Bryant University

HONORS THESIS

Predicting the Effects of Medicaid's Sobriety Requirements on the Spread of Hepatitis C in Rhode Island

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ABSTRACT

Hepatitis C (HCV) is the most prevalent infectious disease in America (1). This virus is spread through blood to blood contact, and disproportionally affects the People Who Inject Drugs (PWID) community. There is a 99% effective curative treatment available. However, Rhode Island Medicaid stipulates that a patient must be six months sober before accessing this treatment. Because of this barrier, less than 16% of people infected with HCV are able to access the curative treatment and the disease continues to run rampant throughout the state. Using SIS disease spread modeling techniques fit to current published Rhode Island Department of Health HCV data, this research modeled how the spread of HCV would be altered if this stipulation was repealed allowing PWID to access the curative treatment. The model showed that by relaxing the stipulation would lead to a conservative estimate of 5,000 fewer HCV infection and 500 HCV related deaths in the state by 2040.

INTRODUCTION

Current State of Hepatitis C in America

More people in the United States are now dying of hepatitis C than all 60 other infectious diseases combined; the virus is also the leading cause for liver transplants (2). Hepatitis C (HCV) is the most common blood borne virus in the U.S., and researchers suggest that less than 25% of those actually infected have even been formally diagnosed (2). According to a 2017 CDC report, around 100,000 people die every year in America from HCV related complications, including liver failure and hepatic cancer, and approximately 3.5 million other Americans are currently living with chronic HCV, a 150% increase from ten years ago. This large spike has been attributed to the growing opioid epidemic in the United States (2).

HCV is transmitted by contact with infected blood, the vast majority of new infections are from the People Who Inject Drugs (PWID) community, and the rate of infection is quickly rising (3). The global presence of HCV is around 2%; however, it is estimated that prevalence ranges between 15-90% among PWID (4). This rate of infection among PWID continues to grow as many remain undiagnosed and untreated.

Curative treatment for HCV has been available since 2001 when a mix of PEGylated interferons and ribavirin was introduced to the market (5). However, this interferon drug mix was to blame for many damaging side effects, such as depression, anemia and many autoimmune disorders and had a less than 55% curative rate in the most prevalent viral genotypes (6). Interferons were the only method of treatment, until direct acting antiviral treatment was approved in 2013. Direct acting antivirals (DAAs) drastically reduced side effects while also increasing treatment efficacy to approximately 99% by specifically

targeting the virus instead of the body's immune response (2). In addition, DAAs also only consists of a eight week course of treatment, as compared to the average 18 month intensive interferon treatment (6). However, even though the scientific community has developed an almost 100% effective treatment with minimal side effects, this deadly disease continues to grow because of barriers to treatment access.

After diagnoses, a hepatitis C patient has multiple hurdles to overcome, many unprecedented in other disease treatments, before they are able to eligible to receive lifesaving treatment. Since more than 82% of newly infected HCV patients live below the national poverty line, Medicaid is responsible for covering the large majority of HCV patients seeking treatment (7, 8). However, each state's Medicaid program has different stipulations to determine if a patient is able to access the treatment or not.

According to a report in 2016 from Harvard's Center for Health Law the three largest barriers to HCV treatment are fibrosis criteria (liver damage and disease progression), prescriber limitations (reimbursement procedures for treatment) and sobriety requirements (periods of complete drug and alcohol abstinence before and during treatment) (9). These identified barriers are also the areas that account for largest differences in Medicaid coverage from state to state. This research will center around how Rhode Island Medicaid's sobriety requirement affect the rates of infection and the percentage of cured patients in the state.

Current Rhode Island Medicaid HCV Sobriety Candidacy Stipulations

In the 2016 National Viral Hepatitis Roundtable's State of Medicaid Access Report Card, Rhode Island was given an access grade of a D-, citing that approximately only 16% of infected Medicaid patients were able to receive treatment (10). The NVHR bases the grade on

the state's level of restrictions concerning prescriber, liver disease progression and sobriety requirements. Rhode Island currently has the second strictest stipulations, requiring that a patient with HCV must have six months of documented sobriety before being considered for treatment coverage.

Sobriety requirements have become antiquated in the field of Hepatitis C treatment. Between 2001 and 2008, 22 separate studies have come out disproving the notion that there is any connection between substance use and HCV treatment adherence and/or efficacy (11). Specifically, a 2012 study concluded that six months of abstention had zero effect on the patient's adherence or the treatment's efficacy in curing HCV (12). Yet Rhode Island Medicaid operates under the mandatory sobriety requirements, denying over 65% of requests in 2015 based on sobriety status (13, 14).

According to the CDC's Office of Infectious Disease's 2017 report Rhode Island has double the percentage of HCV infections than comparable Massachusetts and Connecticut (2). Neither Massachusetts and Connecticut have sobriety restrictions in their Medicaid HCV coverage regulations and both saw drops in infection rate after relaxing their stipulations in 2013 and 2014, respectively (9). The Rhode Island Department of Health predicts that in the next five years, active HCV infections will surpass 15,000 and 200 deaths per year in the state of Rhode Island (2).

Research Scope

This research aims to determine how the sobriety regulations affect HCV rates in Rhode Island through SIS infectious disease modeling. The model would be able to predict

how many fewer people would be infected with HCV if Rhode Island were to eliminate the sobriety requirement, allowing PWID to access treatment.

