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ORIGINAL ARTICLE

Cost-effectiveness and economic investment to eliminate chronic hepatitis C in Mexico

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Abstract

In July 2020, the Mexican Government initiated the National Program for Elimination of Hepatitis C (HCV) under a procurement agreement, securing universal, free access to HCV screening, diagnosis and treatment for 2020–2022. This analysis quantifies the clinical and economic burden of HCV (MXN) under a continuation (or end) to the agreement. A modelling and Delphi approach was used to evaluate the disease burden (2020–2030) and economic impact (2020–2035) of the Historical Base compared to Elimination, assuming the agreement continues (Elimination—Agreement to 2035) or terminates (Elimination—Agreement to 2022). We estimated cumulative costs and the per-patient treatment expenditure needed to achieve net-zero cost (the difference in cumulative costs between the scenario and the base). Elimination is defined as a 90% reduction in new infections, 90% diagnosis coverage, 80% treatment coverage and 65% reduction in mortality by 2030. A viraemic prevalence of 0.55% (0.50–0.60) was estimated on 1st January 2021, corresponding to 745,000 (95% CI 677,000–812,000) viraemic infections in Mexico. The Elimination—Agreement to 2035 would achieve net-zero cost by 2023 and accrue 31.2 billion in cumulative costs. Cumulative costs under the Elimination—Agreement to 2022 are estimated at 74.2 billion. Under Elimination—Agreement to 2022, the per-patient treatment price must decrease to 11,000 to achieve net-zero cost by 2035. The Mexican Government could extend the agreement through 2035 or reduce the cost of HCV treatment to 11,000 to achieve HCV elimination at net-zero cost.

KEYWORDS
economic impact, hepatitis C, elimination, procurement agreement, Mexico

1 | BACKGROUND AND AIMS

Individuals with chronic hepatitis C (HCV) are at high risk of developing advanced stage liver disease.[1] HCV is a leading cause of liver cirrhosis in Mexico,[2,3] the country that reports the highest cirrhosis mortality rate in the region.[4] Additionally, hepatocellular carcinoma (HCC) has been increasing in Mexico in recent decades, with chronic HCV believed to be the primary cause.[5] Over the years, barriers to HCV detection in Mexico have included a lack of screening, complex diagnosis algorithms involving multiple steps

Abbreviations: AAMATES, Ambiente de Administración y Manejo de Atenciones en Salud; CDAF, Center for Disease Analysis Foundation; DAAs, direct-acting antivirals; DALYs, disability-adjusted life years; GNI, gross national income.HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; MXN, Mexican Peso; NP, National Program for Elimination of HCV; SVR, sustained virologic response; WHO, World Health Organization;

and appointments, a shortage of specialized personnel to carry out tests, a lack of access to curative treatment for previously diagnosed patients and issues linking patients to care in the National Health System.[6]

The invention and increasing availability of pangenotypic direct-acting antivirals (DAAs) to treat chronic HCV, which result in cure for over 95% of cases,[7] has accelerated interest in and progress towards HCV elimination efforts globally.[8,9] Treatment regimens using DAAs are short (12 weeks or less), have few side effects, and are effective in preventing advanced liver disease, cancer and liver-related death (LRD). In July 2020, the Mexican Government and the Ministry of Health initiated the first National Program for Elimination of HCV (NP, Programa de Acción Específico) using a procurement strategy to ensure universal free access to HCV screening, diagnosis and treatment from January 2020 through December 2022.[10] As part of the NP, a National Registry was established through the AAMATES platform (Ambiente de Administración y Manejo de Atenciones en Salud), primary healthcare clinics were permitted to apply for certification to treat patients with HCV, and fibrosis and genotype restrictions to access treatment in public institutions were removed. In 2018, DAA accessibility in the public sector was limited in Mexico, but they became widely accessible in 2020 through the NP.[6,10] These key changes helped scale-up access during program roll-out.

