Original Article

Economic Evaluation of Implementing a Rapid Point-of-Care Screening Test for the Identification of Hepatitis C Virus under National Viral Hepatitis Control Programme in Tamil Nadu, South India

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Abstract

Introduction: Viral hepatitis is a crucial public health problem in India. Hepatitis C virus (HCV) elimination is a national priority and a key strategy has been adopted to strengthen the HCV diagnostics services to ensure early and accurate diagnosis. **Methods:** To conduct an economic evaluation of implementing a rapid point-of-care screening test for the identification of HCV among the selected key population under the National Viral Hepatitis Control Programme in Tamil Nadu, South India. Economic evaluation of a point-of-care screening test for HCV diagnosis among the key population attending the primary health care centers. A combination of decision tree and Markov model was developed to estimate cost-effectiveness of point-of-care screening test for HCV diagnosis at the primary health care centers. Total costs, quality-adjusted life years (QALYs) of the intervention and comparator, and incremental cost-effectiveness ratio (ICER) were calculated. The model parameter uncertainties which would influence the cost-effectiveness outcome has been evaluated by one-way sensitivity analysis and probabilistic sensitivity analysis. **Results:** When compared to the tertiary level diagnostic strategy for HCV, the point-of-care screening for selected key population at primary health care level results in a gain of 57 undiscounted QALYs and 38 discounted QALYs, four undiscounted life years and two discounted life years. The negative ICER of the new strategy indicates that it is less expensive and more effective compared with the current HCV diagnosis strategy. **Conclusions:** The proposed strategy for HCV diagnosis in the selected key population in Tamil Nadu is dominant and cost-saving compared to the current strategy.

Keywords: Cost-effectiveness, diagnosis, economic evaluation, hepatitis C, India, key population, point-of-care, screening

Introduction

Viral hepatitis is a global public health problem, which causes high mortality and morbidity comparable to other major communicable diseases such as HIV, tuberculosis, and malaria.[1] Chronic hepatitis C virus (HCV) infection affects approximately 130–150 million individuals worldwide.[2] The number of people living with HCV is increasing due to factors like the delay in diagnosis, asymptomatic nature of disease, and long disease progression.[3] Considering the burden of HCV and its consequences, globally it has been recognized as a public health priority under the Sustainable Development Agenda (SDGs). Under SDGs it has been aimed to reduce the incidence of chronic HCV from the present 6–10 million infections to 0.9 million infections by 2030. In terms of mortality, the aim is to reduce HCV deaths from 1.4

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million to < 0.5 million by 2030.[1] The proposed strategies for achieving this goal are by providing safe, affordable, effective prevention, diagnosis, and treatment services.

HCV remains a major public health problem in India with an estimated prevalence of 0.5%–1.5%. HCV prevalence among blood donors and pregnant women was found to be 0.44% and 0.88%.[4] Among key population, HCV prevalence was found to be higher among people living with HIV, those with sexually transmitted diseases, high-risk sex behavior, injection drug users, and those receiving hemodialysis.[5,6] Chronic HCV infection accounts for 12%–32% of hepatocellular carcinoma and 10%–20% of cirrhosis.[7] India has initiated the National Viral Hepatitis Control Program (NVHCP) in 2018 to eliminate viral hepatitis by 2030. HCV elimination efforts in India aim to reduce new chronic infections by 90% and mortality by 65% in comparison to 2015 status.[8]

To achieve the HCV elimination goals, one of the key strategy adopted is to strengthen the diagnostics services for HCV to ensure early and accurate diagnosis.[9] At present, the delay in the diagnosis of HCV is common due to asymptomatic nature of the disease and lack of access to timely screening. In particular key population with high prevalence of HCV would be highly benefited through early and accurate diagnosis which presently is not optimal in the program. At present, HCV diagnosis in India is provided only at the tertiary health care facility for individuals with abnormal liver functions. Key population with high prevalence are not prioritized for HCV testing. In the backdrop of renewed efforts for HCV elimination under the newly launched NVHCP, efforts are being taken at state levels in India to expand the HCV diagnostic services. Tamil Nadu, a large South Indian state with a considerable burden of HCV had initiated a point-of-care screening intervention strategy for HCV recently.[10] This point-of-care screening intervention is aimed at providing HCV diagnosis at the primary health care level. Considerable resources are being invested for expanding the HCV diagnostic services in Tamil Nadu. Hence, there is a need to conduct an economic evaluation to assess the cost-effectiveness of point-of-care decentralized HCV screening strategy. Thus, the present study aims to conduct an economic evaluation of implementing a point-of-care screening test for HCV among the selected key population under the NVHCP in Tamil Nadu, South India.