METHODS

Data Collection

The main source of data used in this study was from the 2016 "Epidemiological Profile: The Hepatitis C Epidemic in Rhode Island" (15). This is the only recorded time series data set for HCV in the state. The state only has data for "deaths associated with viral hepatitis C" over the period of 2005 through 2014.

Due to the paucity of state published primary data, we had to look to different sources to estimate the true prevalence number in the state. HCV is a notably under-reported disease, due to the PWID community being historically underserved in healthcare. Dr. Lynn Taylor, an expert in HCV in Rhode Island offers the most accepted estimate of 20,000 people currently living with HCV, taking into account the under reporting (16).

From there, we looked to get an accurate estimate of the number of PWID in Rhode Island, who would make up the "susceptible" pool in our model. This is another population size that is not easy to gather primary, accurate data on because of the obvious lack of injection habit self-reporting. Amy Lanksy, the Director of the Office of National AIDS Policy, that asserts HCV infects 43,126 out of every 100,000 PWID in the US (17). By coordinating both the national estimation by Lanksy, with the state specific estimation by Taylor, we were able determine that in 2019, there are approximately 46,375 people who inject drugs in Rhode Island (Appendix A).

Using that number, we concluded that at any time 3.7% of the total state population is injecting drugs, and 1.8% of the Rhode Island population is infected with HCV. Those percentages were used to back estimate both PWID and HCV populations in Rhode Island using Rhode Island state population census data through 1980, giving us 39 distinct time series data points to base our model on (Appendix B). Fit with the epidemiology study death counts, we were also able to determine that .511% of the total HCV infected population dies every year from the disease.

HCV SIS Modeling Limitations

Though there have been theoretical compartmental models showing how HCV is spread before, none have been applied using real case data, such as state epidemiology reports. The current published theoretical models are incredibly thorough in accounting for nuance of the disease spread, however, their exhaustive nature is also their downfall when it comes to applying them to a real-world situation. The scarcity of primary data collected on HCV cannot justify the use of the previously published complex models.

To effectively apply a model to the data available, we chose to greatly simplify the accepted HCV SIS disease spread model published in 2010 by the Journal of Hepatology, in addition to updating it for the age of DAAs (20) (Appendix C). We stripped down the variables to only the most essential values necessary to accurately represent the disease's spread.

Our Model

Compartments

SIS models demonstrate disease spread through a defined population by outlining the definite compartments, or states, that a member of a population can exist in at any time. To build our model we determined that we would solely focus on the active PWID population because that is who is affected by the current Medicaid stipulations.

Table 1: Model Compartments

Variable	Description	Initial Value (1980)	Current Value (2019)	Source
N	Rhode Island State Population	947,154 people	1,063,785 people	(19)
S	People Who Inject Drugs in RI	40,727 people	45,742 people	(19), (17)
I	HCV infected population	17,564 people	19,727 people	(19), (16)
X	Dead via HCV	-	100 people	(15)

Parameters

The model operates in standard SIS model procedure by setting up a constant rate that the population is moved through the compartments. Table 2 outlines each of these set parameters.

Table 2: Model Parameters

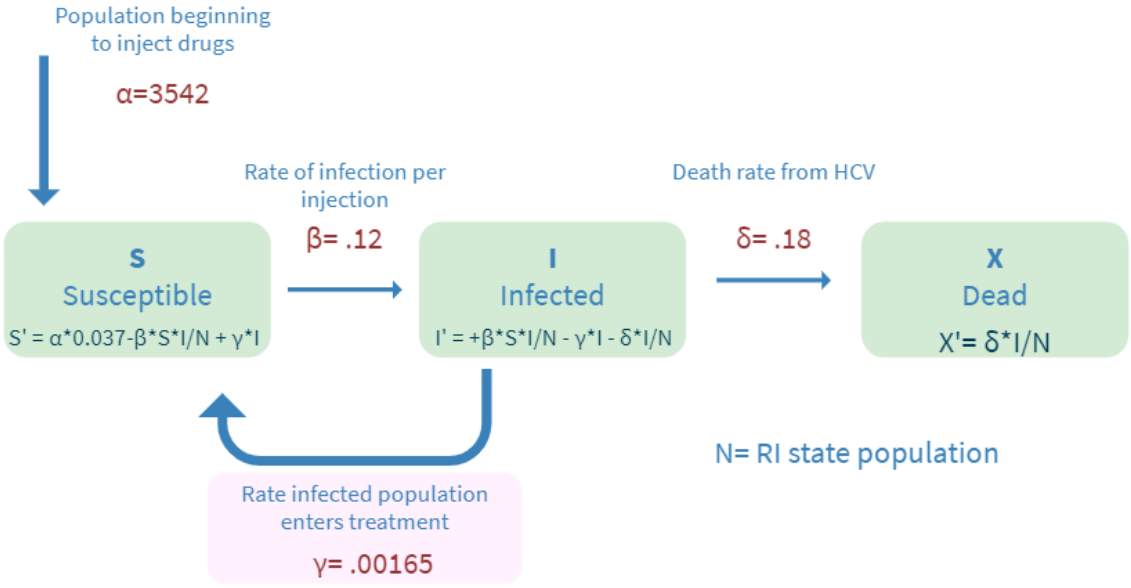
Variable	Description	Value	Uncertainty	Source
α	Rate entering via starting injection	3542	+/- 187.062	(20)
β	Rate of infection	.012	+/- .0155	(20)
δ	Rate of death from HCV	.18	+/- .000899	(20)
γ	Rate of treatment of total RI population	.00165	-	Experimental value

γ is the experimental variable in our simulations. Raising the γ value allows us to predict the effects of increased treatment availability on the HCV prevalence in Rhode Island.