This is the first analysis to evaluate the total cost and burden of HCV on the Mexican economy and report costs accrued under the NP. We report the clinical impact and cost of treatment expansion in 2020 compared with the 2018 historical paradigm, and we calculate a DAA treatment price that achieves net-zero cost by 2035. The procurement strategy for the NP terminates at the end of 2022, resulting in uncertain funding for hepatitis elimination through 2030. In this report, we provide the cost the Mexican Government of extending or terminating the original agreement.

In the first year of the NP, the number of public healthcare units certified to treat for HCV tripled from 106 to 390 nationwide, and nearly 100,000 people living with HIV, the initial target population, were screened for HCV.[10] This analysis presents programmatic costs under various real-word scenarios, building on previous successes. Results can guide programming and ensure the aim of the NP, to achieve the 2030 hepatitis elimination goals, are successful.[9,10]

2 | METHODS

2.1 | Literature review

Epidemiologic data for Mexico were gathered and reviewed during expert panel meetings held from 1st May 2021, through 31st January 2022. The research team followed an iterative method of presenting aggregate data to the expert panel and adjusting estimates based on the group response, known as a modified Delphi process. A literature search was also conducted in PubMed, using the search terms ('hepatitis C' AND 'prevalence' AND 'Mexico') to identify articles and grey literature in all languages published between 1st January 2000 and 31st December 2021.

2.2 | The disease burden model and data inputs

The Markov HCV disease progression model was used to forecast HCV prevalence in Mexico. This Excel-based model has undergone independent review with details published in full.[11,12] Model parameters are reported in Table 1 and methodology specific to this analysis is reported in Appendix, Section S1. In brief, the model tracks HCV progression from acute infection to chronic infection (accounting for spontaneous clearance) and through end-stage liver disease and liver-related mortality or cure. The annual number of infections at each disease stage (incidence) were calculated by multiplying annual progression rates times the prevalent population (stratified by 5-year age cohort and sex) in the previous disease stage. The model accounts for all-cause mortality and was inputted with population and mortality data from 1950 to 2050, and HCV epidemiologic data by year of data availability. In the absence of available data, consensus from the expert panel was required for inclusion. The model also calculates the annual number of screens associated with diagnosing a given number of HCV infections. Starting with the undiagnosed, HCV antibody-positive population, the model uses epidemiologic data, number of screens per person and screening eligibility criteria (i.e. by risk category, age, fibrosis stage, history of screening, diagnosis or sustained virologic response [SVR]) to calculate the size of the population eligible for screening and the number needed to screen to diagnose one HCV antibody positive infection. Model outputs were validated using reported liver cancer trends (Appendix, Section S2). Disease burden outcomes were measured from 2015 to 2030, in line with the time horizon for HCV elimination outlined by the Global Health Sector Strategy Targets.[9]

2.3 | Disease burden scenarios

2.3.1 | Historical Base

The state of care in the absence of the NP: About 3000 patients were treated in 2018, assuming to decline to 1500 by 2024. Treatment is limited to fibrosis stage ≥F2 (2018 treatment guidelines), with an SVR of 88% (based on a mixture of treatment with peg-interferon and DAAs) (Table 2).

2.3.2 | Elimination

Achieve the WHO Elimination Targets by 2030: Involves progressively increasing the number of patients treated annually to achieve the WHO Elimination Targets including a 90% reduction in new infections, 90% diagnosis coverage, 80% treatment coverage, and

TABLE 1 Disease burden input parameters and annual costs per patient.

		Parameter	Value	Year(s)	Source
Disease burden model parameters	Disease burden input parameters	Anti-HCV prevalence	0.55%	2020	EC[13,14]
		Viraemic rate	65%	2020	[14]
		Viraemic diagnosed	8162	2021	EC[a]
		Treated	5500	2021	[14]
		Liver transplants	149	2017	[15,16]
	Model validation	Incident liver cancer cases	7536	2020	[17,18]
		Liver cancers that are HCC	90%	2020	[19,20]
		HCC due to HCV	39%	2011	[17,21,22]
Annual costs per patient	Health stage costs, public (private), MXN	Chronic hepatitis C (CHC)	11,600 (18,900)	2021	[14]
		Compensated cirrhosis (CC)	15,742 (25,742)	2021	[14]
		Decompensated cirrhosis	88,326 (150,826)	2021	[14]
		Hepatocellular carcinoma	33,659 (75,000)	2021	[14]
		Liver transplant	200,000 (2,000,000)	2021	[14]
	Screening and treatment costs, public (private), MXN	Anti-HCV test	13 (900)	2021	[14]
		HCV-RNA/PCR test	1849 (5685)	2021	[14]
		Treatment (per person per year)[b]	151,000/77,838	2018/2020[c]	EC[14]