Methods

Study design

A decision-analytic method, Markov model was used to simulate the cost and effectiveness. Data on transition probabilities and health-related quality of life were used to assess the lifetime cost-effectiveness of the intervention.

Study setting

This study is conducted in consideration of the HCV burden in Tamil Nadu a southern state of India with a population of 10.9 million. Tamil Nadu represents a larger and economically well-developed state of India with rapid urbanization. HCV prevalence in the general population is estimated to be between 0.09% and 15% in India and an estimated 6–12 million people are chronically infected with HCV.[11] A large population-based study conducted in Tamil Nadu found that the prevalence of HCV was 0.30%. Three-fourths of HCV-infected people were male and it was higher in rural, slum area and dialysis unit.[12] The NVHCP is implemented in Tamil Nadu as a vertical program under the National Health Mission. The present program in the state ensures the availability of HCV diagnostic services at district level and further aims to expand till sub-district level in the primary health center in a phased manner. Under NVHCP, 665 HCV testing centers are planned to be established as part of the public sector that can offer access to quality-assured testing and diagnosis for hepatitis over 3 years.

Study perspective

A societal perspective was used for this cost-effectiveness evaluation which considered both the patient's costs and health system costs. At present, HCV diagnostic and treatment services are provided under the NVHCP program of Tamil Nadu and hence the costs of the NVCHP program are included. While the diagnostic services are provided free of cost, still the patients incur costs and expenses to access these services, in the form of direct and indirect costs. Hence, a societal perspective was considered more appropriate for this evaluation.

Time horizon

Considering the nature of HCV disease progression which has lifetime implications for the patients and involves different health states, a lifetime horizon was considered to model the cost and outcomes of the two diagnostic strategies. The lifetime horizon includes both the diagnosis and treatment phase of the HCV patients and since the clinical and treatment costs are subject to considerable changes in a lifetime horizon. A discount rate of 3% was considered for both cost and outcomes in the modeling. This modeling work considered a 1-year cycle to follow-up a cohort of 1000 key population through various diagnostic and treatment states.

Model assumption

This economic evaluation model was conceptualized based on the natural history of HCV diagnosis followed by treatment. The present model considered two different scenarios which included the current diagnostic strategy used for HCV diagnosis under the NVHCP program. This strategy was used to diagnose patient at the tertiary health care level. The intervention scenario considered a strategy in which HCV screening will be performed at the primary health care level. This strategy is considered as decentralised strategy in which a point-of-care diagnosis is provided for those who access primary health care services for HCV. Both the scenarios involve a confirmatory Enzyme-Linked Immunosorbent Assay (ELISA) for HCV. The cost inputs and outcomes of the two diagnostic strategies were modeled using a decision tree and Markov model structure.

Decision tree analysis

Figure 1 provides the assumptions of decision tree which was constructed based on the diagnostic cascade of HCV in

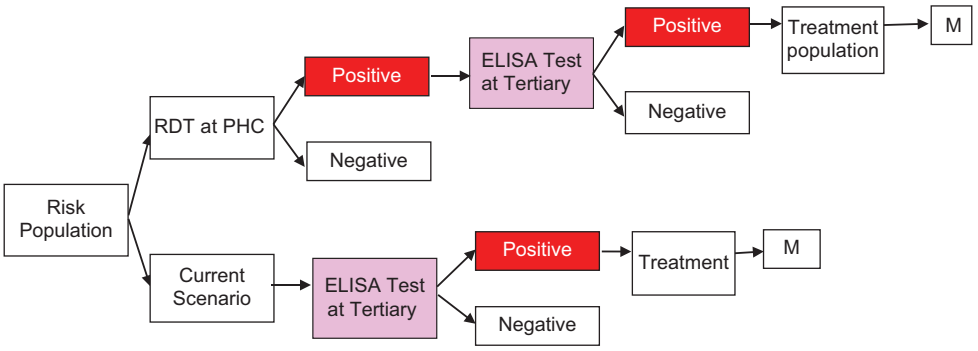

Figure 1: Decision tree for point-of-care HCV screening at primary level as compared to tertiary care level. RDT: Rapid diagnostic test, ELISA: Enzyme-linked immunosorbent assay, PHC: Primary health center, M: Markov model, HCV: Hepatitis C virus

public health facilities. Under the current NVHCP, a passive case finding approach is used in which all individuals with symptoms suggestive of HCV are diagnosed using gold standard ELISA test at tertiary health care level. This strategy involves referral of HCV symptomatics from primary health care facilities to secondary and tertiary health care facilities. Individuals diagnosed with HCV are treated as per the standard treatment guidelines of NVHCP.