Disease Spread Logistics Background

Through DAAs an HCV patient is able to be cured of the virus after infection through a six-week course of oral medication (18). However, once cleared of the disease, a patient is able to become re-infected if exposed to HCV again through blood to blood contact. Since the treatment provides no immunity to HCV, our model accounts for PWID moving back into the susceptible population once treated.

Figure 1: HCV SIS Base Model



Base Simulation

Python

We ran the model by using Python programming language on the Jupyter Lab platform.

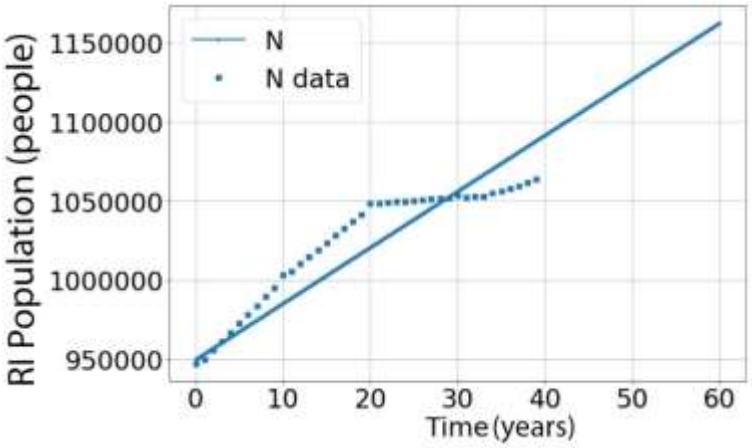
Base Simulation

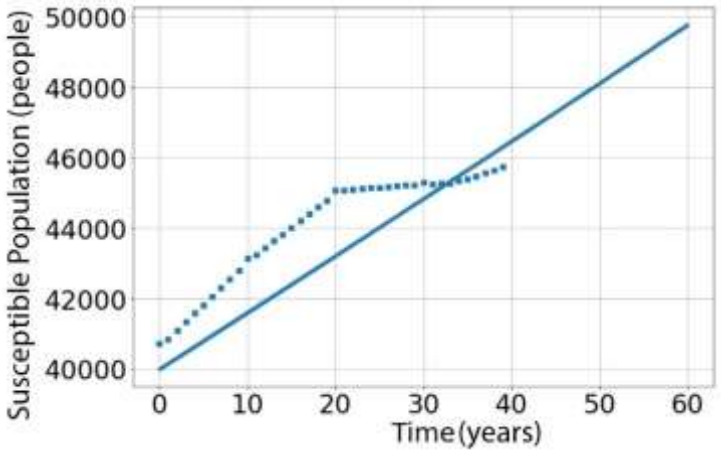
After importing the data from Appendix B, we fine tuned the published parameter values to best fit the Rhode Island specific data. We used Markov chain Monte Carlo (MCMC) distribution analysis to determine the control values.

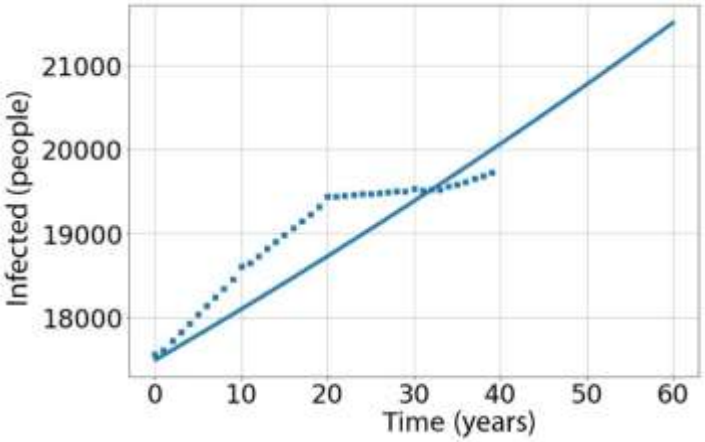
The base simulation outputs the value estimates of Rhode Island population, susceptible population (PWID) and the infected population (HCV) through 2040 if there was no change to current sobriety policy. The base simulation is used as the control to compare the

experimental models to. Time values were adjusted to start at t=0, 1980 and run through t=60, 2040, with t=39 representing 2019, the last year of implicit data.

