable HCV were reported between 1995 and 2016.⁴³ Reported cases were aged from the year of report until 2016, adjusting for viremia (75%), age- and sex-standardized mortality rates, and the number of patients cured each year (in total, 9,297 treated and 6,380 cured). The resulting number of individuals estimated to be diagnosed, alive, and still HCV-RNA+ in 2016 was 38,840.

In 2016 alone, the NM DOH received reports of 8,043 HCV+ cases, and by applying a viremic rate of 75%, we estimated 6,032 patients were newly diagnosed with chronic HCV in that year.⁴⁴

Treated

Between 2008 and 2014, annual US treatment rates were applied to the New Mexico population to estimate the number of treated patients per year.

According to expert consensus, grounded in MCO treatment data, there were an estimated 1,500 patients treated annually in 2015 and 2016.⁴⁵ Treatment restrictions have been eased over the last several years, and in 2017 all patients were eligible for treatment regardless of fibrosis stage.

Subpopulations

Approximately 47% of the total population of New Mexico is currently on Medicaid and, of those, 90% are under the age of 30. The prevalence of HCV in the Medicaid population was unavailable at the time of the analysis.

Universal screening for anti-HCV in the prison populations began in 2009 for all incoming incarcerated people. Between 2009 and 2017, 27,994 unique individuals were screened for anti-HCV and of these, 11,514 (41.13%) were found to be positive. Of the 11,514 screened, 1,540 had a previously negative anti-HCV test upon admission but were subsequently found to be positive while they remained incarcerated. The proportion of people tested for HCV-RNA is unknown; however, of those who had an HCV-RNA test done, 3,287 had quantifiable RNA. As of February 2018, there are currently 7,327 people incarcerated in New Mexico (6,524 men and 803 women). Of the infected incarcerated population, 106 received treatment between August 1, 2015 and December 30, 2017.

There were an estimated 20,150 PWID in NM in 2016 (Data provided by Dr. Page). It was assumed that approximately 60% of the population was anti-HCV positive (expert consensus).

In 2017, approximately 20% of the total population in New Mexico was women of child bearing age. The prevalence of HCV in this population was unavailable at the time of this analysis, but could be estimated using the HCV disease burden model.

Results

Past and Present Burden of Disease

Annual incidence was modeled, considering expert input, to peak in 1989 around the time systematic blood screening began. It was then modeled to increase again in 2010 in order to capture the increase in opioid use in the United States. In 2017, there were approximately 1,100 new cases in New Mexico (52.2 per 100,000).

In 2017, 77%, or 41,000, of the 53,100 viremic infections were diagnosed. Of the total infected population, only 2% (1,300) were treated. Of the 1,300 treated, 90% (1,200) were cured. This cascade of care in 2017 can be seen in Figure 4. The distribution of infected cases by fibrosis stage, which are calculated by the model, can be seen in Figure 5. More than 25% of patients in 2017 were estimated to be fibrosis stage F1, while almost 50% were F2, F3, or cirrhotic.

The prevalence among subpopulations in 2017 was also considered. Within the incarcerated population, there were more than 2,200 RNA+ infections in 2017. This was calculated by applying the anti-HCV prevalence (41.1%) and a viremic rate (75%) to the number of incarcerated persons (7,237). In 2017, 4.2% of all viremic infections (2,230/53,100) were among prisoners.

The prevalence among PWID was also estimated. Assuming 20,150⁴⁶ total PWID in New Mexico in 2016 and applying an anti-HCV rate of 60% and a viremic rate of 75% there would be a total of we estimate that approximately 9,070 HCV-RNA+ PWID, approximately 17.1% of all viremic infections.

The model was used to calculate the prevalence among women of child bearing age (WoCBA) (Females aged 15-49 years) and in baby boomers (persons born in the 1945 to 1965 birth cohort) in 2017. The prevalence by age in the WoCBA population ranged from 0.4%-2.9% in 2017, with the peak prevalence

in those aged 45. In total, 15% of all viremic infections were estimated to be WoCBA. The prevalence by age in the baby boomer population ranged from 2.5%-5.8% in 2017. In total, 45% of all viremic infections were estimated to be among baby boomers.

Figure 4.

