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REVIEW ARTICLE

IMPORTANCE OF HEPATITIS C SCREENING IN HIGH RISK POPULATIONS SUCH AS INJECTION DRUG USERS, FAMILY CONTACTS, SURGICAL AND CHRONIC KIDNEY DISEASE PATIENTS IN INDIA

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ABSTRACT

Aim: The aim of the present review was to understand the importance of hepatitis C screening in high risk populations such as injection drug users, family contacts, surgical and chronic kidney disease patients from a public health perspective.
Methods: A literature search was performed using electronic databases like Pubmed/Medline to identify relevant articles from 1994 to 2016. The search yielded around 32 original studies and review articles from which relevant data was extracted.
Results: Findings from studies suggest transmission of HCV infection among spouses ranges from 24%-46%, which may be attributed to age and duration of marriage playing a fundamental role in transmission. In addition to family contact and sexual behavior, shared use of personal items such as razor blades, toothbrushes, nail clippers and manicure cutters contribute to 33.3%-88.8% intra-familial transmission. Additionally, patients reporting to surgical departments prior to any surgical intervention reported HCV seropositivity ranging from 0.28%-63.2% indicating a need to screen such patients. Renal impairment patients on hemodialysis, or chronic kidney disease patients are also at a higher risk of HCV infection and need to be screened appropriately.
Conclusion: Given the overall burden of HCV infection on the healthcare system, there is a critical need to identify and screen high risk population with linkage to care and access to treatment which has the potential to substantially reduce the transmission of HCV and its associated morbidity and mortality.

INTRODUCTION

Background

Hepatitis C is a chronic, generally asymptomatic, form of viral hepatitis that can lead to cirrhosis and hepatocellular carcinoma. The prevalence of hepatitis C virus (HCV) varies between regions and countries, and an estimated 170 million people, or more than 3% of the world's population, are infected.[1] HCV is transmitted through exposure to infected blood and other body fluids. Owing to the asymptomatic nature of HCV, infected individuals often remain undiagnosed until they test positive for HCV through opportunistic screening (eg, screening blood donors), or when high alanine aminotransferase levels are detected during routine blood work.[2,3] Of individuals infected with HCV, 15%-20% experience spontaneous recovery, while the remaining 75%-85% progress to chronic hepatitis C.[2] When the virus is first detected, individuals with chronic infection may have no symptoms and perhaps mild to moderate liver fibrosis. Over time, however, approximately 60% of individuals with chronic infection progress to advanced fibrosis and cirrhosis. Of individuals with advanced fibrosis or cirrhosis, approximately 5% develop hepatocellular carcinoma within a 5-year period.[3] In addition to increasing mortality, hepatitis C infection with liver failure or liver cancer is the leading cause of liver transplantation worldwide.[4]The objective of the present review is to understand the importance of hepatitis C screening in high risk population such as injection drug users, family contacts, surgical and chronic kidney disease patients for public health evaluation and management of chronically infected HCV patients.

Epidemiology of HCV Infection in India

India accounts a significant share of global HCV infection due to the large population; approximately 12-18 million population is infected with HCV, despite a low to moderate prevalence of HCV (1%-1.5%).[5] National Centre for Disease Control reported 1% prevalence of HCV in India.[6] HCV has been observed to be relatively higher in states of Punjab, Andhra Pradesh, Puducherry, Arunachal Pradesh and Mizoram.[7] A prevalence rate of 3.29%-5.2% was observed in a selected geographical area of northern India[8, 9]while the anti-

HCV antibody prevalence in north-eastern states ranged from 7.89%-90% (in injection drug users).[8, 10-12] On the other hand the prevalence of HCV in southern India ranges from 0.68%-2.4%.[13-16]A community-based epidemiologic study carried out in a district of West Bengal reported 0.87% of HCV prevalence, while only one study conducted on age-specific seroprevalence among healthy volunteers from a rural population in Maharashtra reported one person with anti-HCV positivity indicating low seroprevalence in Maharashtra. [17] Figure 1 depicts prevalence of hepatitis C and distribution of its genotypes across India.[8-16,18-28]Wide diversity of HCV genotypes has been observed in India. Genotype 3 has been observed to be the most predominant genotype (63.85%) followed by genotype 1 (25.72%) in India. Due to genotypic difference in different geographical regions of India, genotype 3 is observed to be common in northern, eastern and western India while genotype 1 is reported to be common in the southern states of India.[29]

