

## Jeevan Rekha: Counter for Hepatitis C in Haryana

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### Abstract

**Aims and Objectives:** To Study the effectivity of state sponsored scheme i.e. Jeevan Rekha in combating the menace of chronic hepatitis C in haryana.

**Introduction:** Hepatitis C is a contagious liver disease that results from infection with the hepatitis C virus. Progression from acute to chronic HCV infection occurs in 50% to 85% of cases. Hepatitis C virus (HCV) is a major cause of liver disease worldwide and a potential cause of substantial morbidity and mortality in the future.

**Materials and Methods:** The patients who were found to be having anti-HCV positive, during evaluation at screening camps, blood donation camps, Pre-anesthetic checkup for various surgeries or incidental detection and subsequently confirmed on HCV RNA quantitative and genotyping were treated with Pegylated Interferon and Ribavirin and followed serially with viral loads at repeatedly intervals, till they reached stage of sustained virological response.

**Results:** Majority of the subjects were male and belonged to younger age group. Genotype 3 was most common, followed by 4 and 1. The compliance rate was excellent i.e.93%. The overall sustained virological response was very high i.e.90%.

**Keywords:** Hepatitis C virus; Sustained virological response; Compliance rate; Genotype

**Abbreviations:** HCV: Hepatitis C Virus; BPL: Below Poverty Line; SC: Scheduled Caste; PGIMS: Post Graduate Institute of Medical Sciences; SVR: Sustained Virological Response

### Introduction

Hepatitis C is a contagious liver disease that results from infection with the hepatitis C virus (HCV). Progression from acute to chronic HCV infection occurs in 50% to 85% of cases. Left untreated, the complications associated with chronic infection are severe. Chronic HCV infection may lead to cirrhosis and subsequently hepatic decompensation, hepatocellular carcinoma and death [1].

In India, the overall prevalence of HCV infection is 1.5% with the North and the North-Eastern parts of the country particularly affected [2-6]. Unsterile therapeutic injections and health care procedures, injection drug use and blood transfusions are the most common routes for HCV transmission [7,8]. Recognizing the need to address this disease, the Government of Haryana developed a first-of- its kind program to provide free Hepatitis C treatment for individuals belonging to Below Poverty Line (BPL)

and Scheduled Caste (SC) categories.

In November 2013, the department of medical gastroenterology at Post Graduate Institute of Medical sciences (PGIMS) Rohtak was identified as the main treatment center in the State. Anti-hepatitis C virus antibody positive patients were referred for confirmatory testing and treatment in Rohtak at PGIMS.

### Patient Enrollment

Patients who were found to be having anti-HCV positive, during evaluation at screening camps, blood donation camps, Pre-anesthetic checkup for various surgeries or incidental detection and subsequently confirmed on HCV RNA quantitative and genotyping were enrolled under this scheme. Every patient underwent detailed clinical examination as well as complete biochemical and ultra-sonogram abdomen testing. On average, 55 patients are enrolled in the program each month (Table 1).

**Table 1:** Summary of patient enrollment in Program.

Enrollment	n
Total patients enrolled	1530
Average monthly enrolment	55

Patients were required to submit documentation that verified their eligibility for program enrollment. Documents include BPL/ SC identification, a baseline HCV RNA report and written consent was taken from patients (Table 2).

**Table 2:** Documentation provided prior to program enrollment.

Document type	No. of documents uploaded	% of enrolled patients
BPL/ SC identification	1530	100%
Baseline HCV RNA report	1530	100%
Prescription for Pegylated Interferon	1530	100%
Program registration	1530	100%
Informed consent	1530	100%

### Patient characteristics

Table 3 and 4 show the age and gender distribution of patients enrolled in the Program. The mean age of enrollees is 36 years; close to two-thirds (60%) are between the ages of 21-40 years. 58% of enrollees are men, while 42% are women.

**Table 3:** Distribution of age among enrolled patients.

Age	n	%
All ages	1530	100
0 - 9 years	2	0.1
10-20 years	40	2.61
21-30 years	496	32.42
31-40 years	428	27.97
41-50 years	322	21.05
51-60 years	126	8.24
61-70 years	108	7.06
71-80 years	8	0.52
81+ years	0	0.00
Mean age (years)	36	NA

NA=Not applicable

**Table 6:** Provision of coupons for on-therapy HCV RNA testing.

Type of test	No. of patients requiring test*	No. of coupons provided	% patients provided coupon
4th week HCV RNA	1530	1528	99.86%
12th week HCV RNA	1530	1493	97.58%
End of therapy (at 24 or 48 weeks)	1530	1423	93%
Sustained Virological Response (SVR)	1423	1280	90%

**Table 4:** Distribution of gender among enrolled patients.

Gender	n	%
Male	888	58.04
Female	642	41.96
Total	1530	100

HCV genotype is an important factor in determining treatment duration. Patients with Genotype 3 were treated for 24 weeks, while patients with Genotypes 1,4, 5, 6 were treated for 48 weeks. It has previously been established that Genotype 3 is most prevalent in India, followed by genotype 1 and then genotypes 2, 4, 5 and 6 [9]. In Haryana too, the majority of patients enrolled in the Program were found to have HCV Genotype 3 (58%), followed by Genotype 4 (25%). The genotype could not be determined for 56 patients (3.66%) because of low viral load (Table 5).