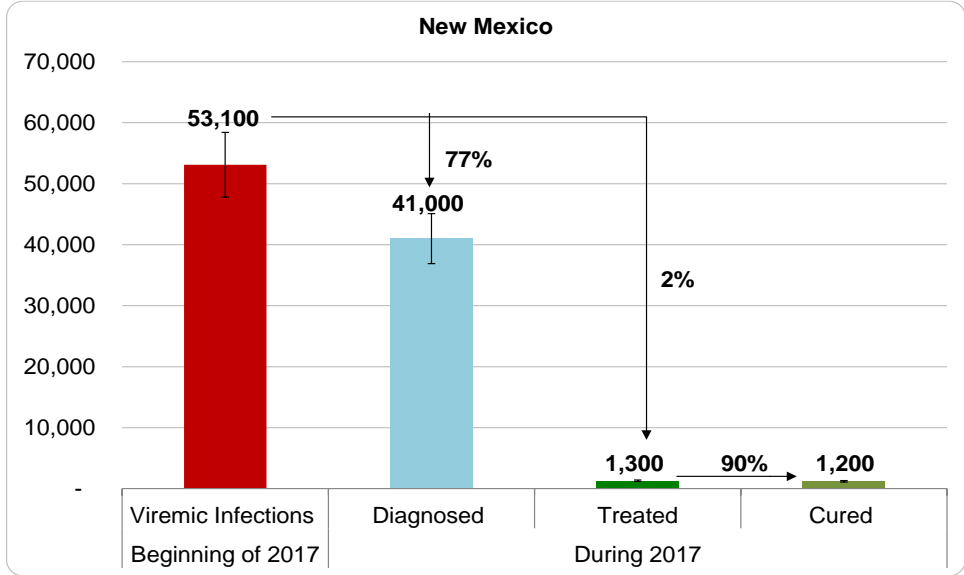
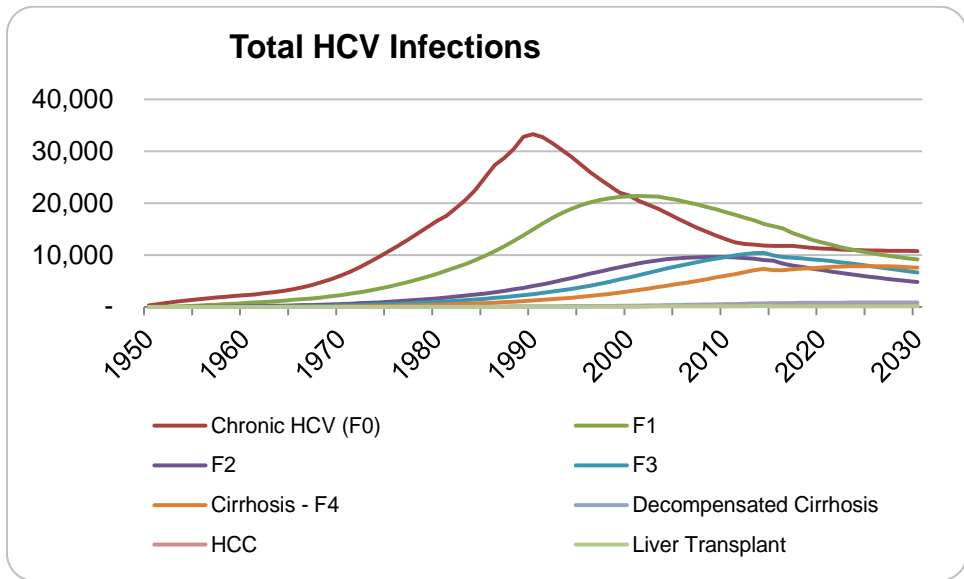


Figure 5.