Under the proposed diagnostic strategy selected key population who are at increased risk for HCV due to their specific health conditions or behaviors are prioritized. The proposed strategy utilizes a rapid test kit at primary health care level followed by a confirmatory testing by ELISA at tertiary level. This strategy provides a point-of-care diagnostic care as compared to the standard diagnostic strategy under NVHCP. Both the diagnostic strategies were modeled parallelly using a decision tree approach and probabilities associated with the HCV diagnosis were used to populate the model [Figure 1]. The standard guidelines for conducting and reporting economic evaluation survey were adhered.

Markov model

After the completion of 1-year cycle as modeled using decision tree, the individuals in the cohort moved to different health states based on the transition probabilities. For modeling these transitions between health state a Markov model was used. Model included a total of seven health states which are asymptomatics, chronic HCV, compensated cirrhosis, decompensated cirrhosis, hepatocellular carcinoma, cure, death due to HCV, and all-cause mortality. The transitions involved asymptomatic patients without treatment developing chronic HCV and further move to cirrhosis and hepatocellular carcinoma states. The individual may remain in one health state without transition to other states. Transitions involved, chronic HCV who are treated, who could get cured, and cured individuals may get transitioned to asymptomatic HCV state. Death due to HCV was the absorption state from which no transition occurred. All the transmission processes between health states are provided in Figure 2.

Transition probabilities

Transition probabilities between health states were collected from the published literature pertaining to HCV infection and related health states from India and other relevant settings.[13] The transition probabilities of treatment cost,[14] diagnostic cost,[15] out-of-pocket expenditure,[14] prevalence rates,[16-20] diagnostic accuracy,[21,22] which were collected from the published literature were used to populate the model. The transition probabilities of disease progression, quality of life (QoL) for each health state, all-cause mortality[13] and mortality due to HCV[23] were obtained from literature review. Information on stage-wise distribution of patients were collected from the NVHCP and published reports.[24]

Model input parameters

Table 1 represents the input parameter values with range (upper and lower limits) used in the base case analysis and the parameters used in the sensitivity analysis. The parameters related to HCV prevalence, natural history of HCV, transition probabilities, health system cost, and out-of-pocket expenditure for the management of HCV are presented in Table 1. Information on life expectancy was taken from the life table published from SRS data.[25] Using expected years to be lived, years of life gained were calculated. Start age of cohort in the model was 35 years, which was calculated based on the mean age of HCV-positive patients.[26] The effectiveness outcomes of the model are expressed with quality-adjusted life years (QALYs). Utility scores for each health state were collected from published literature. The utility score for patients in different health state ranged from 0 to 1.

Base case analysis

Cohort size of 1000 key population entered the decision-analytic model followed by Markov cycle to estimate the incremental costs and QALYs gained by introduction of point-of-care screening services when compared to the current HCV diagnosis. The incremental cost-effectiveness ratio (ICER) was compared with a threshold value of ₹ 100,000 which is equal to India's per capita GDP.[13] This standard threshold was used to interpret the cost-effectiveness of two strategies. Results were also expressed in terms of undiscounted and discounted QALYs gained, life-years gained, and deaths averted.

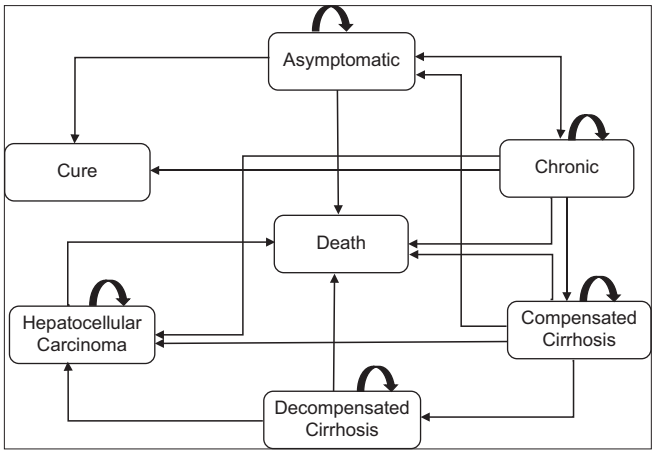

Figure 2: State-transition model illustrating the natural history of hepatitis C virus infection