Abbreviations: EC, expert panel consensus; PCR, polymerase chain reaction; RNA, ribonucleic acid.

[a]Regional average diagnosis rate in Central Latin America (i.e. Costa Rica, Guatemala, Honduras, Nicaragua, Panama, El Salvador and Venezuela) calculated by CDAF (unpublished).

[b]A historic annual per patient treatment cost for peg-interferon in 2018 (151,000) was provided by expert input.

[c]Treatment costs for 2020 includes salary coverage for 120 nurses.

65% reduction in mortality by 2030.[9] Treatment eligibility is open to fibrosis stage ≥0, with an SVR of 97% (2020 treatment guidelines) (Table 2).

2.4 | The economic analysis and data inputs

Costs are comprised of screening (anti-HCV tests), treatment (peg-interferon and/or antiviral treatment), laboratory tests (anti-HCV tests and confirmatory PCR tests) and healthcare costs (chronic and advanced-stage liver disease management) (Table 1). Two elimination scenarios were generated, assuming either the industry agreement (starting 1st January 2020) terminated on 31st December 2022 (Elimination—Agreement to 2022), or continued through December 31, 2035 (Elimination—Agreement to 2035). The industry agreement covers (i.e. at no cost to the Mexican Government) all anti-HCV and PCR laboratory testing costs (and covers treatment costs after 13,000 patients are treated and funded by the Mexican Government). In both elimination scenarios, the number of patients treated exceeds this threshold in 2022, resulting in a lower average treatment cost in 2022. Assuming termination of the industry agreement, the Government of Mexico becomes responsible for all future elimination program costs (Table 3). Healthcare costs were assumed equal across all scenarios, and all treatment costs in 2020 and beyond included salary coverage for 120 nurses.

2.5 | Economic analysis outcomes

Being the first year the agreement began subsidizing some costs under the NP, 2020 served as the starting point for the economic analysis.[23] Economic impact was evaluated through 2035 to ensure all costs associated with implementing interventions were fully realized, per WHO guidelines of at least 10 years, combined with expert panel input.[23] All costs were calculated and reported in Mexican peso (MXN). Feasibility of achieving the NP are detailed in the Appendix, Section S5.[6]

We calculated disability-adjusted life years (DALYs) to evaluate the years of healthy life lost based on time spent in various health states. A health state utility value between 0 and 1 was used.[22,23] An incremental cost-effectiveness ratio (ICER) was also calculated as the net cost (the difference in costs between the scenario and the Historical Base) divided by the net benefit (the difference in DALYs between the scenario and the Historical Base). The ICER investigates if an intervention yields sufficient value to justify its cost, and the economic feasibility of the ICER was assessed in relation to the annual Gross National Income (GNI) per capita.[24] A scenario was considered highly cost-effective if the ICER per DALY averted was less than the 2021 GNI per capita of MXN 169,405. Net-zero cost was defined as the difference in cumulative costs (2020–35) between the scenario and the Historical Base.

3 | RESULTS

3.1 | HCV disease burden

A viremic prevalence of 0.55% (0.50–0.60) was estimated in Mexico on 1st January 2021, corresponding to 745,000 (677,000–812,000) viremic infections. By the end of 2021 (after accounting for new diagnoses and cures), 13% (98,700) of total infections were diagnosed and 1% (5500) of infections were treated (Figure 1). In 2021, an estimated 7500 Mexicans newly acquired HCV (5.5 per 100,000).