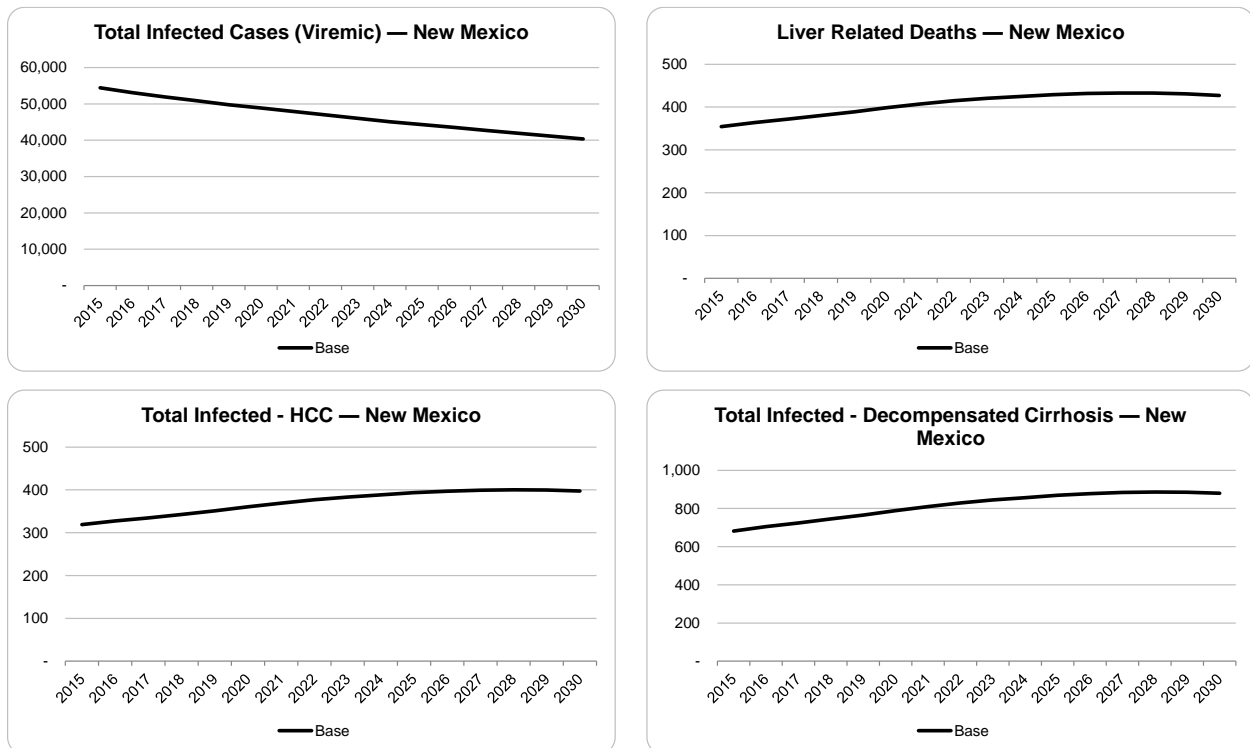
The base case: Assume a 50% decrease in treated and diagnosed by 2025

We calculated the impact on HCV infections and mortality if HCV treatment and diagnosis were to decline by 50% by 2025:

	2015	2016	2017	2018	2020	2025
Treated	1,500	1,500	1,300	1,100	940	750
Newly Diagnosed	5,300	6,000	5,500	4,700	4,000	3,000
Fibrosis Stage	≥F2	≥F1	≥F0	≥F0	≥F0	≥F0
New Infections	1,100	1,100	1,100	1,100	1,100	1,100
Treated Age	15-64	15-64	15+	15+	15+	15+
SVR	90%	90%	90%	95%	95%	95%

Under this scenario, the number of viremic cases peaked in 2003 and will continue to decline by 25% between 2015 and 2030, resulting in 40,400 cases by the end of 2030. However, liver related deaths, HCC, and decompensated cirrhosis will increase by 20-30% as the population ages (Figure 6). Total cases of HCC will increase from 320 in 2015 to 400 in 2030 (25% increase). Total decompensated cirrhosis cases will increase from 680 in 2015 to 880 in 2030 (30%). Given the current standard of care in New Mexico, there would be 80 more liver related deaths by 2030, a 20% increase from 2015.

Figure 6.