Risk Factors Associated with HCV Infection

Hepatitis C is common blood-borne infection which is most efficiently transmitted through parenteral exposure. Risk factors and lifestyle play an important role in the distribution pattern of HCV genotypes in a particular region. The highest prevalence of HCV infection is reported to occur among those with significant and repeated percutaneous exposures.[30] Findings from India have reported injection drug use, unprotected sex, and people engaged in multiple sex partners as some of the more commonly occurring risk factors for HCV transmission.[18, 20, 31] Table 1 outlines some of the common risk factors that have been reported in studies across India.[30, 32]

Transmission of HCV Infection in High Risk Populations

Transmission of HCV infection usually involves parental route. However, there is a growing body of evidence that reports at least 50% of all HCV patients do not have a history

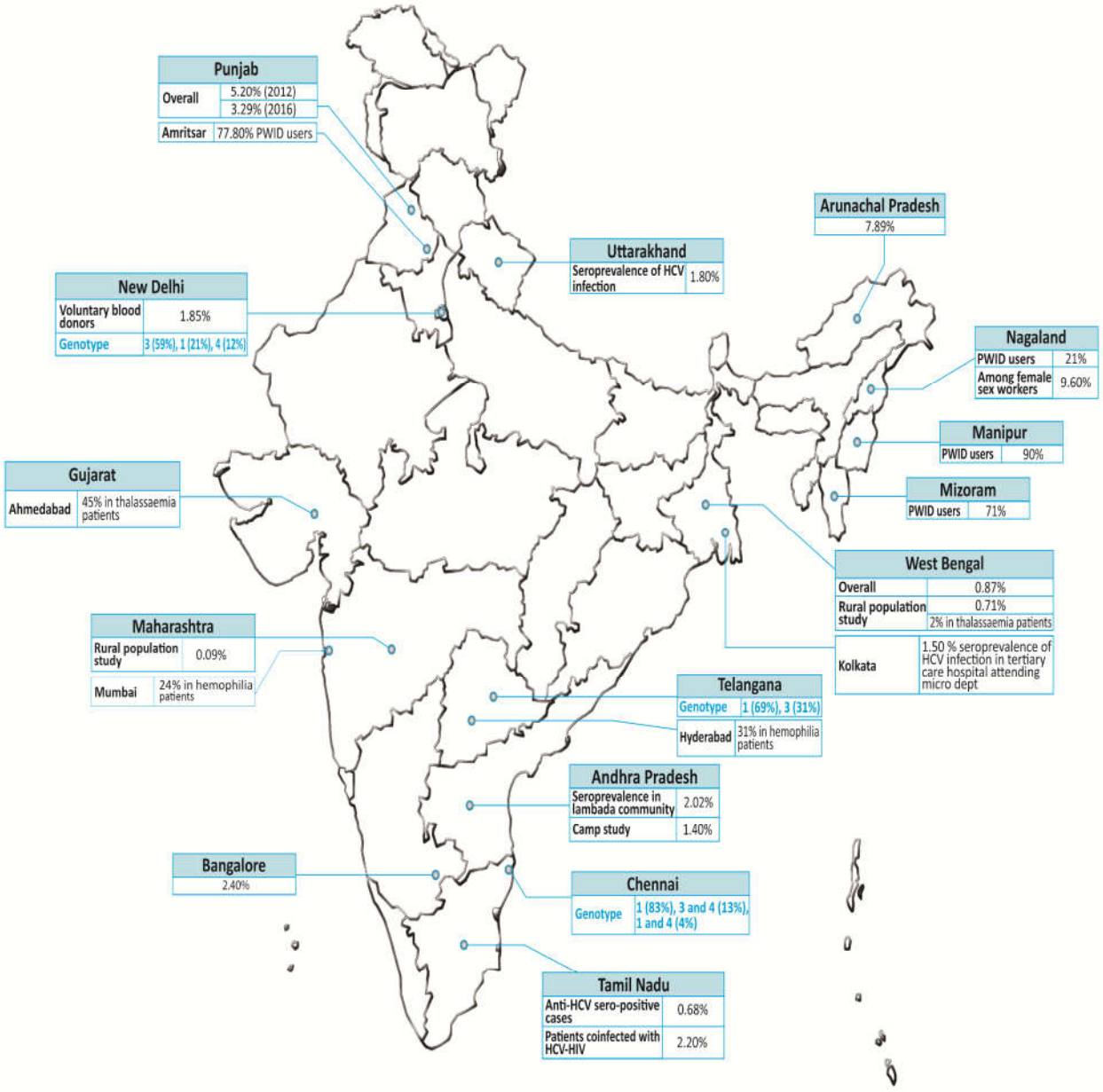

Figure 1: Prevalence of HCV infection and Genotypes across India [8-16, 18-28]

Table 1 Risk factors involved in HCV transmission [30, 32]

- Unsafe therapeutic injections-sharing syringe, reuse of injection accessories[32]
- Occupational injury- by needles and sharp instrument while working in health care environment[32]
- Sharing personal care items- toothbrush, razors, manicure, pedicure equipments contaminated with blood[32]
- Tattoo and piercing- with needles that have not been sterilized or from unregulated establishment[32]
- Blood and blood products- blood transfusion prior to 1992[32]
- Haemodialysis- in case of kidney failure patients where there is poor infection control while dialysis[32]
- Sexual contact- engaging in unprotected sex or sexual activities that increases the potential for exposure to blood, sex with multiple partners or person who inject drug(PWID) user[32]

of blood transfusion or exposure to any other parenteral risk factor.[33]HCV can be transmitted through horizontal transmission to partners or other household contacts. The intrafamilial transmission rates has been observed to be significantly higher between sexual partners than among other household members who do not have sexual contact however, transmission to children has been found to be significantly lower.[34]Spread of HCV within a household is most likely a result of direct, through-the-skin exposure to the blood of an infected household member.[35]

Screening of Family Members

