Public Health Impact of a Population-Based Approach to Hepatitis B Prevention and Treatment in Hawaiʻi

This is a summary of the key outcomes of a hepatitis B transmission, disease burden, and economic impact analysis undertaken by the Center for Disease Analysis Foundation, in collaboration with the Hawaiʻi State Department of Health. This report was released on November 1, 2024.

Key points

- If no change is made to hepatitis B virus (HBV) treatment and prevention in Hawai‘i, then:
    - The total number of HBV infections will decline, but liver deaths and hepatocellular carcinoma (HCC) will increase as the infected population ages.
- We modeled different strategies to assess the impact of different interventions on the future disease burden from HBV:
    - HHS Scenario — developed to meet the HHS targets of 90% of the infected population being diagnosed by 2030, with 80% of those who are diagnosed and eligible being under treatment
    - WHO 2024 Elimination Scenario — developed to meet the HSS targets of 90% of the infected population being diagnosed by 2030, with 80% of those who are diagnosed and eligible being under treatment while expanding those eligible for treatment beyond the AASLD guidelines
        - Based on updated WHO guidelines, this includes all patients who have:
            - ≥ fibrosis score 2 (F2), or
            - HBV DNA > 2,000 IU/mL and ALT>ULN

The results of these strategies:

- Screening and treatment must be drastically increased to reach 2030 HHS targets
    - Prevention of mother to child transmission has been successful with the modeling exercise estimating that Hawai‘i has already met the WHO target of ≤ 0.1% HBsAg prevalence among those aged ≤ 5-year-olds.
- Meeting the HHS 2030 targets in Hawai‘i will result in 90 cases of decompensated cirrhosis averted, 140 cases of HCC averted, and 130 lives saved through 2030.
- If treatment eligibility is expanded per the WHO 2024 Guidelines, then there would be an estimated 100 cases of decompensated cirrhosis averted, 170 cases of HCC averted, and 150 lives saved through 2030.
    - This scenario required the same diagnosis level as HHS; however treatment must be scaled up further and earlier.
- Through 2030, both scenarios were found to be highly cost-effective with the cost per DALY averted being $29,200 for the HHS scenario and $31,000 for the WHO 2024 Elimination scenario.
    - If the number of diagnostics required annually is reduced in the HHS scenario, the cost per DALY averted will drop to $27,200.

Hepatitis B transmission and related disease burden

The prevalence of hepatitis B virus (HBV) infection in the United States (US) has been the subject of a long-running debate. The results of the National Health and Nutrition Examination Survey (NHANES) have shown a relatively stable prevalence over time, with the most recent publication estimating a national HBV prevalence of 0.32% (95% confidence interval (CI), 0.24–0.41%), representing 817,000 (95% CI, 613,000–1,100,000) infected individuals, ≥ 15 years, in the period of 2013–2018 while an older study reported a prevalence of 0.28% (0.22–0.35%) among those ≥ 6 year-olds representing 862,000 (668,000-105,600) infections in 2011-2016 [1, 2]. Other estimates reported a higher prevalence of HBV infections in the US (1.04–2.49 million) [3-5]. Immigrants to the US contribute to a significant portion of the HBV infected population and the under-sampling of the NHANES study in these populations would explain a significantly lower prevalence [1, 6]. Between 1988 and 2012 there were, on average, 3,000 samples per year in NHANES [7]. The study design of NHANES, surveys or door knocks, make responding challenging for foreign-born communities, with limited English proficiency, to participate. Furthermore, there can be hesitation to acknowledge foreign-born status and country of birth. While there is the category for place of birth, US or Foreign Born, there is great diversity in immigrants' country of birth as well as the HBsAg prevalence and vaccination policies in their home country. Thus, it is very difficult to estimate an adjusted HBV prevalence for immigrants using NHANES data.

This is particularly problematic in a state such as Hawaiʻi, which has a large foreign-born population as well as large established immigrant communities. To overcome these biases in NHANES, we developed and published an estimated of HBV based on the lawful permanent resident population.[8] To briefly summarize, the annual number of immigrants receiving lawful permanent resident status in the US was collected from 1900 onward by country of birth, age, and sex. Country level models were available and utilized for 99.4% of all immigrants receiving lawful permanent resident status in the US since 1900. For countries in which immigration data existed but models were not available, a regional average using the Global Burden of Disease regions was applied. Each country-level model compatible with immigration data was used to annually provide two inputs: (1) HBV-positive immigrants entering the US — added to the US prevalent population, and (2) immigrants susceptible to HBV infection entering the US. For the former, the annual HBV prevalence by age and sex in the country of birth was applied to the number of incoming immigrants by age and sex, distributed by the stage of liver disease. This process explicitly considered the historical and continued impact of HBV prophylaxis programs in the countries of birth. For the second set of inputs, the annual proportions of infected and recovered cases or those previously immunized in the countries of birth were applied to the incoming immigrants by age and sex. Once in the US model, the entire population was subject to the disease progression of HBV infection that may lead to HBV-related deaths, the age and sex specific US background mortality and the impact of vaccination, screening, and treatment schedules within the US. The assumptions regarding the US interventions to prevent, screen and treat HBV are detailed in the previous publication [8]. As the PRoGReSs model is dynamic, the added immigrant cases impacted the perinatal and horizontal transmission within the US at the population level.

This analysis provided the age-adjusted prevalence estimate among the foreign-born population by country of birth. The American Community Survey (ACS) 2018-2022 5-year estimate data for place of birth for the foreign-born population in the Hawaiʻi were collected and combined with the modeled prevalence of lawful permeant residents by country of birth [9].

The ACS contains county level population estimates for 127 countries of birth as well as multiple regions. When a country of birth specific modeled immigrant estimate was not available, the regional Global Burden of Disease average was used. When ACS data were only available by region, a regional estimate, as defined by the countries included in ACS regions, was applied.