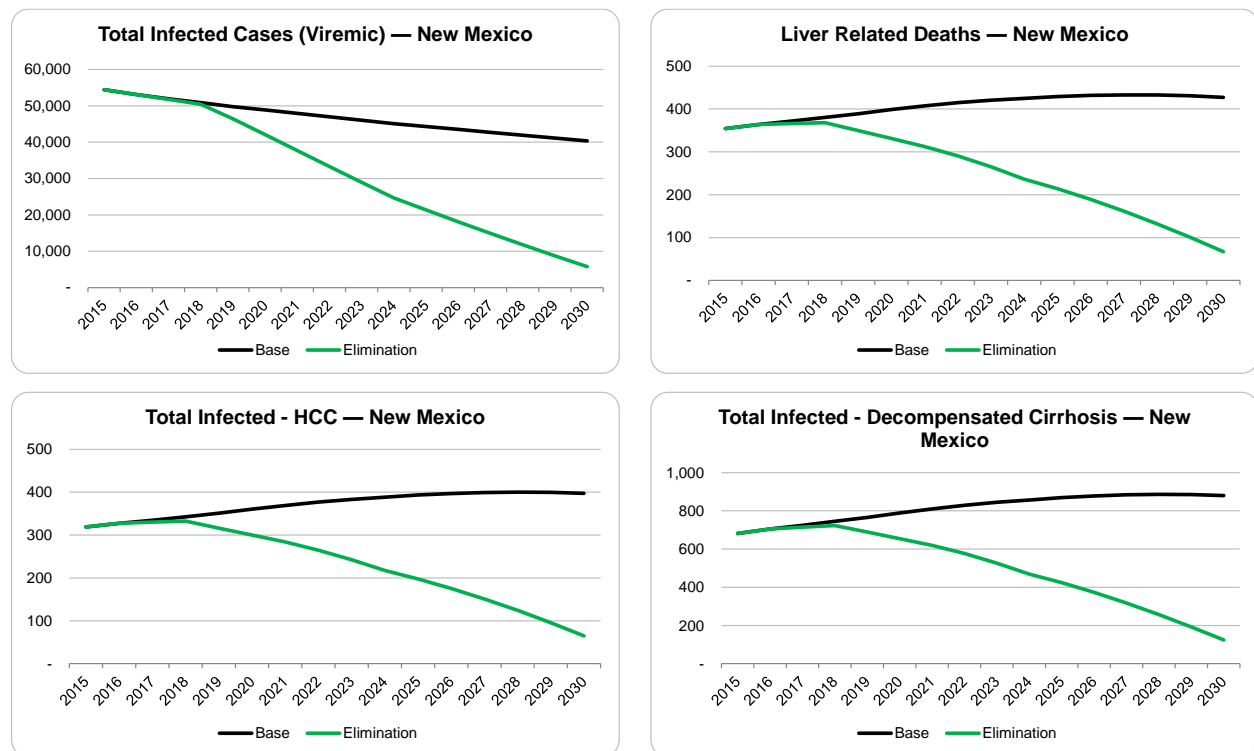
Elimination Strategy

We created an “elimination scenario” defined as a 90% reduction in total viremic infections by 2030. This strategy requires the following numbers of people to be diagnosed and treated for HCV:

	2015-2018	2019	2020	2021	2022	2025
Treated	1,500	4,000	4,100	4,000	4,000	3,000
Newly Diagnosed	5,300	6,000	3,200	360	170	90
Fibrosis Stage	≥F2	≥F0	≥F0	≥F0	≥F0	≥F0
New Infections	1,100	840	420	210	100	50
Treated Age	15-64	15+	15+	15+	15+	15+
SVR	90%	95%	95%	95%	95%	95%

Under this scenario, a total of 43,600 patients would need to be treated over the course of 2018-2030, or an average of 3,400 per year. Implementing these changes would result in an 80% reduction in HCV-related decompensated cirrhosis, HCC cases, and liver related deaths by 2030 (Figure 7). In 2030, 120 cases and 60 cases of decompensated cirrhosis and HCC, respectively, would remain. By achieving elimination, more than 1,260 incident cases of decompensated cirrhosis and more than 1,570 incident cases of HCC could be averted by 2030. Additionally, 2,400 lives could be saved by implementing this strategy.

Figure 7.



Discussion

The ability to forecast the HCV disease burden in the presence and absence of interventions allows policy makers the ability test hypotheses and quantify the impact of decisions. Using a Microsoft Excel based Markov model a team of state collaborators was able to develop consensus estimates to answer three primary questions - 1) Who in the state is most affected by HCV? 2) How do current policies positively or negatively impact indicators such as HCV prevalence, and HCV-related liver cancer and mortality? 3) What level of effort will be necessary to eliminate HCV?

Currently in New Mexico more patients are being treated annually than are newly infected with HCV. Alongside increased mortality from an aging population, this means that the number of HCV+ cases is declining in the state. At the same time, the aging population is progressing to costly advanced liver disease, which can be prevented through timely treatment. Although the number of new cases occurring annually is low compared with the number of patients being treated, most new infections are not diagnosed for many years. Without an active screening campaign to identify these individuals, they could remain silent carriers for decades, and may continue to transmit the virus and progress in their liver disease.

Elimination of HCV could be achieved in New Mexico by diagnosing more than 15,470 individuals and treating more than 43,600 between 2018 and 2030. Although more than 75% of the population is estimated to be diagnosed, this does not indicate that all patients are linked to care. Efforts will be needed to screen and diagnose new patients as well as to engage previously diagnosed patients with services.

New Mexico has been at the forefront of innovative policies and programs to address HCV prevention and care. Project ECHO has its roots at the University of New Mexico and now provides access to treatment and services for the entire state. There has also been increased access to prevention services such as statewide syringe services programs, Medication Assisted Treatment (MAT), and treatment and prevention programs in New Mexico prisons.⁴⁷ Additionally, New Mexico has progressive Medicaid Treatment Coverage, with the removal of all fibrosis restrictions in 2017.⁴⁸ Despite these efforts, further prevention of new infections is needed in order to achieve elimination. Strategies such as expanding existing coverage of MAT services, improving access to clean needles and syringes, and test-and-treat programs for high risk populations (including active drug users) could all contribute to this prevention effort.

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