If treatment and diagnosis efforts in Mexico decline under the Historical Base, total liver-related deaths (LRDs), incident hepatocellular carcinoma (HCC) and incident decompensated cirrhosis (DC) would increase by 75%–80% from 2015 to 2030 (Figure 2). Under Elimination, interventions would need to ramp up gradually, harm reduction practices could be used to balance treatment efforts, and about 23,500, 13,600 and 11,000 incident cases of LRDs, HCC and DC, respectively, could be averted between 2015–2030 (Figure 2). Since all elimination scenarios treat the same number of patients, an equal number of DALYs are averted; 859,000 cumulatively for 2020–2035 (Table 3).

3.2 | Economic impact

Under the Historical Base, annual costs are projected to remain stable at about 2.4–2.5 billion between 2020 and 2035 (Figure 3a), with cumulative costs projected to reach 39.7 billion by 2035 (Figure 3b, Table 4). Under Elimination—Agreement to 2035, annual costs are projected to peak at 2.6 billion before declining to 350 million by 2035 (Figure 3a). Cumulative costs are expected to reach 31.2 billion, resulting in net-zero cost by 2023 (Figure 3b, Table 4). If the industry agreement ends in 2022, the Mexican Government would incur additional costs to achieve elimination. Under the full treatment price of 77,838 per patient (Elimination—Agreement to 2035 (77,838/txt)), annual costs would peak at 8.1 billion (Figure 3a), with the Mexican Government incurring higher total costs for treatment and laboratory services than all other scenarios (Figure 3c–f) and totalling 74.2 billion cumulative costs by 2035 (Table 4, Figure 3b).

The price of HCV treatment must decrease to 11,000 per patient to achieve net-zero cost by 2035, demonstrated in the scenario Elimination—Agreement to 2022 (11,000/txt). If the agreement

TABLE 2 Input parameters for the Historical Base and Elimination scenarios, 2018–2030.

(a) Historical Base					(b) Elimination				
Year(s)	Treated	Fibrosis stage	Newly diagnosed	SVR	Year(s)	Treated	Fibrosis stage	Newly diagnosed	SVR
2018	3000	≥F2	4200	88%	2021	5500	≥F0	8200	97%
2021	1700	≥F2	2400	88%	2022	8000	≥F0	20,000	97%
2022	1600	≥F2	2200	88%	2023	12,000	≥F0	30,000	97%
2023	1500	≥F2	2100	88%	2024	22,000	≥F0	48,000	97%
2024	1500	≥F2	2100	88%	2025	50,000	≥F0	70,000	97%
2025–2030*	1500	≥F2	2100	88%	2026-2030*	85,000	≥F0	90,000	97%

* Inputs are annual and assumed constant for each of the six consecutive years.

TABLE 3 Screening and treatment costs to the Mexican Government by scenario, 2020–2035.

Scenario	Funding duration	Funding source for testing	Cost per test to the Mexican Government, anti-HCV/HCPCR (MXN)	Funding source for treatment	Per patient avg. treatment, cost to the Mexican Government (MXN)
Historical Base	2020–2035	Government	13/1849	Government	151,000[a]
Elimination—Agreement to 2035	2020–2021	Government	13/1849	Government	77,838[b]
	2022	Industry	0/0	Industry discounted[c]	19,460
	2023–2035	Industry	0/0	Industry	0
Elimination—Agreement to 2022	2020–2021	Government	13/1849	Government	77,838[b]
	2022	Industry	0/0	Industry discounted[c]	19,460
	2023–2035	Government	13/1849	Government	77,838

[a]Average treatment cost of peg-interferon and direct-acting antivirals combined.

[b]Treatment cost of direct-acting antivirals (used for 100% of HCV treatment) under the National Program (NP).

[c]From January 2020 through December 2022, the industry agreement covered all treatment costs ($0 cost to the Mexican Government) after a cumulative of 13,000 patients were treated for HCV. In both elimination scenarios, the number of patients treated exceeds this threshold in 2022, resulting in a lower average treatment cost in that year.

ends, lowering treatment costs to 11,000 would reduce the total cost of laboratory and treatment services of elimination by 35 billion (42.8 billion–7.8 billion) (Table 4). All elimination scenarios will decline below the highly cost-effective threshold of 169,405 in 2023. Achieving elimination could save 6.5 billion in healthcare costs (30.3 billion vs. 36.8 billion) and avert 859,000 DALYs. Only the discounted scenarios (Agreement to 2035 and Agreement to 2022 (11,000/txt)) achieved a net-zero cost during the time frame of the study (Table 4).