Figure 3: Base Simulation Time Series Projections Through 2040







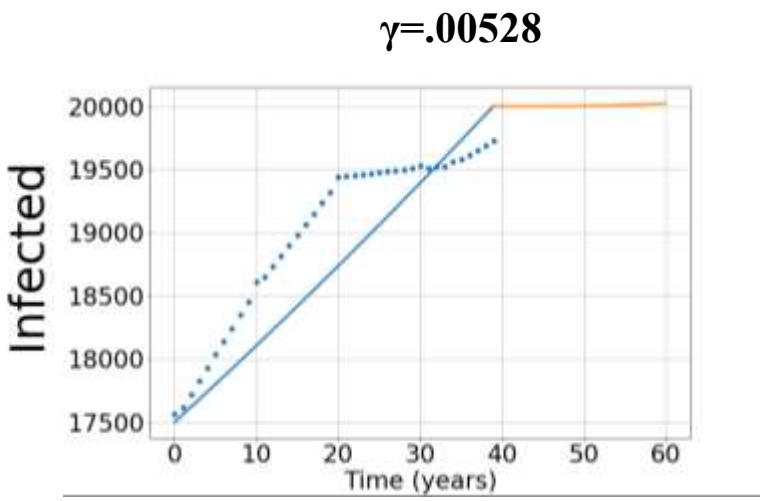
Experimental Simulations

Stopping the Growth of HCV

In an era where a curative treatment is available, there is no excuse for the HCV rates to still be increasing from year to year. Our first experimental simulation aimed to determine how many people would have to be treated to stagnate the growth of HCV in Rhode Island among the PWID community. This would mean that even though new people were entering the susceptible pool from beginning injecting, the same number of people would be infected.

This value was obtained through MCMC analysis of the γ value that would produce a $t>39$ slope of 0 in the infected population.

Figure 4: Stopping Disease Growth Simulation Projection Through 2040

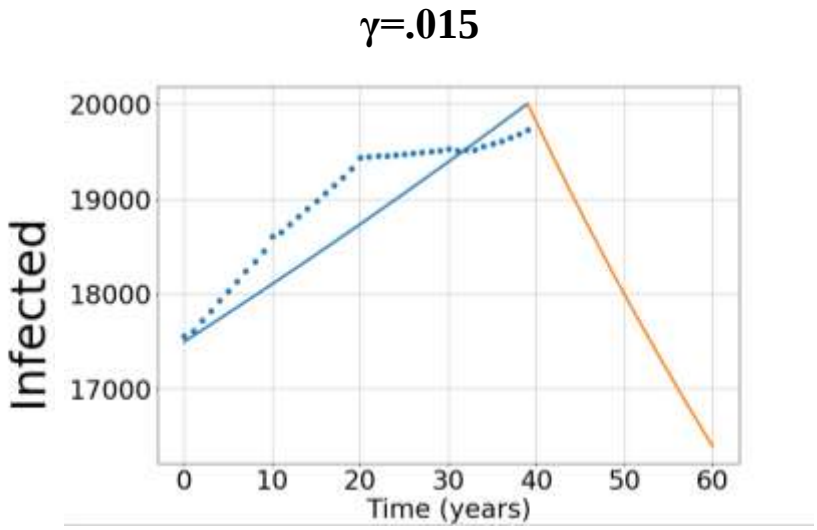


85% HCV Treatment Access Simulation

To model disease spread if the Medicaid sobriety stipulation was to be repealed, we had to formulate an estimate as to what percent of HCV would realistically access the treatment now available. Other states without sobriety stipulations have reported ~90% of their infected population accessing treatment (21). We opted for a conservative estimate of 85% of the infected population would, in fact, access and be cured by the treatment.

The 2019 estimate of 85% of HCV is 15,956 individuals, or 1.5% of Rhode Island. For this simulation γ was set to .015 to reflect the scenario.

Figure 5: 85% of HCV Accessing Treatment Projection Through 2040

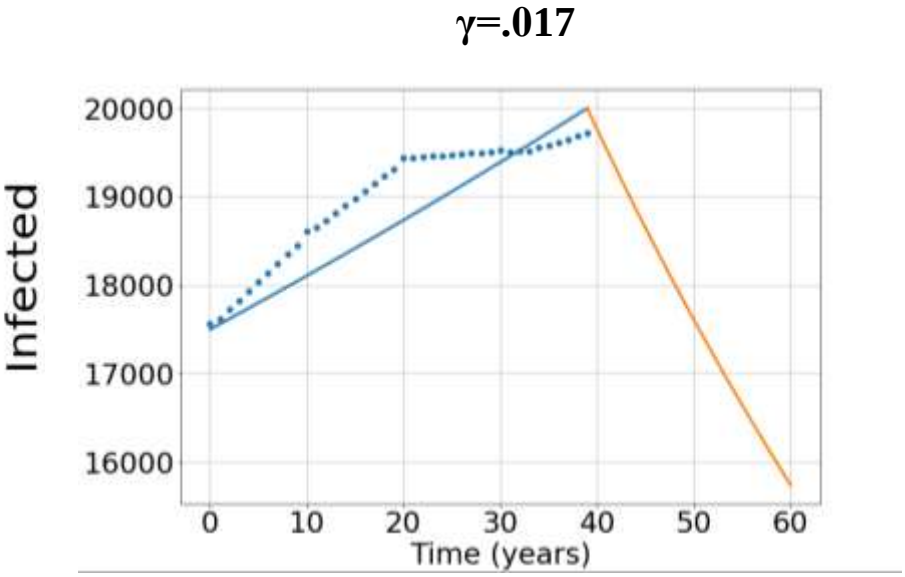


92% HCV Treatment Access Simulation

Lastly, we estimated an optimistic scenario in which 92% of the HCV population accessed treatment.