Findings from studies conducted in the Northern parts of India have reported that high anti-HCV positivity has been observed among spouses (24%), followed by children (11%) and siblings (10%) of a HCV infected individual. Majority of anti-HCV positive contacts (65%) were family members of patients aged more than 50 years.[36]A study conducted in Ludhiana (North India) reported that the prevalence of anti-HCV antibodies among family contacts of patients with HCV related chronic liver disease was found to be 16% which was significantly higher ($p<0.001$) than that in volunteer blood donors in the hospital.[37]Findings from these studies highlight that family members of infected individuals are prone to acquire infection. This arises a need to screen immediate family members who are in close contact withthe person infected with HCV.

Data from two Egyptian studies relating to the transmission of HCV infection between the spouses reported 36%-46% transmission of HCV from wife to husband while transmission from husband to wife ranged from 18%-25% which indicates that sexual intercourse with a positive HCV female, more than 4 times a month, is 66 times likely to transmit HCV infection to her husband.[38, 39] Furthermore, a study by Bourlet *et al* reported that the seminal plasma of 12.5% subjects was found positive for HCV RNA and that the shedding of HCV RNA in the female genital tract was associated with the presence of blood. Thus trauma to the mucosa as well as high viremia levels during sexual intercourse increased the risk of viral transmission.[40]

HCV infection in spouses has been observed to increase with the duration of marriage ranging from 1 to 60 years.[41]The duration of relationship plays a fundamental role, suggesting that the difference in the seropositive prevalence rates among sexual (12.1%) and non-sexual contacts (2.5%) could be explained by a time factor wherein the length of time of the relationship (OR=1.06, 95% CI: 1.00-1.11) was significantly associated with HCV seropositivity.[42]Statistically significant differences were observed in prevalence of anti-HCV antibodies among different age groups, with patients in age group ≥40 years showing highest seroprevalence ranging from 44.5%- 65%.[43]This indicated that higher prevalence among older contacts may be due to the longer duration of relationship with their partners. Additionally, children born to HCV positive parents have also shown evidence of serological prevalence. Approximately, 1.3% children (6.8% son and 4.94% daughter) showed serological evidence for HCV infection transmitted through close family contact in over 10-15 years.[39, 44]