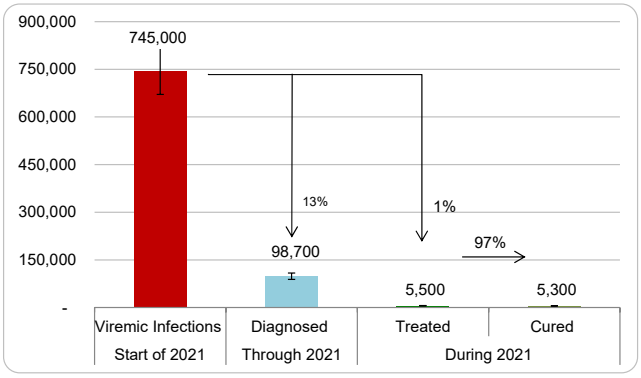

FIGURE 1 HCV cascade of care for 2021 in Mexico. Includes the total number of viraemic infections, the number of viraemic diagnosed patients and the number of patients treated and cured for HCV.

4 | DISCUSSION

This is the first analysis to evaluate the total economic burden of HCV in Mexico, including a projection of future cost and the impact of various control strategies. Eliminating HCV will require an up front investment in diagnosis and treatment; however, reducing the disease burden will cut direct costs (healthcare costs from advanced disease) and indirect costs (loss of productivity due to life lost and disability), reducing total expenditure. Results demonstrate that HCV elimination can be accomplished at net-zero cost to the Mexican Government, either by (1) extending the procurement agreement through 2035 or (2) reducing the cost of HCV treatment from 77,838 to 11,000 per person per treatment. Alternatively, the Mexican Government must increase national budget allocation to the NP to achieve elimination targets by 2030.

Approximately 3,900 Mexicans die each year due to HCV-related complications and this number is expected to increase to 5,700 deaths annually by 2030. Total infections were projected to decline between 2015 and 2021 due to the recent availability of treatment and cure. Treatment expansion and advancement is evident in the data; before 2015, experts reported an average SVR of 60%, increasing to 88% by 2018 and 97% by 2020. As the infected population ages and develops advanced liver disease, healthcare costs will rise. This is demonstrated through cumulative healthcare costs reaching 36.8 billion in the Historical Base scenario due to a lack of investment in prevention. Redirecting resources towards prevention