The 2019 estimate of 92% of HCV is 18,084 individuals, or 1.7% of Rhode Island. For this simulation γ was set to .017 to reflect the scenario.

Figure 6: 92% of HCV Accessing Treatment Projection Through 2040



FINDINGS

As predicted, by allowing more people to access curative HCV treatment, fewer people would be able to spread the disease, meaning fewer people would be infected. This conclusion could be deduced from any of the theoretical models that have been previously published, however, our model provides tangible population sizes that translate to real Rhode Islanders currently battling HCV.

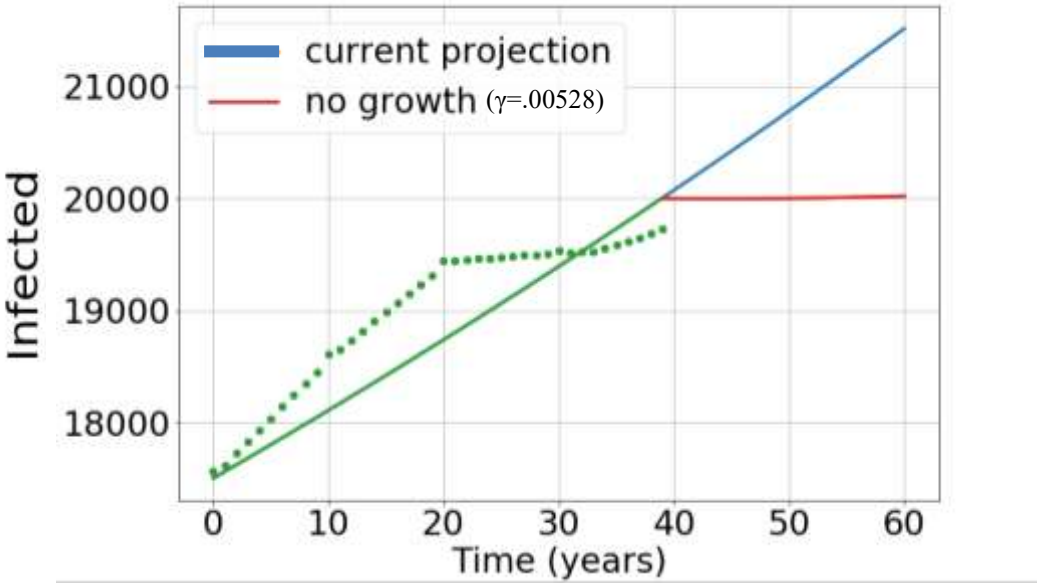
Current Treatment Access

The current population size able to access treatment was estimated by fitting the models to the 1980-2019 data. The MCMC analysis showed that the γ value for the base model was .00165. $\gamma = .00165$ represents 1755 HCV people accessing treatment, which is 8.7% of the total infected PWID population. Since Rhode Island Medicaid requires 6 months of full sobriety to be eligible for treatment, this 8.7% accessing treatment must come from PWID with private insurance.

No Growth Simulation

The minimum number of people accessing treatment needed to stop HCV growth in Rhode Island was determined by looking at the γ value that would produce a $t>39$ slope of 0 in the infected population graph, Figure 7.

Figure 7: Stopping Growth of HCV vs Current Projection through 2040



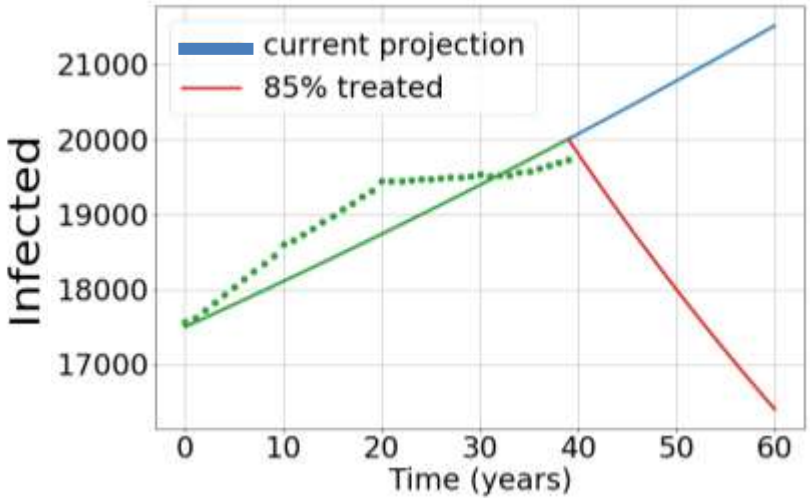
Without reform, in 2040, there will be an estimated 21,250 people infected with HCV in Rhode Island. Growth of the infected population is stagnated at 20,000 people by allowing approximately 28% of the infected population to access treatment.

28% of the current infected population is approximately 5,616 people that would have to be treated to stagnate HCV growth in Rhode Island. Even by only allowing 28% of the infected population to access treatment, Rhode Island Medicaid would avoid 1,250 fewer active HCV infections by the year 2040.

85% of HCV Accessing Treatment

In this simulation we adjusted γ to reflect 85% of the infected population accessing treatment. 85% of the HCV population in 2019 is 15,956 people accessing treatment.