Calibration and sensitivity analysis

The estimates of the model were tested for their robustness by conducting sensitivity analysis. Through sensitivity analysis, the input parameters were varied between 20% to assess their impacts on the estimated ICER values. The sources of parameter uncertainties which would influence cost-effectiveness outcome was evaluated by one-way sensitivity analysis. The robustness of the model was further evaluated by probabilistic sensitivity analysis. Monte Carlo simulations involving 1000 iterations were used to assess the probability of ICER with 95% confidential intervals.

Results

Base case analysis

The findings highlight that when compared to the current diagnostic strategy for HCV, the point-of-care screening test for HCV for selected key population at primary health care level resulted in a gain of 57 undiscounted QALYs and 38 discounted QALYs for a cohort of 1000 population. In terms of life years gained, four undiscounted life years, and two discounted life years were gained. The total of four deaths were averted as a result of the intervention. The incremental cost saving for this point-of-care screening test was ₹114,571.

Incremental cost-effectiveness ratio

The negative ICER (−114571) of the proposed intervention indicates that the point-of-care screening at primary health care facility followed by early treatment was less expensive and more effective in comparison with the current diagnosis at tertiary health care facility [Figure 3].

Out-of-pocket expenditure

With respect to out-of-pocket expenditure, the point-of-care screening strategy would reduce ₹65,497 per person for HCV management. It was found that the proposed intervention resulted in reduction of out-of-pocket expenditure due to the annual reduction in the number of chronic HCV cases.

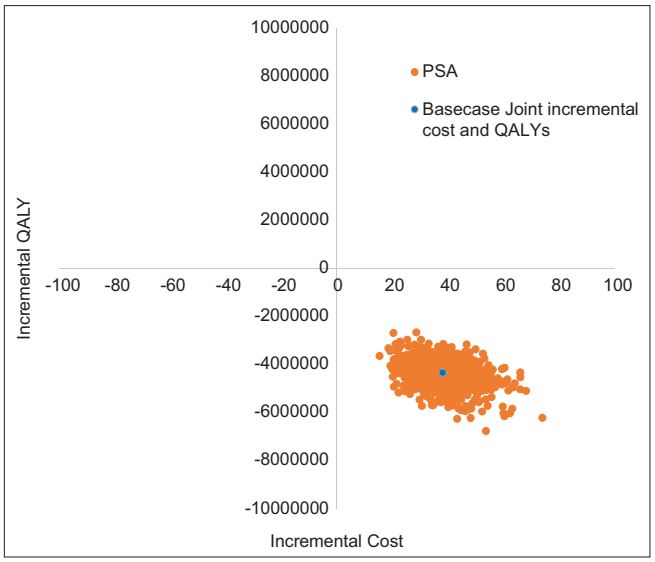

Figure 3: The cost-effectiveness plane for point-of-care hepatitis C virus screening at primary care level as compared to tertiary care level

Sensitivity analysis

Individual parameters influencing the ICER value were identified using sensitivity analysis. One-way univariate sensitivity analysis found that ICER was most influenced by QoL of asymptomatics patients and QoL of patients with compensated cirrhosis. The ICER range estimated for parameter changes in QoL of asymptomatics HCV patients was −299,966 to −70,808, and ICER range estimated for parameter changes in QoL of patients with compensated cirrhosis was −82,283 to −188,561 [Figure 4]. Probability sensitivity analysis was conducted to find out the influence of joint uncertainty in parameter values. It was found that decentralized point-of-care strategy had 100% probability of being dominant when compared to the current strategy.

Discussion

India is committed to achieve the SDGs and one of the objectives is to eliminate viral hepatitis. Since HCV is a public health challenge, Government of India had developed an action plan which calls for evidence-based strategies for implementation under the newly initiated NVHCP in 2018. The current study finding provides an important evidence for the NVHCP to strengthen its diagnostic strategy. Implementation of point-of-care screening test for HCV was found to be cost-effective as compared to the current strategy which involves referrals and tertiary level care. Further, this decentralized screening of key population would prevent patients with chronic liver-related problems through early diagnosis and thus improve QoL. A recent review on the cost-effectiveness of different testing strategies for chronic HCV in low- and middle-income countries reported that focused testing among high-risk groups, particularly persons who inject drugs, prisoners, and men who have sex with men was consistently cost-effective.[27,28]