**Table 5:** Distribution of genotype among enrolled patients.

Genotype	n	%
1	206	13.46
2	0	0.00
3	884	57.78
4	376	24.58
5	4	0.26
6	2	0.13
Not defined	58	3.79
Total	1530	100

### On-therapy diagnostic testing

During the course of treatment, the viral load of patients is tested at specific time points to assess responsiveness to therapy and likelihood of achieving a virological cure.

- After 4th week injection
- After 12th week injection
- End of Therapy (after 24th or 48th week injection)
- Sustained Virological Response (24 weeks after End of Therapy)

**Table 7:** Diagnostic reports and results received.

Type of report	No. of patients supposed to be receive coupon	No. of reports received	% of reports received	% patients negative on HCV RNA report
4th week HCV RNA	1530	1528	99.86%	90%
12th week HCV RNA	1528	1493	97.70%	92%
End of therapy (24/48 weeks)	1493	1423	95.31%	91%
Sustained Virological Response (SVR)	1423	1423	100%	90%

Table 6 shows the test status of all patients enrolled in the program. Table 7 shows that the Program received almost all diagnostic reports for patients who were provided on-therapy HCV RNA coupons. All reports were validated and uploaded to the online system (100%).

The viral load of positive patients is also entered into the online system to facilitate monitoring of treatment response. Table 7 shows that 90% of patients achieved a Rapid Virological Response; that is, their 4<sup>th</sup> week HCV RNA test was negative. Similarly, 92%, 91% and 90% of patients respectively achieved an Early Virological Response, End of Therapy stained virological response respectively. That is, the HCV RNA test for these patients was negative at 12 weeks, 24/ 48 weeks and after six months of completion of treatment respectively. On analysis of SVR in different genotypes, 91.5% was seen in Genotype 3, 87% in Genotype 4, 87.5% in genotype 1, 100% in patients with undetermined genotype due to low viral load and in six patients belonging to genotype 5 & 6. Thus making overall 90% SVR in the treated patients.

### Patient counseling

Counseling services significantly increased the likelihood that patients adhere to the prescribed therapy schedule. Program patients were counseled at enrollment on several topics including the disease and its symptoms, modes of transmission, treatment, length of treatment, diagnostic testing schedule, typical side effects and side effect management. Table 8 shows that all patients received counseling at the time of enrollment.

**Table 8:** Patients provided counseling at enrollment.

Counseling	n	%
Provided	1530	100%
Not provided	-	-
Total	1530	100%

### Therapy completion

The online system enabled the progress and adherence of patients to be tracked from enrollment to therapy completion. Based on the date when therapy was first initiated, the online system projected a weekly dosing schedule across the entire treatment period (24 or 48 weeks) for each patient. The therapy status of each patient was tracked on regular basis.

### Therapy adherence

In order to be considered adherent, patients must follow their weekly schedule and complete therapy within the designated treatment period (Table 9).

**Table 9:** Adherence to therapy schedule.

Therapy adherence	n	%
Total enrolled patients	1530	100%
Total adherent among all enrolled patients	1423	93%
Total non-adherent among all enrolled patients	107	7%

### Summary

Haryana is the first State in India to develop a comprehensive program to address Chronic Hepatitis C. 1530 patients from BPL/SC categories received free treatment for Chronic Hepatitis C and were enrolled in an integrated disease management program that provided counseling and on-therapy diagnostic testing. An online system was also developed to enable efficient capture and tracking of patient information. The Program has been successful on several fronts. Documentation of patient eligibility, provision of coupons for diagnostic testing, and report validation and upload were conducted in compliance with Program guidelines. Through counseling and monitoring, a high percentage of patients (93%) have adhered to their prescribed treatment regimen. Patient outcomes have also been extremely encouraging i.e. SVR of 90%. In India, the overall prevalence of HCV infection is 1.5% with the North and the North-Eastern parts of the country particularly affected. The Jeevan Rekha project at Department of Medical Gastroenterology at PGIMS Rohtak can serve as a model for the rest of the Nation (Figure 1).



**Figure 1:** Jeevan Rekha: Counter for Hepatitis C in Haryana.

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