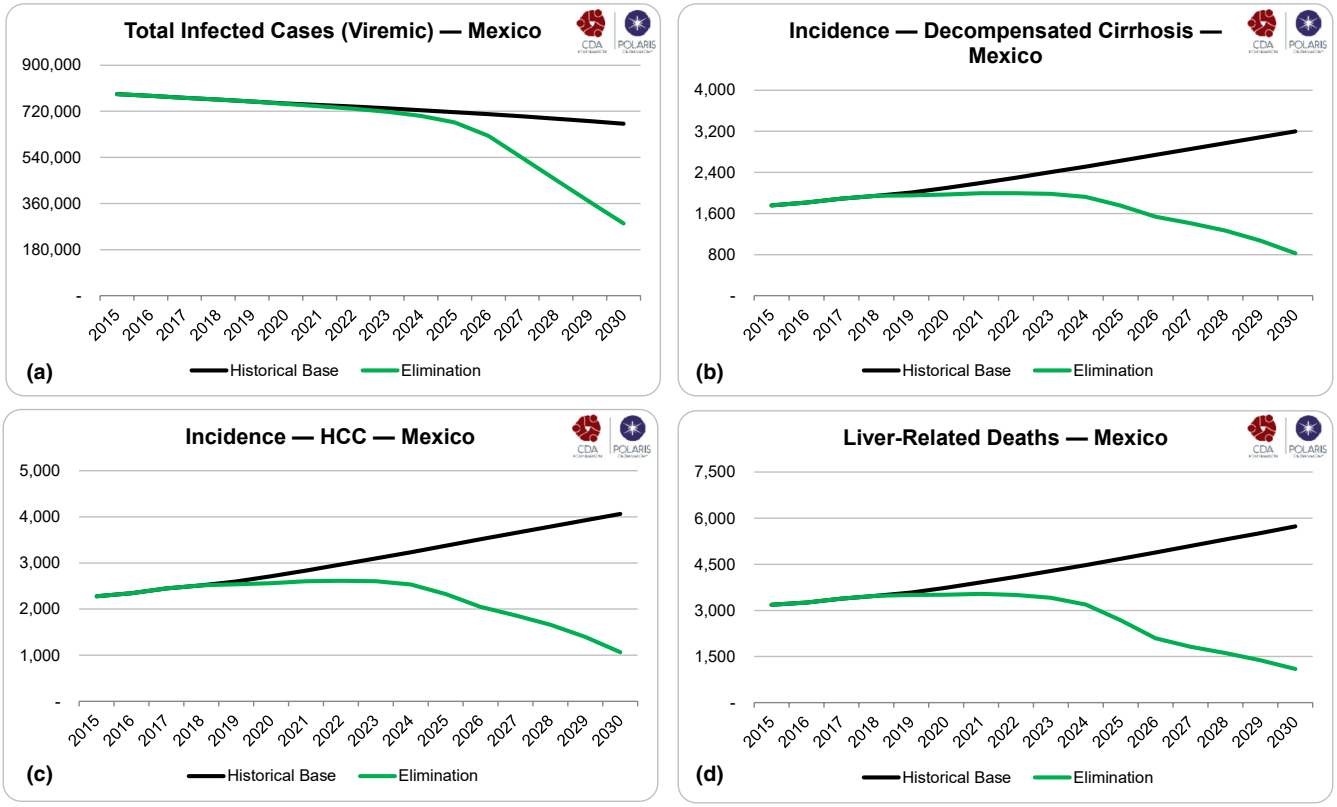

FIGURE 2 Hepatitis disease burden outcomes by scenario in Mexico, 2015–2030. (a) Total viraemic HCV infections. (b) Incident cases of HCV liver-related deaths. (c) Incident cases of hepatocellular carcinoma. (d) Incident cases of decompensated cirrhosis.