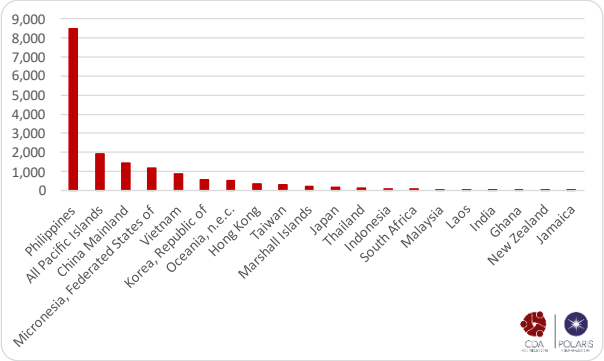
The ACS also estimates the non-foreign-born population by county and territory.[10] The non-foreign-born population was divided into two populations – Asian and Pacific Islanders and the remainder.[11] This split was necessary, as it has been well established that Asian and Pacific Islanders historically have the highest HBV prevalence among racial and ethnic groups in the US.[1, 7] However, NHANES does not differentiate between non-foreign-born and foreign-born Asian and Pacific Islanders. To overcome this shortcoming, we developed a US model that only considered Asian and Pacific Islanders and immigrants from these countries. This exercise resulted in a prevalence of 0.69% among non-foreign-born Asian and Pacific Islanders. This was the base estimate in the analysis. For the uncertainty analysis, the non-foreign-born estimate of 0.12% was applied for the low, and the 5.20% estimate among Asians was applied for the high.[1] For the remainder of the non-foreign-born population, the most recent NHANES published estimate of 0.12% (CI:0.07–0.20%) was applied.[1]

This methodology resulted in an estimated statewide prevalence of 1.3% (UI: 0.5-4.0%) in Hawaiʻi, representing 19,100 (UI: 7,500-57,400) people living with HBV.

County	HBV Prevalence (%)
Honolulu	1.4% (0.6%-4.2%)
Maui	1.2% (0.4%-3.8%)
Kauai	1.2% (0.3%-4.0%)
Hawaiʻi	0.9% (0.3%-3.0%)

County	HBV Prevalence (UI)
Honolulu	14,500 (6,100-42,100)
Maui	2,000 (580-6,300)
Hawaiʻi	2,000 (200-3,000)
Kauai	900 (530-6,000)

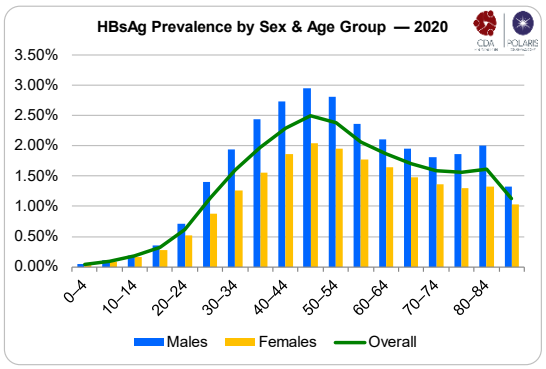
This analysis estimated that 79% of people living with HBV in Hawaiʻi are foreign-born, and that 17% are among Asian Pacific Islanders born in Hawaiʻi.



*All Pacific Islands includes all pacific islands, including those listed separately (ex. FSM)

The presence of HBeAg was estimated to be 21% among women of childbearing age (ages 15-49) that were also positive for HBsAg based on a study from North California [12]. It was estimated that 90% of those that were HBeAg+ had a high viral load (defined as ≥20,000 IU), and 13% of those that were HBeAg- had a high viral load [13]. Approximately 29.7% of the infected population was estimated to have a high viral load. The proportion of the population with a high viral load is what drives transmission (perinatal and horizontal) within the model, and those individuals with a high viral load progress faster in the model relative to those with low viral loads.

The national estimate for the age and sex distribution of people living with HBV was then scaled up to match the 19,100 cases in Hawai‘i [8].

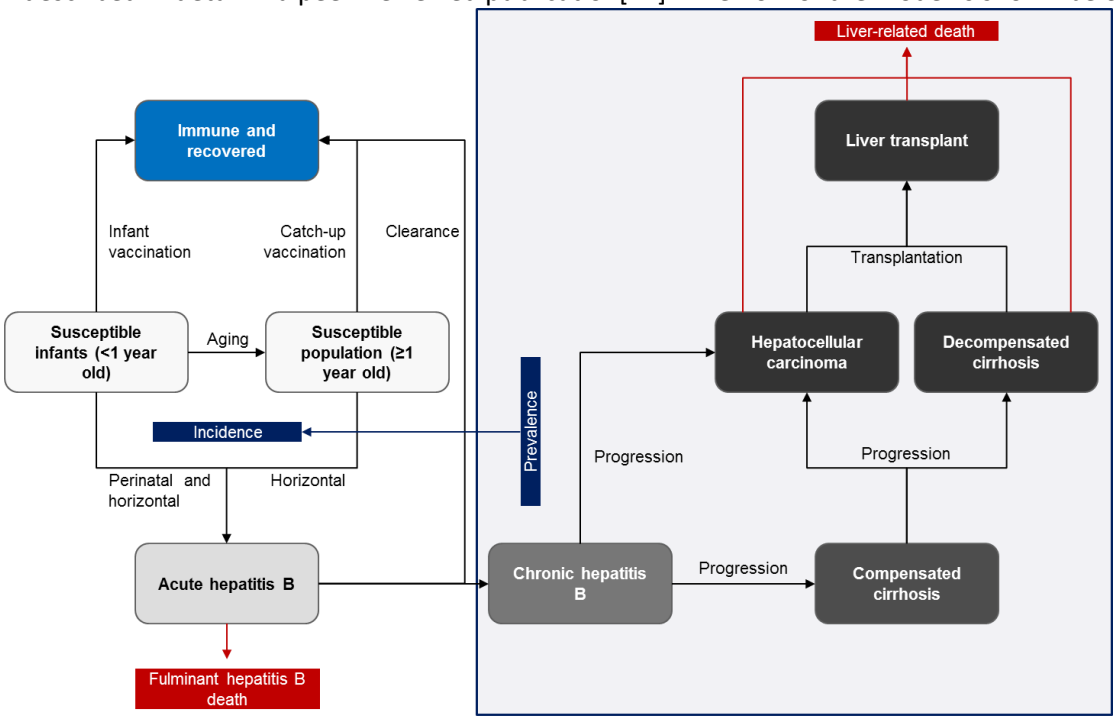


Hawai‘i started universal three-dose vaccination for hepatitis B in 1993, adding birth dose in 2002. However, vaccination of infants born to HBsAg+ mothers started in 1990 and maintained higher levels of coverage than in the general population.

While there is no cure for chronic hepatitis B, treatment results in a reduction of viral load which in turn slows the progression of the disease.