Table 1: Input parameters used for model based cost-effectiveness analysis of hepatitis C virus screening through rapid test followed by enzyme linked immunosorbent assay

Type of parameter	Input parameter	Base case	Range	Distribution	Parameter (α)	Parameter (β)	Reference
Demographic	Mean age of HCV infection	35	28-42	Log normal	3.550169	0.101779	[14]
	Cohort population	1000	750-1250	Log normal	6.90258	0.10178	Assumption
	Life expectancy	44	35-53	Log normal	3.778773	0.104079	[25]
Mortality	All-cause mortality (%)	0.00951	0.007133-0.011888	Log normal	−4.66059	0.101779	[22]
	Mortality-decompensated cirrhosis	0.13	0.0975-0.1625	Log normal	−2.0454	0.101779	[23]
	Mortality-hepatocellular carcinoma	0.43	0.3225-0.5375	Log normal	−0.84915	0.101779	[23]
Prevalence	Prevalence of HCV	0.01	0.028-0.042	Beta	95.06611	9411.544	[15-19]
Diagnostic accuracy	Sensitivity of ELIZA	1	0.75-1.25	Beta	−1	0	[20]
	Specificity of ELIZA	1	0.75-1.25	Beta	−1	0	[20]
	Sensitivity of rapid diagnosis test	0.985	0.73875-1.23125	Beta	0.455547	0.006937	[21]
	Specificity of rapid diagnosis test	1	0.75-1.25	Beta	−1	0	[21]
Probability of disease progression	Asymptomatic carrier to chronic	0.69	0.632-0.948	Log normal	−0.37624	0.101779	[22]
	Asymptomatic to normal	0.25	0.1875-0.3125	Log normal	−1.39147	0.101779	[22]
	Chronic to compensated cirrhosis	0.13	0.104-0.156	Log normal	−4.82107	0.101779	[22]
	Chronic to hepatocellular carcinoma	0.00067	0.000503-0.000838	Log normal	−7.31341	0.101779	[22]
	Compensated to decompensated cirrhosis	0.03	0.0225-0.0375	Log normal	−3.51174	0.101779	[22]
	Decompensated to hepatocellular carcinoma	0.03	0.0225-0.0375	Log normal	−3.51174	0.101779	[22]
RR	Asymptomatic carrier to chronic	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Chronic to compensated cirrhosis	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Chronic to hepatocellular carcinoma	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Compensated to decompensated cirrhosis	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Decompensated to hepatocellular carcinoma	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Mortality-compensated cirrhosis	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Mortality-decompensated cirrhosis	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
	Mortality-hepatocellular carcinoma	1	0.75-1.25	Log normal	−0.00518	0.101779	NVHCP
QoL	Normal	1	0.75-1.25	Beta	−1	0	[22]
	Asymptomatic HCV	0.9	0.675-1.125	Beta	8.703647	0.967072	[22]
	Chronic HCV	0.7	0.525-0.875	Beta	28.11094	12.04755	[22]
	Compensated cirrhosis	0.55	0.4125-0.6875	Beta	42.66641	34.90888	[22]
	Decompensated cirrhosis	0.49	0.3675-0.6125	Beta	48.4886	50.46773	[22]
	Hepatocellular carcinoma	0.58	0.435-0.725	Beta	39.75532	28.78833	[22]
Discount rate	QALY	0.03	0.0225-0.0375	NA			[22]
	Cost	0.03	0.0225-0.0375	NA			[22]
Diagnostic	Screening cost of rapid test	115	86.25-143.75	Gamma	96.03647	1.197462	NVHCP
	Screening cost of ELISA	2000	1500-2500	Gamma	96.03647	20.82542	NVHCP
	Cost of RNA, LFT, Fibro-scan	8000	6000-10,000	Gamma	96.03647	83.30169	[14]
	Follow-up cost	6000	4500-7500	Gamma	96.03647	62.47627	[14]
Treatment cost	Treatment cost inactive chronic	17,280.16	12,960.12-21,600.2	Gamma	96.03647	179.9333	[13]
	Cost for liver disorders	112,658	84,493.5-140,822.5	Gamma	96.03647	1173.075	[13]
	Drug cost	21,283	17,026.4-25,539.6	Gamma	96.03647	221.6137	[13]
	Out-of-pocket expenditure	98,956	74,217-123,695	Gamma	96.03647	1030.4	[13]
Stage-wise distribution of HCV patients	Delayed clearance	0.014	0.01-0.02	Beta	29.6814	2090.419	NVHCP
	Chronic hepatitis	0.79	0.63-0.095	Beta	6.245939	1.660313	NVHCP
	Compensated cirrhosis	0.13	0.10-0.15	Beta	90.23955	603.9108	NVHCP
	Decompensated cirrhosis	0	0	Beta			NVHCP
	Hepatocellular carcinoma	0.07	0.06-0.08	Beta	174.9853	2324.804	[24]