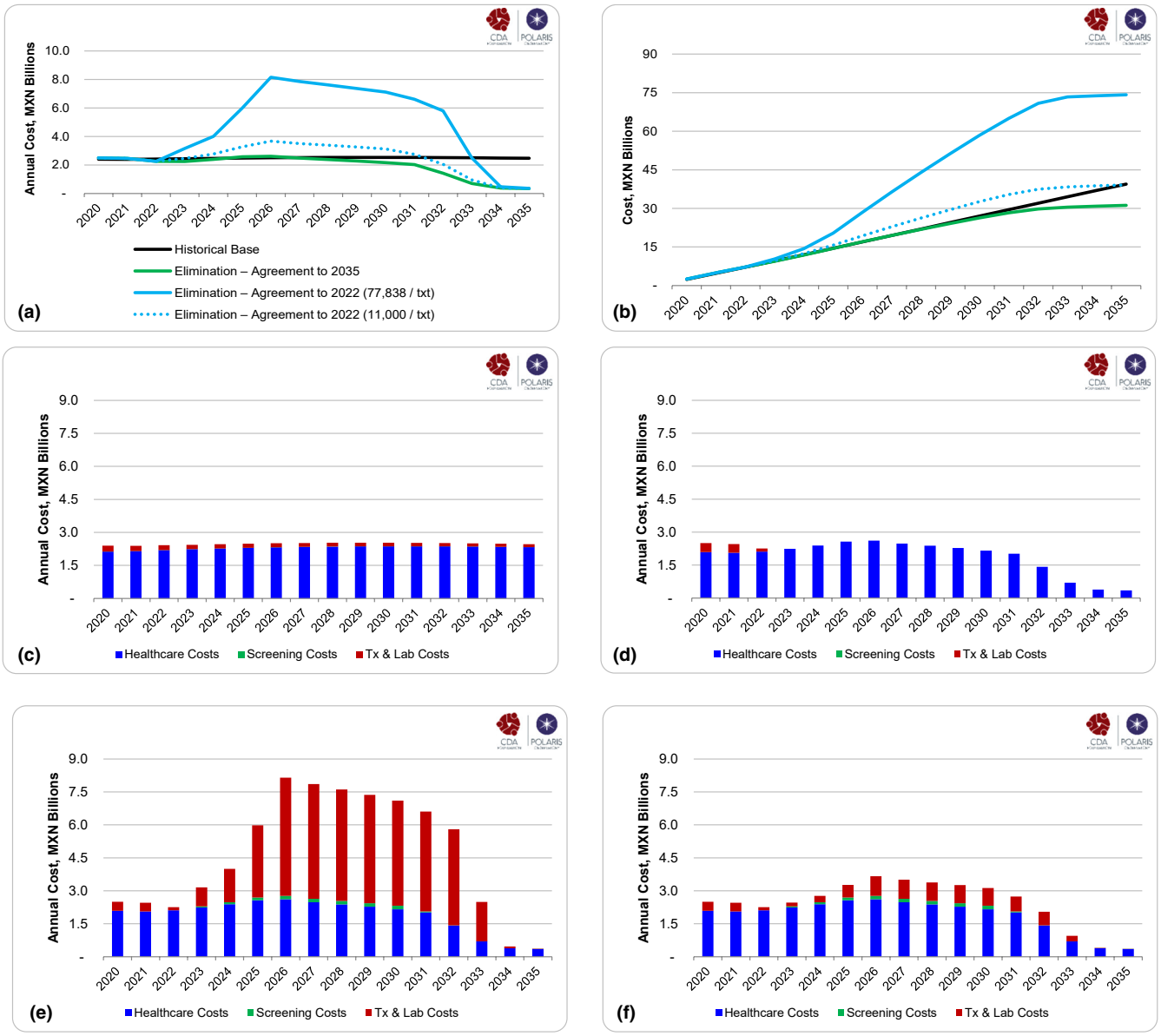

FIGURE 3 Economic analysis outcomes by scenario in Mexico, 2020–2035. (a) Annual cost by scenario. (b) Cumulative cost by scenario. (c) Annual costs for Historical Base. (d) Annual costs for Elimination—Agreement to 2035. (e) Annual costs for Elimination—Agreement to 2022 (77,838/txt). (f) Annual costs for Elimination—Agreement to 2022 (11,000/txt).

and treatment could save 6.5 billion in healthcare costs, reduce morbidity and save 23,500 lives.

Mexico must actively increase diagnosis and treatment and reduce new infections to achieve the WHO elimination targets by 2030. Historically, the National Center for the Prevention and Control of HIV and AIDS (CENSIDA) in Mexico successfully stabilized the HIV epidemic through diagnosis and monitoring of key at-risk populations. These tools and experiences in infection prevention and treatment can be leveraged to service the HCV-infected population.[6] Also, previously diagnosed patients can be identified, linked to care and recorded in the national surveillance system to reduce duplicative screening. Health professionals can retrospectively evaluate hospital and blood bank records to identify patients who have already tested positive, and prospectively monitor blood banks to ensure appropriate patient referral. Clinicians can also screen patients for HCV during routine healthcare evaluations. New HCV infections can be actively reduced by establishing and improving infection control committees in hospitals to track and reduce new infections. To achieve significant reductions in new infections through harm reduction, the WHO recommends providing 200–300 sterile needles and syringes per person who injects drugs per year. Recent studies have shown that opioid substitution therapy can reduce the risk of new HCV infections by 50%, Needle Syringe Programs can reduce risk by 76%, and a combination of the two can reduce new infections by 74%.[25]

Several study limitations exist, the impact of which the authors have worked to minimize. In the case of modelling exercises, results are only as good as the data inputs. This analysis relied on a panel

TABLE 4 Economic costs to the Mexican Government and outcomes, by scenario, 2020–2035.