The model

The PRoGReSs Markov model was used to calculate the disease progression of HBV infected populations as well as the impact of the prophylaxis programs. The PRoGReSs model is a dynamic mathematical model developed in Microsoft Excel which was calibrated using reported, Hawai'i specific, epidemiologic data. The disease progression rate and the impact of the prophylaxis programs are universal and have been described in detail in a peer- reviewed publication[14]. The flow of the model is shown below:

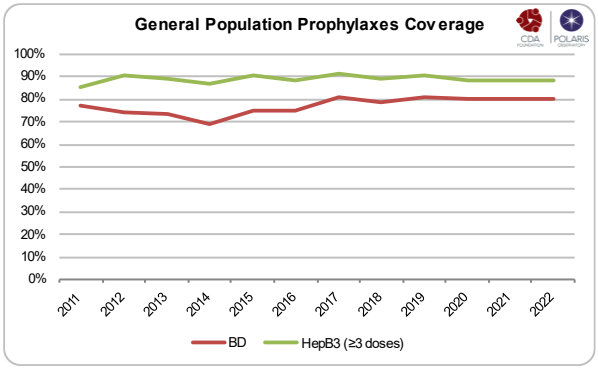


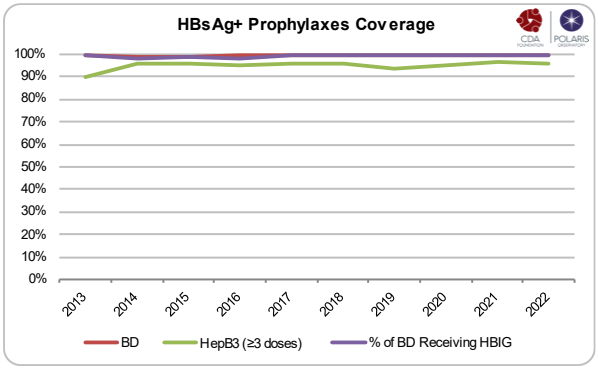
Input data

The following epidemiologic data were inputs into the model:

Historical Input	Estimate	Estimate Year
HBsAg infections	19,100	2020
Total Diagnosed	3,600	2022
Annual Newly Diagnosed	160	2023
Annual Number Treated	1,660	2023

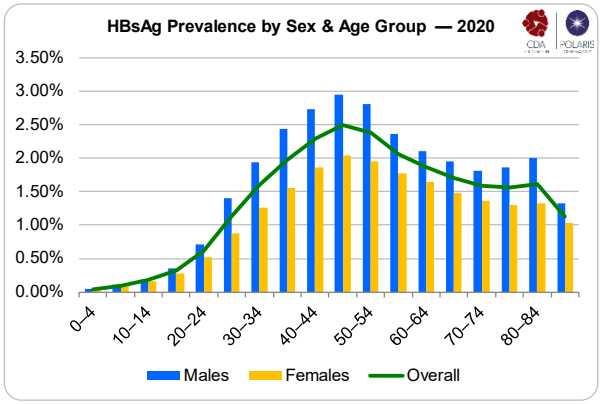
The three-dose coverage of vaccination was assumed to stay constant at the 2020 level of 89% and the timely birth dose coverage to remain constant at 81%. Among infants born to HBsAg+ mothers, it was assumed that 96% received timely birth dose, hepatitis B immunoglobulin, and the two additional doses based on Hawai'i data. A national estimate that 24% of pregnant women who are eligible for anti-viral treatment to prevent mother to child transmission was also utilized [15, 16].
The historical Hawai'i vaccination coverage is shown below:



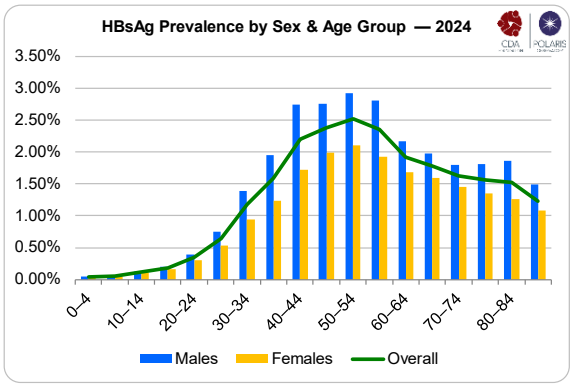


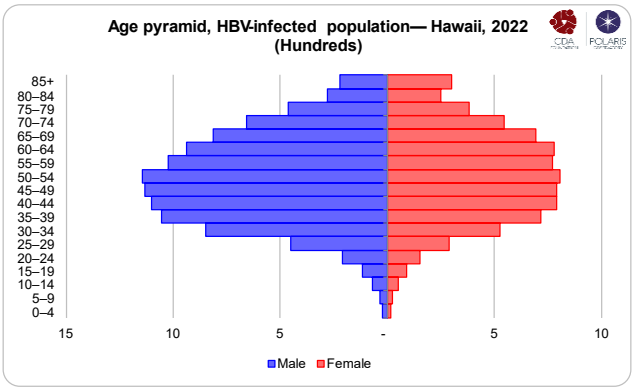
The Base Case (Status Quo): If there is no change in policy through 2030

We calculated the impact on the HBV infections, morbidity and mortality if there is no change to HBV treatment and prevention policies. The starting age and sex distribution is estimated to be the following:

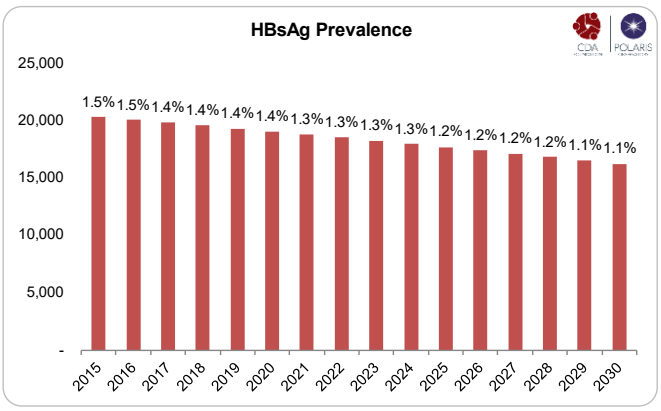


The PRoGReSs model includes the impact of HBV vaccination (on incidence), aging of the population, and mortality to forecast the age distribution of the HBV infected population in 2024.