Figure 8: 85% HCV Accessing Treatment vs Current Projection through 2040



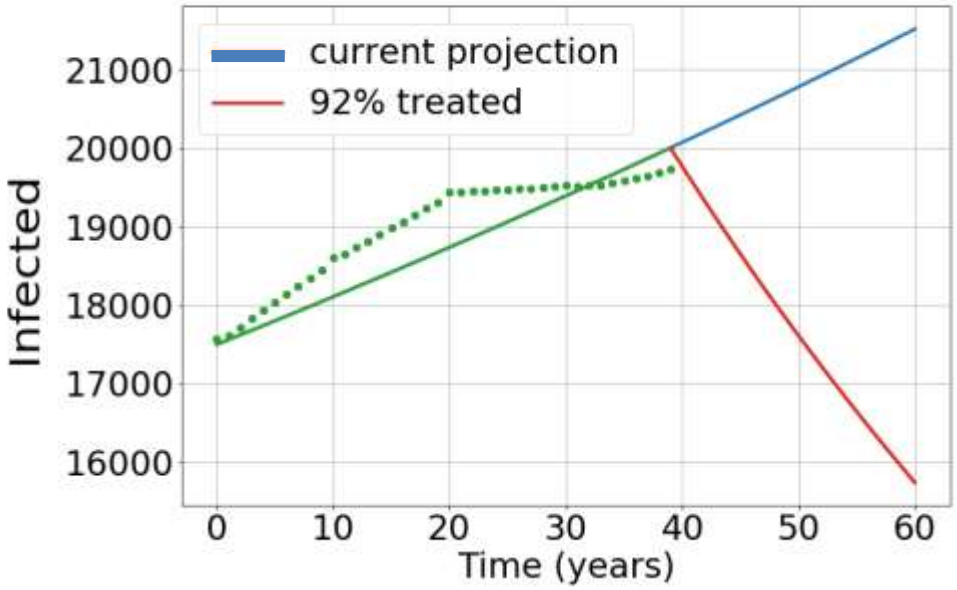
Without reform, in 2040, there will be an estimated 21,250 people infected with HCV in Rhode Island. By repealing Medicaid's sobriety stipulation, allowing for 85% of infected people to be treated, approximately 16,250 people would be infected in 2040.

In a conservative estimation of 85% of infected people accessing curative HCV treatment, 5,000 fewer people would be infected with HCV in 2040. In 2040 there would be 3,750 fewer people infected than in 2019.

92% of HCV Accessing Treatment

In this simulation we adjusted γ to reflect 92% of the infected population accessing treatment. 92% of the HCV population in 2019 is 18,084 people accessing treatment.

Figure 9: 92% HCV Accessing Treatment vs Current Projection through 2040



Without reform, in 2040, there will be an estimated 21,250 people infected with HCV in Rhode Island. By repealing Medicaid's sobriety stipulation, allowing for 92% of infected people to be treated, approximately 15,850 people would be infected in 2040.

In an optimistic, yet realistic, estimation of 92% of infected people accessing curative HCV treatment, 5,400 fewer people would be infected with HCV in 2040.

DISCUSSION

Research Implications

The models show how effective a repeal in Medicaid's sobriety stipulation would be in greatly reducing the prevalence of HCV in Rhode Island. Figure 9 demonstrates how receptive the disease spread would be to even a small percentage of the PWID population accessing treatment. In addition, even our simulations using a conservative outreach estimation showed the gross benefit that repealing this barrier to treatment would have on

overall public health by both greatly reducing the number of HCV infections in the state and in turn the reducing in HCV related mortality in Rhode Island.

Since the beginning of this research, Rhode Island's Department of Health has recently announced that it will make efforts to systematically repeal their sobriety requirements for curative HCV treatment in the coming years (22). Though Rhode Island often prides itself for being one of the most progressive states in the union, it remains one of the only states to continue to deny lifesaving treatment to its citizens based on sobriety status (10). In addition, studies have been published asserting that even though Medicaid costs would initially rise to cover the increased distribution of DAAs, in the long run the state would save money from not having to pay for all of HCV's tertiary effects, such as liver cancer and liver transplants (23). Yet, there are still people suffering from the horrors of HCV's deadly and painful symptoms that are forced to see curative treatment available across the counter at the pharmacy, but not able to access it. As conscious citizens, we must ask ourselves: how did we get into this mess and how can we continue to justify simply turning the other way to let fellow Rhode Islanders die preventable, painful deaths?

Why Has Reform Taken So Long?

Intuitively it is easy to theorize the inverse relationship between increased treatment access and declining disease prevalence on a macro level. In addition, this SIS model allows us to examine the direct, quantitative effects of increased treatment access on a state specific level. So, with this information available, why has Rhode Island Medicaid taken so long to reform its stipulations?

To examine this pressing question, we must step back and look at one of the most fundamental characteristics of HCV: what population it affects. In almost all aspects of life, People Who Inject Drugs (PWID) are pushed to the side of society's view (8). There is a common question that tends to arise whenever discussing opening up state funded treatment to PWID: why should we help people that did this to themselves? This stance often comes from viewing addiction as a transgression of morality instead of the biologically driven disease that it is. In the last ten years, a multitude of studies have been published linking the pathology of addiction more akin to diseases such as cancer and diabetes, than a sign of weak character (24). Though addiction experts have asserted this point, this progressive sentiment has not filtered down throughout a majority of society (25).