	Costs				Outcomes			
	Total healthcare costs (MXN Billions)	Total laboratory and treatment costs (MXN Billions)	Total screening costs (MXN Billions)	Cumulative costs (MXN Billions)	ICER (MXN/DALY)	Year to achieve net-zero cost	Year to be highly cost-effective	DALYs averted
Historical Base	36.8	2.9	<0.1	39.7	-	-	-	-
Elimination—Agreement to 2035	30.3	0.9	0.0[a]	31.2	(9900)	2023	2023	859,000
Elimination—Agreement to 2022 (77,838/txt)	30.3	42.8	1.1	74.2	40,100	>2035	2023	859,000
Elimination—Agreement to 2022 (11,000/txt)	30.3	7.8	1.1	39.1	(680)	2035	2023	859,000

Abbreviations: DALY, Disability-adjusted life years, calculated to evaluate the years of healthy life lost based on time spent in various health states; ICER; Incremental cost-effectiveness ratio, calculated as net cost per DALY gained.

[a]Under this scenario, 100% of screening costs are covered by the industry agreement.

of experts to review and approve all inputs, and was measurably strengthened by this collaboration, since the best available data were unpublished. Close collaboration with the organization that oversees the NP, the Mexican Ministry of Health, resulted in use of current screening, treatment and cost data. Our work together began with an assessment of the feasibility of achieving the NP goals,[6] and this plan was quickly determined to be unrealistic, (Appendix, Section 4) leading to custom design of a new, attainable elimination scenario using diagnosis and treatment targets determined by the expert panel. The analysis also accounts for the initial effects of the COVID-19 pandemic since data for 2020 and 2021 are provided. However, we did not consider all administrative costs, other than salary coverage for healthcare services which was embedded in the data. CDA has leveraged this combination of modelling and consensus finding to develop HCV disease burden predictions with leaders in 83 countries and results have been published in over 100 manuscripts in peer-reviewed journals.

Reiable disease burden estimates, particularly prevalence, are a crucial starting point for elimination target setting. Mexico has conducted National Health and Nutrition surveys over the years, with anti-HCV prevalence ranging from 1.4% in 2000 to 0.38% in 2018, primarily among younger adults.[26] Studies have shown that national health surveys are not designed to estimate the prevalence of conditions that are uncommon; however, since they omit populations at increased risk of HCV infection including homeless, incarcerated or other marginalized persons.[27] For this analysis, real-time data from the National Program was instead used to inform prevalence, and we considered prevalence in both low- and high-risk populations in the final estimate (Appendix, Section S1). Ranges were also applied to viremic prevalence to capture the uncertainty in this estimate, and the outputs of the model were validated using empirical data on HCC cases due to HCV in Mexico (Appendix, Section S2).

The National Program for HCV Elimination in Mexico began at a difficult time, amidst a global pandemic; however, the program successfully expanded screening and treatment countrywide; demonstrating measurable progress and momentum. It is our hope that the results of this analysis can maintain a clear vision forward and support the successful elimination of HCV in Mexico.

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CONFLICT OF INTEREST STATEMENT

EM, IG and HR are employees of the Center for Disease Analysis Foundation (CDAF). CDAF has received research funding from Gilead, AbbVie and Vaccine Impact Modelling Consortium in previous years. CDAF has also received grants from the Centers for Disease Control and Prevention Foundation, John Martin

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DATA AVAILABILITY STATEMENT

For a period of one year after publication, the authors will share the data used in the figures in an Excel format after written request to the corresponding author. Data sharing will be limited to government agencies, academic institutions and non-profit organizations, and will not apply to for-profit or consulting organizations. Additionally, select data from the manuscript will be available publicly on the Polaris Observatory website https://cdafound.org/polaris-countries-dashboard/.

ETHICAL APPROVAL

Ethics approval was not required for study as it does not involve human participation or personally identifiable data.

PATIENT CONSENT STATEMENT

Patient consent was not required for study as it does not involve human participation or personally identifiable data.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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