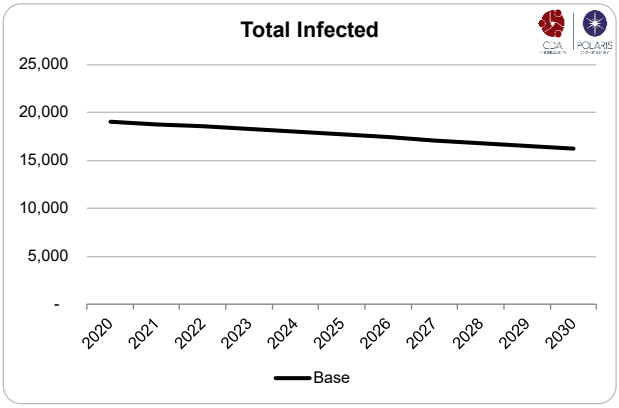


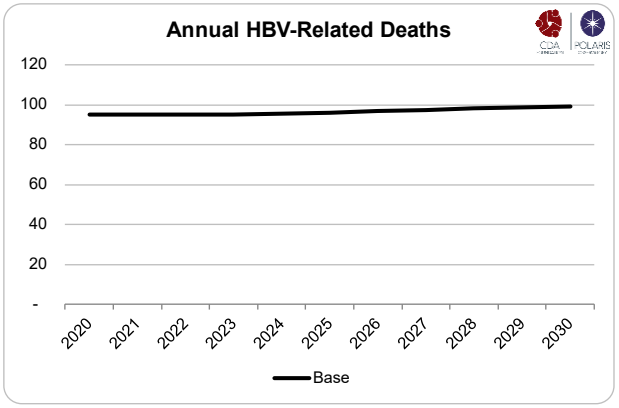


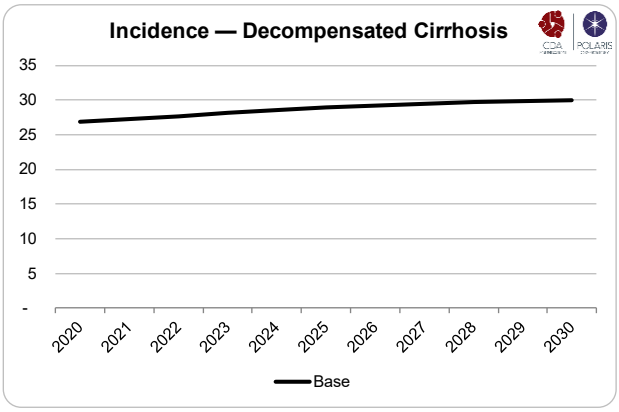
It was assumed that curative HBV therapies would not be available, and the current antiviral therapies continue to be the backbone of HBV treatment. As a result of continued vaccination and mortality, HBV prevalence is expected to decrease to 16,300 infections, a prevalence of 1.12% by 2030:

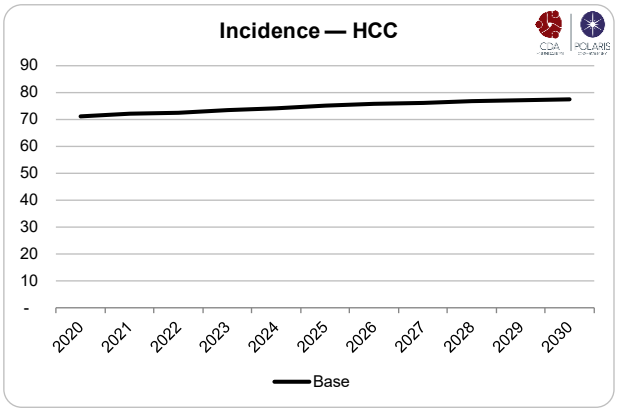


Total number of HBV infections will decline, but the number of decompensated cirrhosis, HCC & HBV-liver related deaths will increase as the infected population ages:

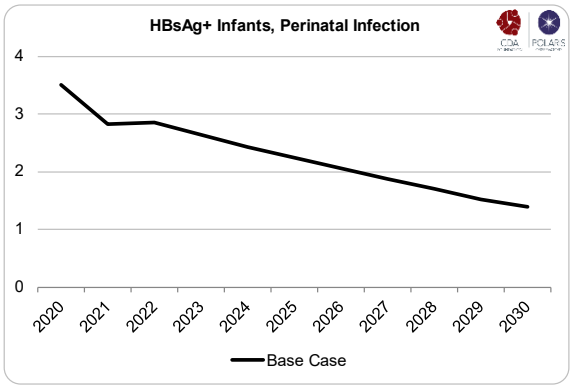


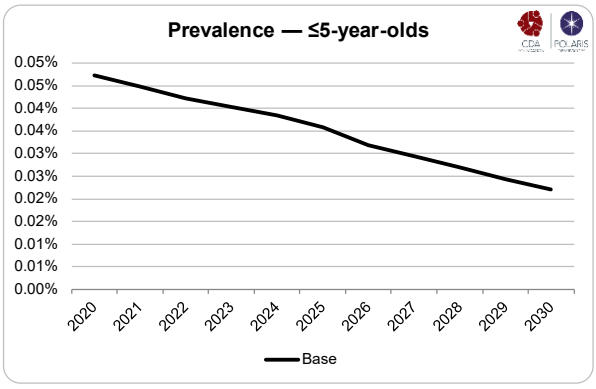






Hawai‘i was estimated to have already surpassed the WHO target of ≤0.1% prevalence among those aged ≤5 years old before 2030, thus no additional scenarios were created to work towards the elimination of mother to child transmission.





In addition to the Base Scenario, two other strategies were also modeled:

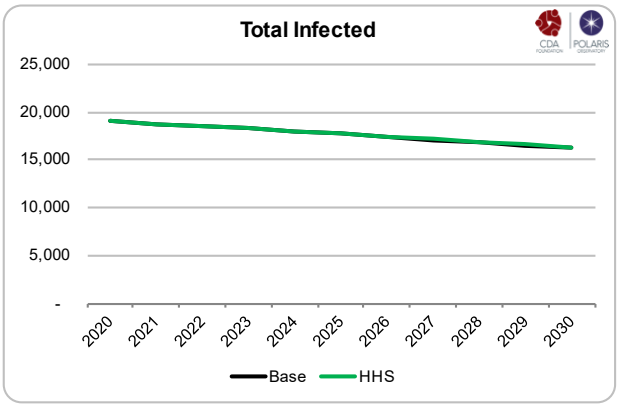
- HHS Scenario — developed to meet the HHS targets of 90% of the infected population being diagnosed by 2030, with 80% of those who are diagnosed and eligible being under treatment
- WHO 2024 Elimination Scenario — developed to meet the HSS targets of 90% of the infected population being diagnosed by 2030, with 80% of those who are diagnosed and eligible being under treatment while expanding those eligible for treatment beyond the AASLD guidelines
    - ≥F2 or HBV DNA > 2,000 IU/mL and ALT>ULN