RR: Relative risk, HCV: Hepatitis C virus, NVHCP: National Viral Hepatitis Control Programme, QoL: Quality of life, QALY: Quality adjusted life years, NA: Not applicable, ELISA: Enzyme-linked immunosorbent assay, LFT: Liver function test

Experiences from HIV and TB diagnostic programs have highlighted the importance of targeted or focused screening of high-risk population.[29,30] Similarly, in the context of HCV such emphasis towards risk population-based screening has not been studied specifically. Our study for the first time had attempted an economic evaluation of risk population-based screening strategy to inform and strengthen implementation of NVHCP at subnational level. The current evidence shows that

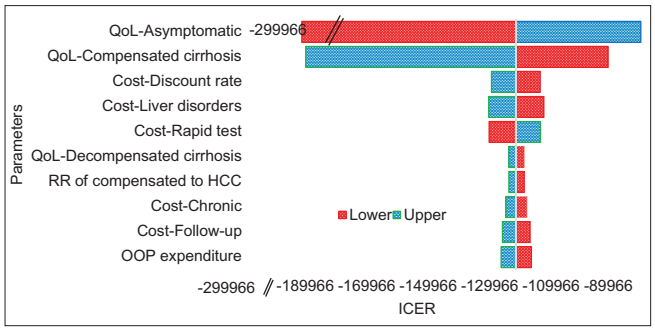

Figure 4: Tornado plot illustrating the effect of individual parameters on incremental cost-effectiveness ratio

risk population-based screening could be cost cost-effective due to the high prevalence of HCV infections in these groups which leads to early diagnosis and by preventing progress to chronic liver disorders.

Our study finding reemphasis the importance of point-of-care testing for HCV which has been proven cost-effective even in low HCV prevalence setting.[31,32] While point-of-care testing could be cost-effective, still the coverage of target population could be a crucial factor which will determine the outcomes. In our study setting, the access of decentralized health services at primary health care level has remained suboptimal and hence implementation of HCV screening at this decentralized level may be less utilized. Our finding should be interpreted with such limitations pertaining to access of care. Measures to improve access of services at primary health care level through information, education, and communication would be an essential step to ensure optimal access of HCV point-of-care diagnostic services.

This study provided estimates of QALYs saved using rapid diagnostic test followed by early diagnosis and treatment for HCV among selected key population. The findings highlight that the point-of-care screening strategy was dominant compared with current practice. The cost saving of proposed strategy could be due to the identification of HCV infection among the asymptomatics and resulted in increased gain of QoL. Sensitivity analysis showed that QoL of patients had more influence on ICER value. We also hypothesize that screening of asymptomatics of HCV, diagnosis at an early stage could potentially reduce the health care expenditure to patient and their family. Our findings found that the point-of-care screening strategy reduces the out-of-pocket expenditure to the patients and their family.

Limitations of the study

Our economic evaluation findings are in particular reference to a single state in India. Thus, the model is representative of Tamil Nadu state alone and may require modifications for other states with different scenarios. The findings may vary based on the prevalence of HCV among the key population.

Conclusions

Based on the present economic evaluation, the decentralized point-of-care screening strategy for HCV at primary health care level for a selected key population in Tamil Nadu is cost saving. Our findings could strengthen the implementation of HCV screening strategy under the present NVHCP in Tamil Nadu and similar states in India. The use of focused testing in key populations was cost-effective and our model demonstrated that the proposed strategy will likely identify many cases of HCV infection among asymptomatics, prevent chronic cases and would improve QoL, and reduce out-of-pocket expenditure.

Research quality and ethics statement

This study was approved by the Institutional Review Board/ Ethics Committee of National Institute of Research in Tuberculosis, India. IRB No 2019026. The authors followed applicable EQUATOR Network ("http:// www.equator-network.org/) guidelines during the conduct of this research project.

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Conflicts of interest

There are no conflicts of interest.

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