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Outcome of Hepatitis C Patients Treated with Sofosbuvir/Daclatasvir in the Hepatitis Clinic at Georgetown Public Hospital Corporation September 2022 - September 2023

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Abstract

Introduction: *Before July 2022 hepatitis C treatment was not available in Guyana. On July 28th, 2022, the Ministry of Health of Guyana in collaboration with PAHO launched Guyana's National Hepatitis C program, a pioneer health project to treat patients affected with Hepatitis C free of cost with direct acting anti-viral agents.*

Study Goals and Objectives: *To determine the demographics of patients infected with hepatitis C enrolled in the clinic and their response to treatment using direct-acting antiviral agents.*

Methodology: *This will be a retrospective chart review of all patients enrolled in the hepatitis C clinic during the study period. Relevant data needed to complete the research were extracted from patients' charts, entered into a specially designed, protected Microsoft Office Excel spreadsheet, and analyzed to meet the objectives outlined above.*

Results: *Forty-eight patients had a positive Hepatitis C antibody and viral load, 58% being males and 42% being females with a mean age of 52.8. Geographically, 37.6% of the patients were from region 2, while 37.5% from region 4. Treatment was initiated on forty-two patients. Twenty-nine patients completed treatment at the end of the study period, 11 were still on treatment while two defaulted. Twenty patients who completed treatment had a sustained virologic response 12 weeks after completing treatment, representing 83% sustained virologic response.*

Conclusion: *It can be concluded that the treatment regimen is effective at treating chronic HCV. This research serves to provide data for prospective studies on HCV in Guyana and the Caribbean.*

Keywords: Hepatitis C, Sustained Virological Response, Direct-Acting Antivirals.

List of Abbreviations

CKD :Chronic Kidney Disease
DAA :Direct acting antivirals
DM :Diabetes Mellitus
GPHC :Georgetown Public Hospital Corporation
HBV :Hepatitis B Virus
HCV :Hepatitis C virus
HIV :Human Immunodeficiency Virus
NCTC :National Care and Treatment Centre
PAHO :Pan American Health Organization
PCR :Polymerase Chain Reaction
RNA :Ribonucleic acid
SVR :Sustained virological response
WHO :World Health Organization

Introduction

As per the World Health Organization, Hepatitis C is defined as inflammation of the liver that occurs as a consequence of infection with the hepatitis C virus. This virus can cause both acute and chronic hepatitis which can range from a mild illness with the possibility of progression to end-stage liver disease as well as hepatocellular carcinoma.

In Guyana, there have been cases of hepatitis C found incidentally through patient screening and contact with physicians, as well as through blood drives where donors are screened for the virus. Access to treatment was either not readily available or unaffordable for these patients, nor was there any epidemiological data available regarding the condition's prevalence in Guyana.

On July 28th, 2022, which was also world hepatitis day, it was announced that the Ministry of Health of Guyana partnered with the Pan American Health Organization (PAHO) to provide treatment to patients affected with Hepatitis C free of cost with a direct-acting anti-viral agent (sofosbuvir and daclatasvir) for the first time in this country [1].

This research will identify demographic data of the patients affected by hepatitis C in Guyana as well as highlight the effectiveness of the treatment regimen in attaining a sustained virological cure in patients affected and treated for hepatitis C. Guyana is also the first country in the Caribbean to offer this treatment free of cost or in public health facilities for patients infected with hepatitis C. This research can be used as a model for implementation throughout the Caribbean in countries with limited resources to aid in Hepatitis C eradication.

Literature Review

Hepatitis C (HCV) was first discovered and diagnosed in 1989 and has since been a major public health problem estimated to be affecting approximately fifty million people worldwide as per the World Health Organization (WHO) 2024 Global Hepatitis Report. According to the report, there were 1.3 million deaths from viral hepatitis in 2022, of which hepatitis C caused 244,000 deaths. High-impact interventions are available, such as an effective cure for hepatitis C, but access to these interventions must be urgently expanded to save lives as the implications of being affected chronically with hepatitis C (60-80%) include portal hypertension, cirrhosis, hepatic encephalopathy, and cancer [2].

No studies have been done in Guyana to identify the incidence of Hepatitis C however according to a registry there may be approximately two hundred (200) cases known to be Hepatitis C antibody positive as per our National Blood Bank registry. However, according to the World Health Organization Global Health Observatory, the number of persons living with chronic hepatitis C in Guyana as of 2022 was 4979 [3]. It was also noted with a high prevalence in eastern Caribbean countries such as Mexico with especially among intravenous drug users [4].