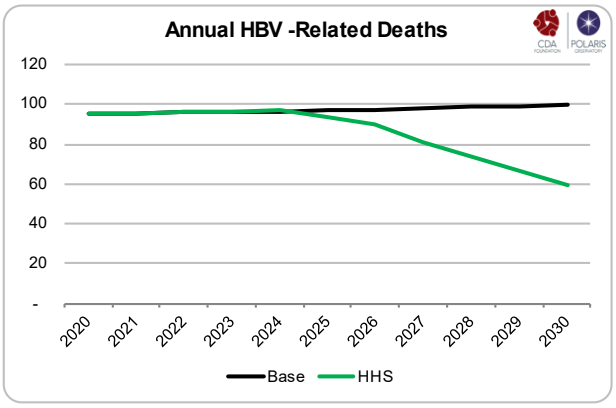
HHS Scenario

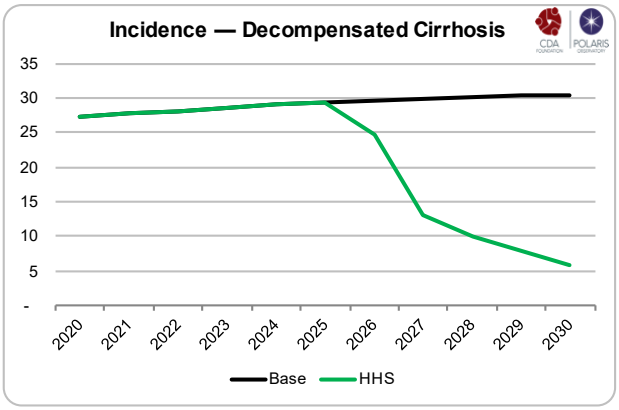
This strategy would diagnose 90% of individuals infected with chronic HBV by 2030 and treat 80% of those eligible and diagnosed in line with the US Department of Health & Human Services Viral Hepatitis National Strategic Plan for the United States [17]. A gradual increase in treatment was considered to model a feasible strategy. The following assumptions were used in this scenario.

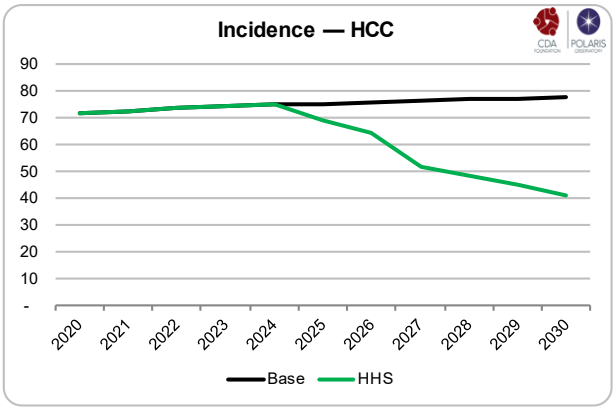
	2022	2025	2026	2027	2028	≥2029
Total Treated	1,660	2,000	2,800	3,300	4,100	5,500
Newly Diagnosed	160	500	1,500	2,500	3,000	2,200

This strategy will have little impact on the total number of infected individuals as there is currently no curative therapy. However, there will be an estimated 90 new cases of decompensated cirrhosis and 140 new cases of HCC averted, resulting in 130 lives saved through 2030.







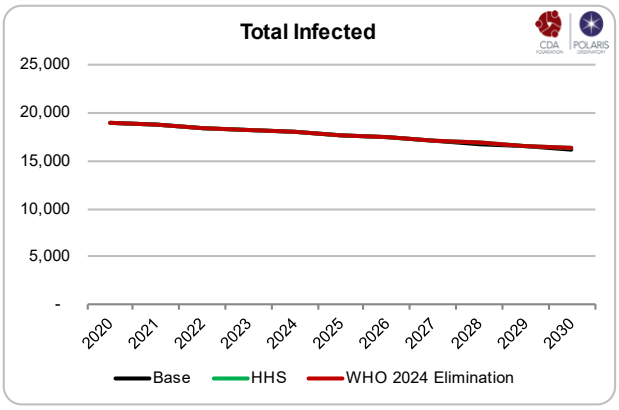


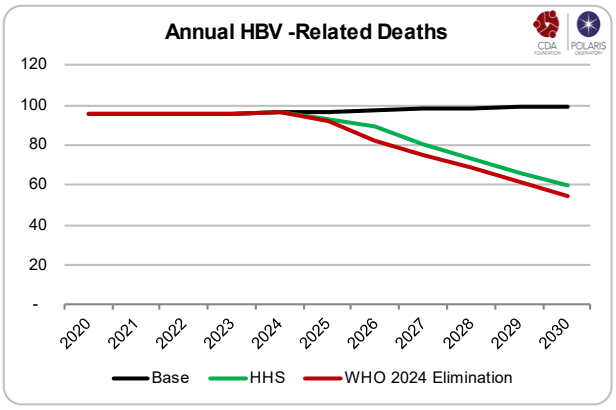
WHO 2024 Elimination Scenario

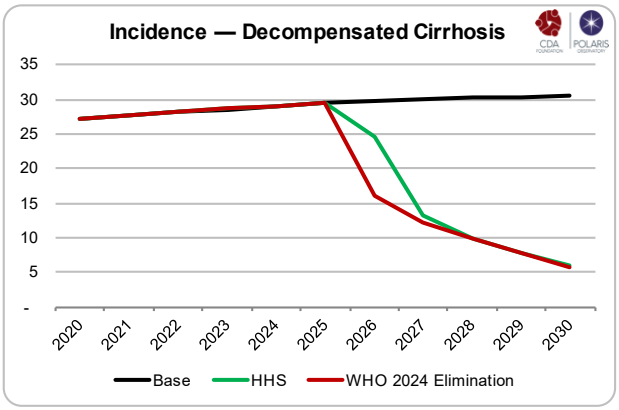
This strategy would still diagnose 90% of individuals infected with chronic HBV by 2030 and treat 80% of those eligible and diagnosed. However, it would expand treatment based on the new WHO 2024 treatment guidelines [18]. As the 90% diagnosis target remained unchanged, this scenario simply scaled of treatment faster and to a higher level than the HHS Scenario. The following assumptions were used in the scenario.