These lack of interest in the diseases that disproportionally affect the PWID, is clearly demonstrated in the lack of recorded data on HCV in Rhode Island. The state of Rhode Island offers no estimate as to how many people are currently infected with HCV, the leading infectious disease. The only empirical, time series data that Rhode Island has published was death counts provided by hospitals, consisting of only nine years (15).

By current medical standards, the idea of someone being denied cancer treatment because they have asthma seems absurd and grossly unrealistic. However, if we recognize addiction as a biological disease, that is exactly what Rhode Island Medicaid is doing by denying curative HCV treatment to people struggling with addiction. By demonizing PWID and unethically oppressing them through Medicaid sobriety stipulations, Rhode Island has made the conscious decision to allow HCV rates to rise and Rhode Islanders to die preventable deaths.

Advocacy Hurdles

In an era of questioning and pushing back against systematic oppression of marginalized groups, how, as a society, do we still remain largely ignorant to the pressing issue of HCV in the PWID community? One explanation is the lack of advocates working for PWID. Taylor illuminates the lack of advocacy channels available to the PWID by contrasting the response to the HCV epidemic to the HIV epidemic in the 1980s (8). Though both are spread through relatively taboo means, HIV began to affect many rich, white, educated people in the US. Once HIV spread to the upper echelon of society, persistent, financially supported advocacy groups quickly began to crop up across the US (26). Marches on Washington were organized, and prime cable news segments were allocated to making the severity of the disease known. These advocates were so successful in pushing for change that HIV was pushed to the forefront of medical research, highly effective treatments were developed, and the epidemic was quelled (26).

The difference between HIV and HCV is that HCV almost solely affects marginalized groups who have little to no pull in society (8). With approximately 82% of the HCV infected population living below the national poverty level, they have little means to advocate for themselves. Forming organized, well-funded advocacy coalitions gets pushed down the list of importance when someone is worried about where they will sleep for the night and if they can feed their children.

Going Forward

Though Rhode Island has decided to follow through on this much needed Medcaid reform, 20 other states in 2019 still have sobriety requirements restricting access to curative

treatment. The methods used in this study could be applied to any of these states to see how, on a case specific level, their state could benefit from repealing this discriminatory barrier to treatment.

Without being able to advocate for themselves, the HCV community in these 20 other states has to rely on outside parties to advocate on their behalf. By continuing to research and ask questions about problems that affect marginalized populations, scientific research like this study can begin to bridge the gap and work to reduce inequality in the medical field.

APPENDICES

Appendix A – Population Estimation Equations

HCV in RI Calculation
Current RI population: 1,063,785 people (19)

Current HCV infections: 20,000 (16)

20,000 HCV
---------- = 1.8% of population is infected with HCV
1,063,785 total population

PWID in RI Calculation

HCV in RI: 20,000 (16)

HCV/PWID: 43,126 people infected with HCV per 100,000 PWID (17)

43,126 HCV 20,000 HCV in RI
---------- = ----------
100,000 PWID X

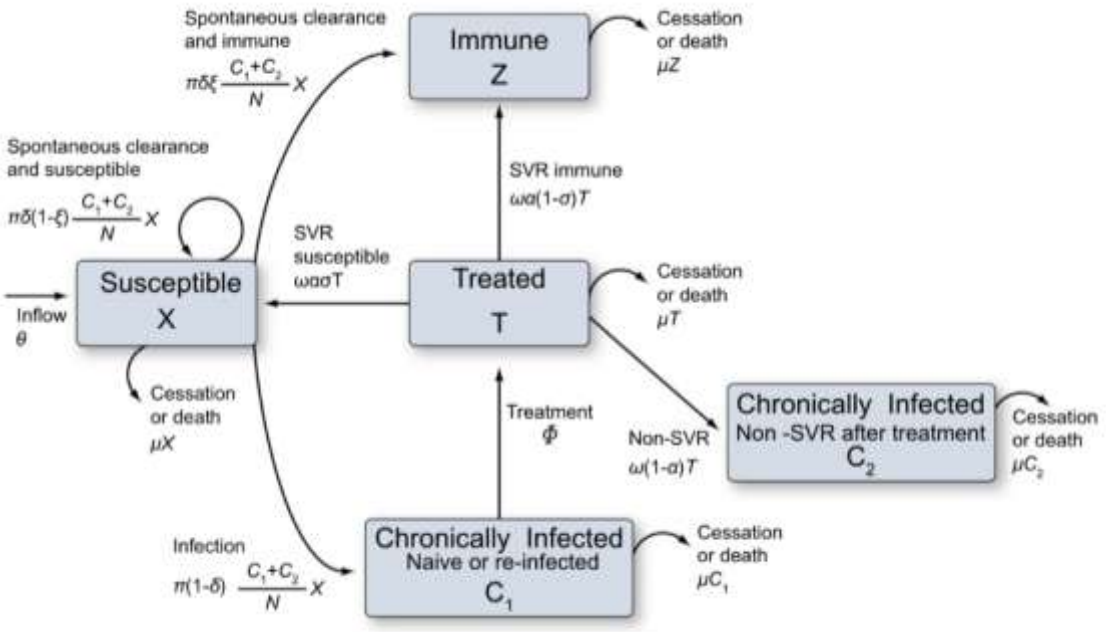
X= 46,375 PWID in RI
4.3% of RI population is PWID