In addition to family contact and sexual behaviour, the shared use of personal items such as razor blades, toothbrushes, nail clippers and manicure cutters might be important factors for the intra-familial transmission of HCV. Shared personal hygiene items have also shown a correlation with the possible route of transmission. A study indicated that 33.3% couples shared toothbrushes, 77.8% shared razor blades, 88.8% shared nail clippers, and 66.7% shared manicure cutters.[45] This indicates that in addition to familial and sexual behavioral patterns, shared used of personal hygiene items might be important for intrafamilial transmission of HCV. Furthermore, risky behavioral practices adopted by anti-HCV positive household contacts compared to HCV-negative household contacts contribute to acquiring HCV infection. Anti-HCV positivity among household contacts giving IV injection to their index cases[39] or those who were being assistants of familial HCV patients during bleeding episodes[43] were found to be statistically significant ($p<0.05$) higher risk of infection.[39]

Screening of Person Who Inject Drugs

Furthermore, person who inject drug (PWID) remain at high risk for both acquisition and transmission of HCV. Findings from Eastern Europe, East Asia and Southeast Asia have reported around 10 million injection drug users being HCV positive. In India, HCVsero-positivity in PWID patients ranges between 20% and 90%.[46] A study conducted amongst PWID users in Amritsar showed 41% drug abuse behaviors such as history of needle, syringe, paraphernalia sharing indicating transmission of HCV infection.[47] Further it was observed that high risk sexual practices (encounter with commercial sex workers and multiple sexual partners) or unprotected sex was seen in 34%-67.1%[18, 47] of PWID user's which increases the chance of HCV infection. This suggests that indulging in drug abuse behavior and sexual contact with PWID users elevates the spread of HCV infection. Moreover, unsafe injecting practices such as indirect sharing of paraphernalia i.e., drug preparation equipments usually, cookers or spoons, cotton filter and water used for cleaning syringes may result in the spread of virus to family members.[48-50] Thus PWIDs users may also result in intrafamilial transmission of infection.

Screening in Selected Medical Condition

Additionally, high presence of chronic liver disease in index cases (16.98%) has been one of the factors in transmission of HCV, compared to the negative counter parts (12.02%, $P<0.05$).[39] In a cross sectional study involving 154 patients with HCV-related chronic liver disease, hepatitis C virus was detected in 42 spouses, of whom 25 were positive for HCV RNA.[41] This may be attributed to the increase duration of

marriage and sexual contact with the index patient. In addition to chronic liver disease, HCV prevalence has also been observed in thalassemia patients. In a multitransfused Egyptian thalassemia patients, 34.4% of patients were positive for anti-HCV antibodies and RNA, 24 families of HCV positive patients showed 14 affected family members (19.2%) indicating role of intrafamilial transmission in the spread of HCV.[51]

Pre-surgery Screening

Screening and testing patients from not only general population but also from selected segments of population with potentially higher risk of HCV transmission is important. Screening of patients reporting to surgical departments prior to any surgical intervention can be useful in preventing transmission of new HCV infection, as this information will guide the clinician in educating the patient and providing them with a preventive plan along with initiating timely and appropriate treatment. Findings from two Indian studies reported HCV seropositivity ranging from 0.28%-63.2% prior to surgeries. Similarly, four studies from Pakistan reported 5.1%-27% HCV seropositivity prior to surgeries while one study from US reported 4.8% seorpositivity. Table 2 outlines the HCV seropositivity observed due to screening of patients prior to invasive surgeries.[52-58] This indicates that HCV RNA testing and viral load performed on HCV reactive patients before surgery identifies a notable proportion of HCV carriers which could be excluded, and other preventative measures could be used more rationally.