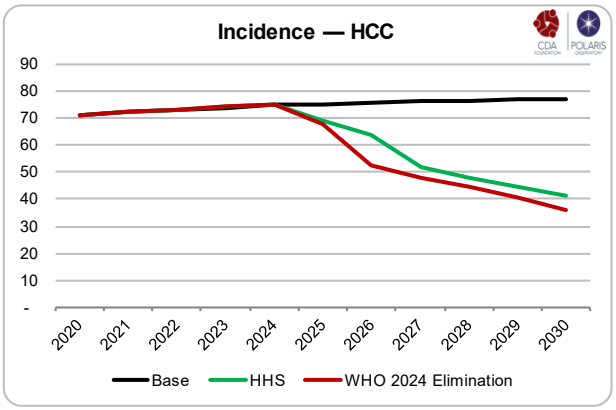
	2022	2025	2026	2027	2028	≥2029
Total Treated	1,660	2,800	3,200	3,900	5,200	8,400
Newly Diagnosed	160	500	1,500	2,500	3,000	2,200

This strategy will have little impact on the total number of infected individuals as there is currently no curative therapy. However, there will be an estimated 100 new cases of decompensated cirrhosis averted and 170 new cases of HCC averted, resulting in 150 lives saved through 2030.









Economic Impact Analysis

Direct costs

Direct costs included all costs associated with managing HBV infection, cirrhosis and liver cancer. They included:

- Healthcare costs
  - Costs of hospitalization for HBV sequelae
  - Inpatient and outpatient costs
  - Treatment costs for cirrhosis and liver cancer
- Diagnostic and other blood tests (HBsAg, confirmatory & HBV DNA)
- Liver disease staging
- Antiviral therapy costs

The healthcare costs were estimated utilizing previous publications:

Annual Cost per diagnosed patient*	Price (USD)	
Compensated Cirrhosis	2,076	[19]
Decompensated Cirrhosis	35,464	[20]

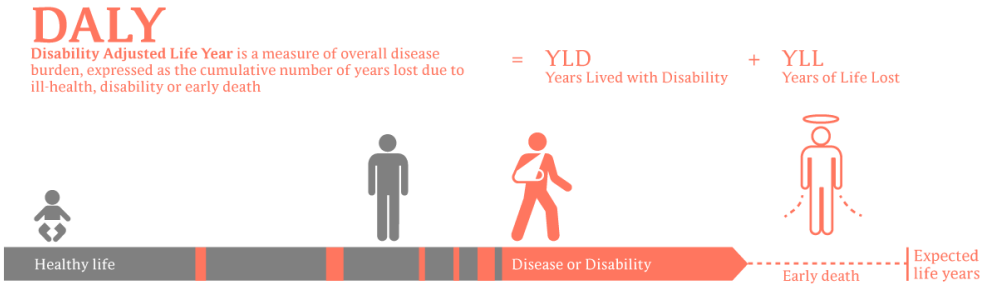
Hepatocellular Carcinoma	56,569	[20]
Liver Transplant	224,574	[20]
Liver Transplant – Subsequent years	48,910	[20]

***These does not include the cost of anti-viral treatment or HBV specific di considered separately**

The following diagnostic costs were utilized and extracted from the US Centers for Medicare & Medicaid Services [21].

Intervention	Price (USD)	# for screening	# for confirmed case	Annual # for Tx	Annual # for Tx ineligible
HBsAg	10.33	1	1	0.79	0.79
Anti-HBs	10.74	1			
anti-HBc	10.52	1			
HBeAg	11.53		1	0.21	0.21
Viral load testing	42.84		1	3	3
Hepatic function panel	8.17		1	3	3
Eco exam of abdomen	93.17		1	1.25	1.25
HAV, HCV, HDV	45.14		1		
Alpha-fetoprotein	16.77		1	1.25	1.25

Indirect economic losses



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Health effects are denominated in disability-adjusted life years (DALYs)

- DALY = Years of Life Lost (YLL) + Years Lost due to Disability (YLD)
  Years of Life Lost (YLL)
  Number of deaths —HBV-related deaths calculated in model (as the result of fulminant hepatitis, decompensated cirrhosis, and hepatocellular carcinoma)
  Life expectancy at age of death — available from national census data or extrapolated based on estimates from UN World Population Prospects
  Discount rate — depends on analysis
  Years Lost due to Disability (YLD)
  Number of incident cases by stage of liver disease — calculated in model

Disability weight — published estimates
Duration of disability — calculated in model

The following parameters were utilized for the calculation of DALYs:

Parameter	Value	Source
Disability weights F0-F4 Decompensated cirrhosis Hepatocellular carcinoma Liver transplant	0 0.178 0.466[†] 0.024[‡]	[22]
Discount rate	3%	[23]
Age-weighting modulation constant	0 (none)	
GNI per capita in the US	$76,770	[24]

Economic losses associated with HBV infection are calculated in the economic impact analysis and assume the value of one DALY averted equals the GNI per capita of a country [25]. The economic losses are calculated for DALYs incurred at ages 20-69.

An additional scenario was created to examine the economic impact. This assumed that in any elimination program, unnecessary costs would be cut. Thus, the number of annual diagnostics were greatly reduced in the HHS Simplified scenario. This assumes that all patients would be receiving laboratory testing annually, with the exception of those who are already cirrhotic or later (~25% of the population) who would receive staging twice a year.