Appendix B – Population Sizes Data Table

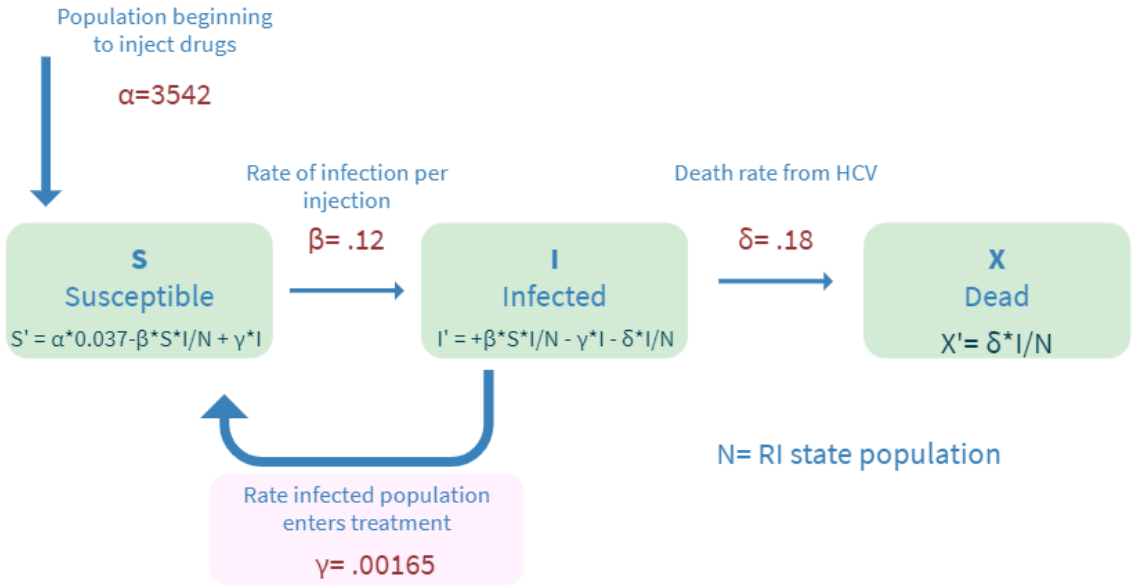
	YEAR	N	PWID	HVC	DEATHS	DEATH/HVC *100
0	1980	947154	40727.622	17564.194264	NaN	NaN
1	1981	949999	40849.957	17616.952456	NaN	NaN
2	1982	955627	41091.961	17721.319101	NaN	NaN
3	1983	961255	41333.965	17825.685746	NaN	NaN
4	1984	966883	41575.969	17930.052391	NaN	NaN
5	1985	972527	41818.661	18034.715743	NaN	NaN
6	1986	978154	42060.622	18139.063844	NaN	NaN
7	1987	983782	42302.626	18243.430489	NaN	NaN
8	1988	989410	42544.630	18347.797134	NaN	NaN
9	1989	995054	42787.322	18452.460486	NaN	NaN
10	1990	1003464	43148.952	18608.417040	NaN	NaN
11	1991	1005730	43246.390	18650.438151	NaN	NaN
12	1992	1010212	43439.116	18733.553166	NaN	NaN
13	1993	1014706	43632.358	18816.890711	NaN	NaN

	YEAR	N	PWID	HVC	DEATHS	DEATH/HVC *100
14	1994	1019188	43820.084	18900.005126	NaN	NaN
15	1995	1023670	44017.810	18983.120741	NaN	NaN
16	1996	1028151	44210.493	19066.217211	NaN	NaN
17	1997	1032645	44403.735	19149.554756	NaN	NaN
18	1998	1037127	44596.461	19232.669771	NaN	NaN
19	1999	1041609	44789.187	19315.784786	NaN	NaN
20	2000	1048319	45077.717	19440.216233	NaN	NaN
21	2001	1048534	45086.962	19444.203232	NaN	NaN
22	2002	1048958	45105.194	19452.065964	NaN	NaN
23	2003	1049383	45123.469	19459.947241	NaN	NaN
24	2004	1049807	45141.701	19467.809973	NaN	NaN
25	2005	1050233	45160.019	19475.709794	25.0	0.128365
26	2006	1050658	45178.294	19483.591070	42.0	0.215566
27	2007	1051082	45196.526	19491.453803	52.0	0.266784
28	2008	1051507	45214.801	19499.335079	76.0	0.389757
29	2009	1051933	45233.119	19507.234900	61.0	0.312704
30	2010	1053169	45286.267	19530.155506	80.0	0.409623
31	2011	1052154	45242.622	19511.333164	75.0	0.384392
32	2012	1052761	45268.723	19522.589481	87.0	0.445638
33	2013	1052784	45269.712	19523.015997	76.0	0.389284
34	2014	1054782	45355.626	19560.067269	100.0	0.511246
35	2015	1055916	45404.388	19581.096369	NaN	NaN
36	2016	1057566	45475.338	19611.694266	NaN	NaN
37	2017	1059639	45564.477	19650.136351	NaN	NaN
38	2018	1061712	45653.616	19688.578436	NaN	NaN
39	2019	1063785	45742.755	19727.020521	NaN	NaN

Appendix C – Theoretical HCV Disease Spread Model



Our Model



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