Table 2 Detection of HCV seropositivity prior to surgery[52-58]

Surgical Department	Seropositivity for HCV
General Surgery[52]	63.23%
Gynecology/obstetrics[52]	10.97%
Otorhinolaryngology[52]	16.13%
Ophthalmology[52,53,54]	0.65% - 27%
Orthopedic[52]	9.03%
Elective operations[55]	12.8%
Cardiac surgery (requiring cardiopulmonary bypass)[56]	4.8%
Various surgeries, ranging from – elective oesophagectomies to simple abscess drainage procedure and for trauma condition[57]	5.1%
Cataract[58]	0.28%
Oculoplasty[58]	4.54%
Trauma[58]	1.25%

Screening in Renal Impairment Patients

In addition to this, renal impairment patients on hemodialysis should be tested for HCV when they first start hemodialysis or when they are transferred from another hemodialysis facility.[59] Findings from few Indian studies have reported a 4.3%-42% of HCV prevalence rate in hemodialysis patients.[60-62] Further, Dialysis Outcomes and Practice Patterns Study (DOPPS) survey, which included nearly 80,000 patients on maintenance dialysis from the industrialized world, reported 13.5% mean prevalence of anti-HCV positive.[63]Moreover, it is suggested that chronic kidney disease (CKD) patients should be tested for HCV because HCV infection is associated with various types of glomerulonephritis (GN) such as cryoglobulinemic GN, membranoproliferative glomerulonephritis, focal and segmental glomerulosclerosis, and membranous GN indicating HCV testing logical in CKD patients.[64-66]Thus renal impairment patients are at high risk for blood borne infection because of prolonged vascular access and the potential for exposure to infected patients and contaminated equipment.[67] HCV infection acts as an important cause of morbidity and mortality in patients with end-stage renal disease (ESRD) on renal replacement therapy and after kidney transplantation.[68] Thus screening for HCV as a part of routine preoperative investigations prevent transmission of HCV from patient to healthcare workers and aids in taking adequate precautions in the form of enhanced personal protective equipments (PPE) during surgical procedures.

Management of Hepatitis C Patients

Patient and Family Counseling

Awareness about the infection allows people to seek health care they need and to take precautions against spreading the infection to others.[69] People with HCV infection in India are unaware about their infection status. Lack of knowledge about disease status and disease transmission dynamics among family contacts along with lack of confidence in initiating HCV treatment, fear of side effects, and lack of financial resources are some of the noted factors for persistently low HCV screening, evaluation, and treatment rates.[70]As multiple health-care providers play a role in identifying individuals with HCV infection they should seek ways to implement testing for HCV in clinical settings such as primary care, obstetrician, and other physician offices, substance abuse treatment programs, dialysis clinics, homeless shelters, prisons, employee health clinics, university health clinics, and other venues. In addition, community outreach and education, conducted through developing partnerships between health departments and community organizations, is needed to encourage community members to seek HCV screening. These partnerships might be particularly important to overcome social and cultural barriers to testing and care.

Medical providers should advise patients identified as HCV positive regarding measures they can take to prevent transmission to others and protect their health or refer patients for counseling if needed. Patient education should be conducted in a culturally sensitive manner in the patient's primary language (both written and oral whenever possible). It is advised that to prevent risk of transmission patient should be advised to - (a) notify their spouse, household, and needle sharing contacts that they should be tested for markers of HCV infection; (b) use methods (eg. condoms) to protect non-immune sex partners from acquiring HCV infection; (c) cover cuts and skin lesions to prevent the spread of infectious secretions or blood; (d) refrain from donating blood, plasma, tissue, or semen; (e) refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could become contaminated with blood; and(f) avoid or limit alcohol consumption and NSAIDS to protect the liver from further harm.[71,72] Moreover, PWID patients require integration of counseling services along with the treatment. PWID patients should be counseled and advised for (a) implementation of alcohol reduction strategies (b) implementation of rapid vaccination regimen (c) avoidance of discrimination and stigmatization (d) providing drug dependency services for the provision of opioid substitution therapy and sterile injection equipment (e) implementation of harm reduction strategies to prevent acquisition of other blood-borne viruses such as HIV.[73]