Intervention	Price (USD)	# for screening	# for confirmed case	Annual # for Tx	Annual # for Tx ineligible
HBsAg	10.33	1	1		
Anti-HBs	10.74	1			
anti-HBc	10.52	1			
HBeAg	11.53				
Viral load testing	42.84		1	1	1
Hepatic function panel	8.17		1	1	1
Eco exam of abdomen	93.17		1	1.25	1.25
HAV, HCV, HDV	45.14		1		
Alpha-fetoprotien	16.77		1	1.25	1.25

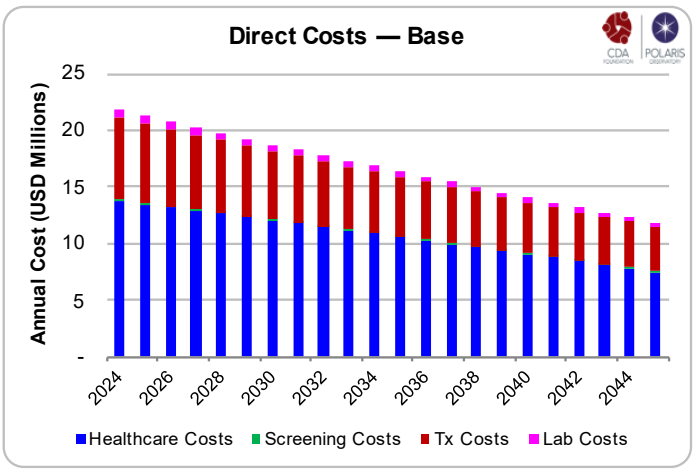
The WHO 2024 Elimination scenario only applied eco exam of abdomen and alpha-fetoprotein to those who had progressed to cirrhosis or later, as the hepatic function panel includes the test necessary to be in line with WHO 2024 guidelines.

Intervention	Price (USD)	# for screening	# for confirmed case	Annual # for Tx	Annual # for Tx ineligible
HBsAg	10.33	1	1		
Anti-HBs	10.74	1			
anti-HBc	10.52	1			

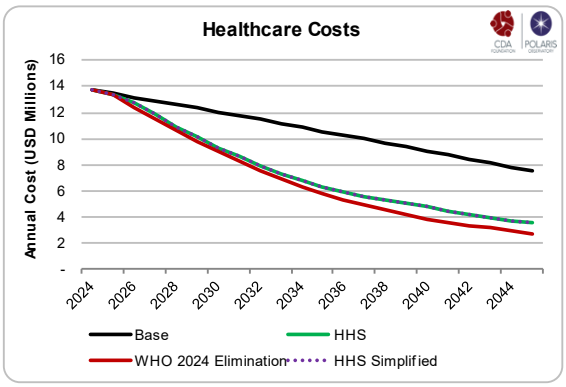
HBeAg	11.53				
Viral load testing	42.84		1	1	1
Hepatic function panel	8.17		1	1	1
Eco exam of abdomen	93.17		1	0.25	0.25
HAV, HCV, HDV	45.14		1		
Alpha-fetoprotien	16.77		1	0.25	0.25

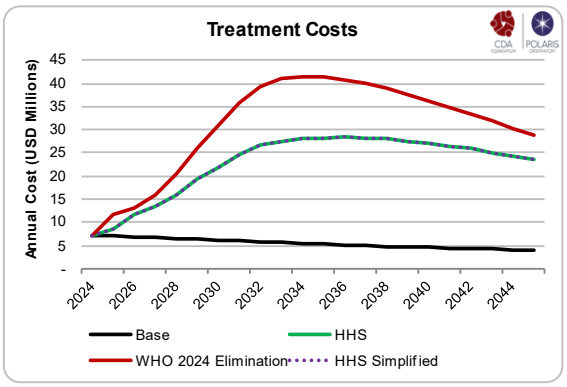
Costs to Hawai'i society

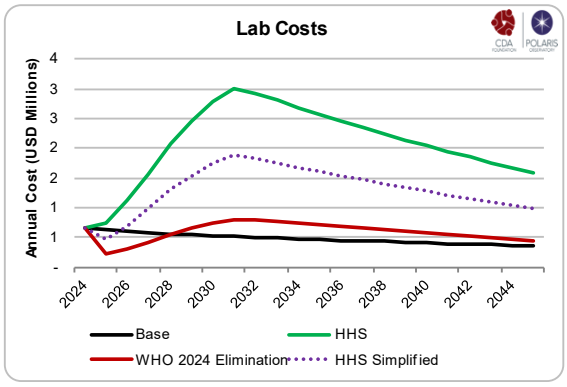
Under the current treatment and screening paradigm, there is estimated to be over $20 million spent annually on the direct medical costs of HBV in Hawai'i. The vast majority of costs are healthcare costs, but there are significant amounts being spent on treatment and lab costs as well. Although the costs are expected to decrease, they are not expected to drop below $10 million through 2045.

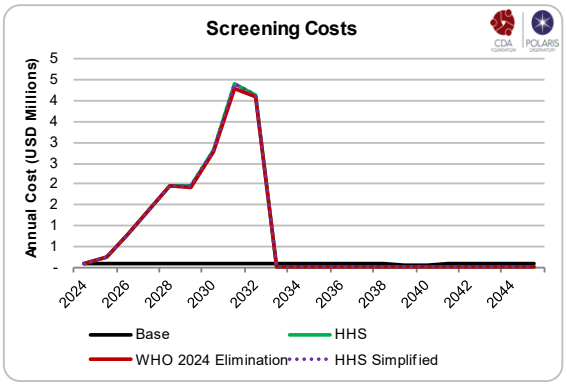


All scenarios require a large upfront investment in screening and expanded treatment. Changing the annual number of diagnostics run for each patient receiving care can drastically reduce the lab costs, as seen in the difference between HHS and HHS Simplified. The trade-off for more money allocated to screening and treatment, is that there are fewer healthcare costs as later stages of the disease are prevented.