In view of occurrence of HCV infection in family members, there is a growing need for better counseling and vigorous

screening of family members, to identify asymptomatic cases in the community and target this pool for curative as well as preventive measures. Improving the identification and public health management of family members of people with chronic HCV infection can help prevent serious sequelae of chronic liver disease and complement strategies to reduce HCV transmission. Safe and effective antiviral agents are now available to treat chronic hepatitis C, approximately 90%-100% chronic hepatitis C individuals can be expected to respond to treatment, if they are identified before they progress to advanced stages.[74-79] Early identification of these individuals can also aid in primary prevention of ongoing HCV transmission by enabling persons with chronic infection to adopt behaviors that reduce the risk of transmission to others and allow for early identification of close contacts who require testing. Therefore, it might be imperative to identify this population who might benefit from early medical evaluation, management, and antiviral therapy when indicated.

Pharmacotherapy

Pharmacotherapeutic approach for chronic hepatits C started with the use of pegylated interferon (PegIFN) and ribavarin[80] which now have been revolutionized with the approval of newer directly acting anti-viral drugs (DAAs) such as simeprevir, sofosbuvir, ledipasvir, and daclatasvir from 2013 to 2015.[81-84] Among these drugs sofosbuvir, a direct acting pyrimidine nucleotide analog has shown higher success rate with potent antiviral activity, favorable pharmacokinetic profile, limited drug interaction, excellent tolerability and high genetic barrier against all HCV genotype in combinations.[85] Table 3 represents sofosbuvir based regimens for treating various genotypes.[75, 86-94]

a behavior change intervention– for prescribers to convince the patients not to systematically prefer injectable medications which has been successful in reducing injection use and reuse in Indonesia, Pakistan and India.[96-98] Further, India took a giant leap towards promoting safe injection practices once the injection problem was recognized at a high political level.[99] The Indian Medical Association (IMA) and the Indian Academy of Pediatrics (IAP) issued injection safety policies and endorsed the use of safe injections in 2004.[100] Andhra Pradesh state IMA started a Program for Appropriate Technologies in Health (PATH) to educate members about injection safety and safe administration in medical practice.[101] In addition to this, policies related to promotion and introduction of re-use- prevention (RUP) injection devices, rational prescription guidelines, training of healthcare work force, and economic incentive for reuse prevention and sharp injury prevention devices may aid in avoiding injections and their reuse.[95] The Indian government decided to switch to Autodisable (AD) syringes that prevent reuse.[95]

Patient Support Program

Management of hepatitis C in India is challenging in several way. Firstly, the varied distribution of genotype across country makes it difficult to correctly diagnose the genotype and treat accordingly. It is also important to note that, in India only 24% of the population is covered by some form of health insurance either through government sponsored schemes or private health insurance.[102] Majority of the population therefore, has no access to any form of health security, leading to a significant out-of-pocket spending on health. However, the reduced cost of newer treatments in India compared to other countries is expected to increase accessibility and affordability

Table 3 Sofosbuvir based regimens for various genotypes

Study Author	Regimen	Duration	Patient Type	Overall Observed Sustained Virologic Response 12
Genotype 1				
Afdhal N, *et al*[86,87]	Sofosbuvir + Ledipasvir	12 weeks	Treatment Naïve & Non-cirrhotic	100%
		12 weeks	Treatment Naïve & cirrhotic	97%
Afdhal N, *et al*[88]	Sofosbuvir + Ledipasvir	12 weeks	Treatment experienced &Non-cirrhotic	95%
		24 weeks	Treatment experienced & cirrhotic	99%
Kowdley KV, *et al*[89]	Sofosbuvir + Ledipasvir	12 weeks	Treatment Naïve & Non-cirrhotic	95%
Mizokami M, *et al*[90,91]	Sofosbuvir + Ledipasvir	12 weeks	Treatment Naïve & Non-cirrhotic	100%
		12 weeks	Treatment Naïve & cirrhotic	100%
		12 weeks	Treatment experienced & Non-cirrhotic	100%
Genotype 2				
Lawitz E, *et al*[75]	Sofosbuvir and Ribavirin	12 weeks	-	97%
Zeuzem S, *et al*[92]	Sofosbuvir and Ribavirin	12 weeks	-	93%
Jacobson IM, *et al*[93]	Sofosbuvir and Ribavirin	12 weeks	-	93%
Jacobson IM, *et al*[93]	Sofosbuvir and Ribavirin	12 weeks	-	86%
Genotype 3				
Nelson DR, *et al*[94]	Sofosbuvir + Daclatasvir	12 weeks	Without cirrhosis	96%
Genotype 4				
Lawitz E, *et al*[75]	Sofosbuvir + peginterferon alfa and ribavirin	12 weeks	-	96%

Safe Injection Practices

Healthcare injection use has been observed to be very common across South Asia, with cross-country rates ranging from 2.4 to 13.6 injections /person/year and that 5% to 50% of these injections are provided with reused syringes.[95] Thus adopting safe injection practices to prevent transmission of HCV is essential. Multilevel interventions aiming at patients, providers and the healthcare system are needed to reduce injection use and reuse. Interactional Group Discussion (IGD) has proposed

In addition, patient support programs and schemes become crucial to curb out-of-pocket spending for a better health. Several initiatives that can aid to prevent out-of-pocket spending include access to free medicines in welfare schemes. Certain schemes at national and state level also allow people living with HCV-related liver disease (PLHCV) to access HCV related treatment services either at subsidized rate or free of cost.[102] Table 4 enlists such schemes introduced by Indian government to support patients for HCV treatment.[102]Such

patient support programs will aid in providing cost-effective/affordable HCV intervention to HCV patients belonging to low socio-economic strata.

Table 4 Schemes to support HCV patients in India[102]

State	Scheme	Patient Criteria
Tamil Nadu and Rajasthan	Provides medicines listed under State's Essential Medicines List (EML) free of cost	Who access treatment at public hospitals
Punjab	Free treatment under MukhMantri Punjab Hepatitis C Relief Fund considering high prevalence	For HCV residents of the state
Tamil Nadu and Manipur	Tamil Nadu Chief Minister's Comprehensive Health Insurance Scheme and Manipur State Illness Assistance Funds- reimbursement of treatment and hospitalization cost	To below poverty line people
Haryana	Provides free diagnostics and treatment	To schedule caste and below poverty line families
Mizoram	Mizoram Health Care scheme-government has now included sofosbuvir in the list of reimbursable medicines	-
-	Central Government Health Scheme (CGHS) and Employees State Insurance Scheme (ESIS) scheme availing reimbursement of HCV-related treatment expenses	Government employees linked to public undertakings, railways and state governments

Lastly, several barriers which exist in eradication of HCV include:- lack of screening and confirmatory testing, lack of specialist/referral availability, high DAA cost, treatment efficacy-low efficacy of IFN-based regimens, lack of vaccine and finally chances of reinfection.[103] It has been estimated that 30%–50% of anti-HCV-positive persons never receive confirmatory HCV RNA testing.[104] For referral only one-half of HCV-infected patients were referred to a specialist for evaluation and management.[105] It has been estimated that 80% of chronic HCV patients are managed by 20% of gastroenterologists[106] focusing on the less availability of the physicians. Further, challenges in disease related communication between HCV-infected patients and their physicians acts as another barrier in eradicating HCV. In a cross-sectional study at a tertiary care centre, 41% patients reported communication difficulties. [107] This highlights the importance of need for physicians to give more time to address patient needs.

In conclusion, lack of hepatitis C screening among high risk population has raised interest and concern for the transmission of hepatitis C infection. There is an urgent need to raise awareness and educate people to screen for hepatitis C infection. Though recent advances in HCV treatment offer the potential for high cure rates and shorter treatment duration, widespread of HCV infection can be identified and limited through screening and diagnosis of high risk population. Poor awareness, exaggerated fears, lack of specialist and vaccine all contribute to strikingly low treatment rates. Recognizing the burden of HCV infection, there is a critical need to identify and screen high risk population with linkage to care and access to treatment which has potential to substantially reduce transmission of HCV and eventually morbidity and mortality.

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