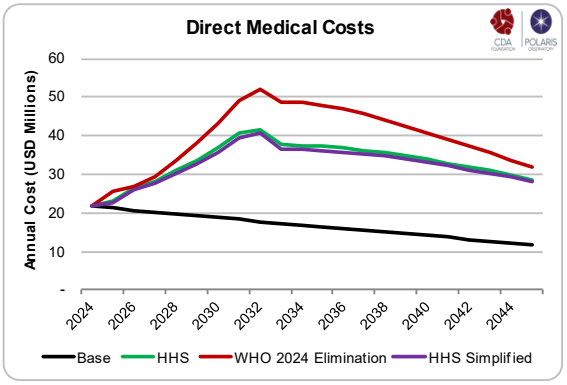




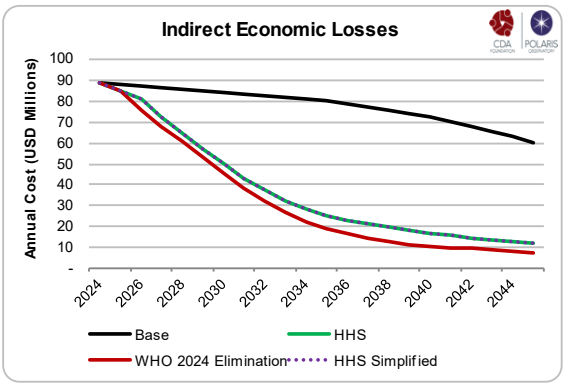


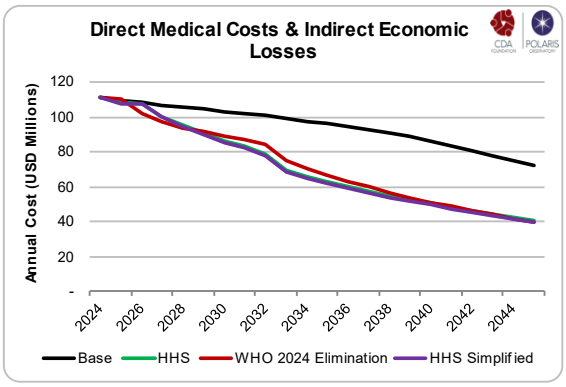


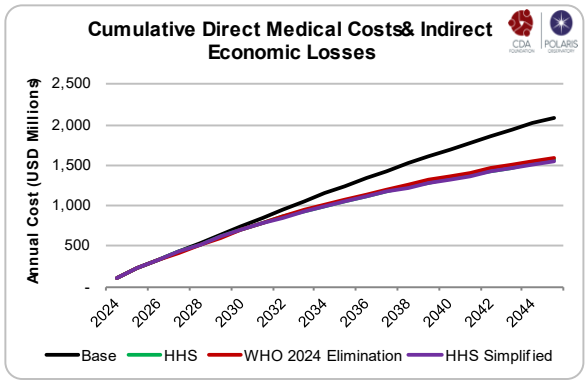
When these costs are combined, we can observe that the direct medical costs would be doubled to achieve HHS or WHO elimination targets by 2030 when compared to the Base.



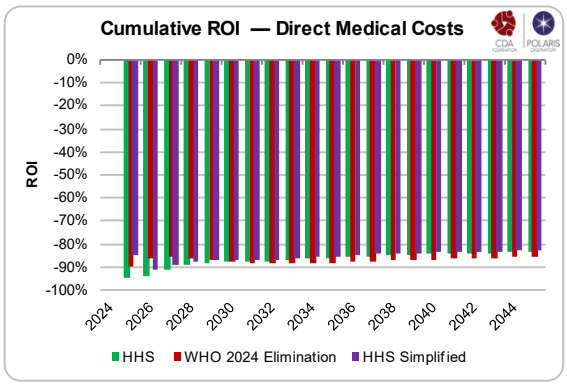
Expanding treatment reduces morbidity and mortality associated with HBV, and individuals are thus able to live healthier lives. This results in significant reductions in indirect economic losses. When both direct medical costs and indirect economic losses considered, the annual costs are almost immediately less than the Base scenario. This in turn results in lower cumulative direct medical and indirect economic losses than the base scenario through 2045.

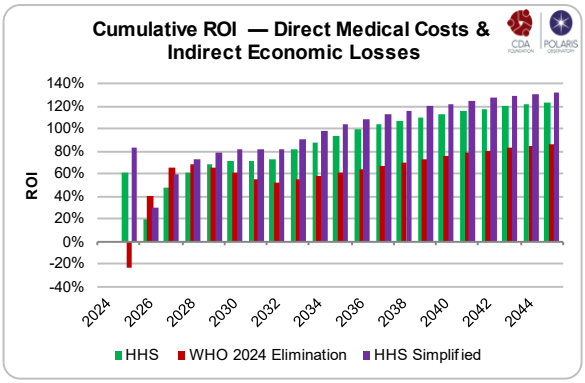




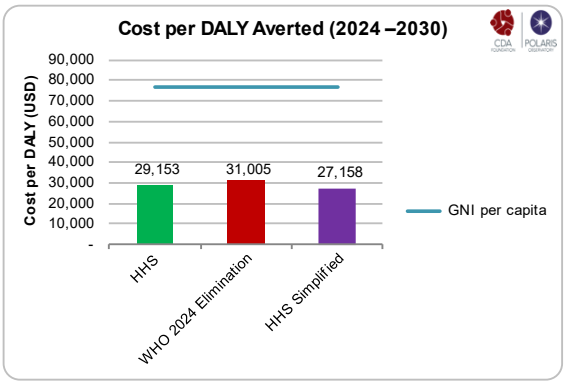


Another way to examine these data is to show that there is an immediate positive return on investment when taking both direct medical costs and indirect economic losses into account for both the HHS and HHS Simplified scenarios, with WHO 2024 Elimination having a positive return on investment in 2026. However, through 2045 there is no positive return on investment when only based on direct medical costs.





Through 2030, all scenarios were found to be highly-cost effective (less than the GNI per capita). HHS Simplified had the lowest cost per DALY averted, $27,158, however HHS and WHO 2024 Elimination were comparable at $29,153 and $31,005 per DALY averted respectively.



Conclusions

Hawaiʻi has the highest prevalence of hepatitis B in the United States with almost 100 people dying each year. Hawaiʻi has already taken prevention measures seriously, ensuring high coverage rates the infants born to HBsAg+ mothers, and having general population vaccination rates higher than the national average. This has led to Hawaiʻi already meeting the impact target WHO target for elimination of mother to child transmission.

Scaling up diagnosis, linkage to care, and treatment would require large upfront costs, but all scenarios found these scale ups to be highly-cost effective. As shown with the cost comparison of the HHS and HHS Simplified scenarios, reducing the number of tests necessary for surveillance and treatment can have a major impact on the cost-effectiveness. These simplifications will also be necessary in order to ensure that all health care providers are able to treat early-stage HBV, an integral step towards making elimination achievable. The cost effectiveness can also be impacted by lower diagnostics and/or treatments costs. The treatment costs considered here are based on the national weighted treatment costs. These could be reduced if there are higher shares of individuals in Hawaiʻi receiving generic drugs. Additionally, there has been recent pushes to make rapid tests for HBV available in the US. If these efforts are successful, it could reduce the screening costs to 10% of the current costs which would have major impacts on the upfront costs associated with diagnosing 90% of the infected population.

While the task may seem daunting, the elimination of viral hepatitis as a public health threat in Hawaiʻi is a realistic goal. One that goes far beyond the cost-effectiveness analysis, but one that ensures a higher quality of life for the peoples, their families, the communities of Hawaiʻi, not just today but for generations to come.

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