HCV is a member of the Flavivirus family and is an enveloped, spherical, positive-strand ribonucleic acid (RNA) virus that is approximately 55 nm in diameter [5]. It is mainly transmitted through percutaneous exposure to infected blood. Other modes of transmission include vertical transmission or mother-to-infant and contaminated devices shared for noninjecting drug use. It is more common among injection drug users in Europe. Sexual transmission also occurs but is generally inefficient except among HIV-infected men who have unprotected sex with men [6].

The natural progression of the virus varies among individuals but usually, it is detectable in plasma within days of exposure, often 1 to 4 weeks but peaks in the first 8 to 12 weeks of infection, and then plateaus or drops to undetectable levels (viral clearance. This leads to spontaneous resolution in some patients however in the majority, 50% to 85% it persists. When a chronic infection is established, the inflammatory response to the infection leads to fibrogenesis. Other risk factors that lead to acceleration of the established fibrosis include alcohol consumption, HIV/HBV coinfections, Genotype 3 infection, insulin resistance, obesity, and nonalcoholic fatty liver disease. The severity of liver fibrosis tightly correlates with the increased risk of hepatocellular carcinoma [7].

Treatment is not based on just a positive hepatitis C antibody test because a positive HCV antibody test can indicate a current (active) HCV infection (acute or chronic); a past infection that has resolved; or a rare false positive. Therefore, before initiating treatment, testing to detect HCV viremia is required to confirm active HCV infection and guide clinical management. This is done through HCV-RNA PCR testing [8].

The breakthrough in the discovery of safe, well-tolerated, and highly efficacious (>95% cure rate) direct-acting antiviral (DAA) therapy for HCV infection has ushered in an era in which elimination of hepatitis C is conceivable. In 2016, the World Health Organization (WHO) proposed a global health sector strategy to eliminate hepatitis C as a public health threat by 2030 and developed an action plan to facilitate this goal [9, 10].

The main goal of HCV therapy is sustained virologic response (SVR) or virologic cure which is the continued absence of detectable HCV RNA for at least 12 weeks after completion of therapy. This also reduces symptoms and mortality from severe extrahepatic manifestations, including cryoglobulinemic vasculitis, a condition affecting 10% to 15% of HCV-infected patients. Patients who achieve SVR have a substantially improved quality of life, including physical, emotional, and social health [11].

For the clinic in Guyana, the drug that has been procured is the sofosbuvir and daclatasvir combination. Sofosbuvir has activity against all HCV genotypes while daclatasvir is also pan genotypic. Results from clinical studies as well as preliminary real-life data regarding this combination have shown that with once-daily oral dosing, a low pill burden, good tolerability, and limited drug–drug interaction, it is becoming one of the most promising combinations to treat hepatitis C. This combination also has high pan-genotypic antiviral potency regardless of the severity and patient characteristics [12-14].

Butt N. et al conducted a prospective study from January 2017 to December 2018 in Karachi, Pakistan where the effectiveness of Sofosbuvir and Daclatasvir was assessed in patients with chronic hepatitis C, compensated cirrhosis, and decompensated cirrhosis. Three hundred (300) eligible patients were enrolled in the study with an achievement of sustained virological response was achieved in 88.3% of the patients treated [15].

Ali et al also conducted a similar study using the same regimen in Egypt in 2020 with an achievement of more than ninety-six (96%) sustained virological response. This study also monitored the viral load routinely after each month of treatment and showed a reduction of more than sixty five percent (65%) starting at week four (4) of treatment [16].

Study goal and Objectives

The overarching goal of this study research is to assess the efficacy related to treatment outcomes of the newly implemented treatment protocol introduced for treating Hepatitis C at the National Care and Treatment Centre within GPHC. This will be achieved through the following objectives:

- To determine the demographical profile of patients infected with hepatitis C enrolled at the Hepatitis treatment clinic.
- To assess the medical treatment outcome of the patients enrolled who were treated according to the newly implemented guideline.

Study Design
This is a retrospective cohort study where hepatitis C patients' charts were reviewed.

Study Setting
The study was conducted using patients enrolled at the Hepatitis C clinic which is located in the National Care and Treatment Centre at Thomas Street, the main care and treatment site for HIV. The hepatitis C clinic was established at the beginning of August 2022 within the NCTC and caters to patients who tested positive for hepatitis C antibodies.

On the initial visit to the hepatitis C clinic a, detailed history, physical exam, baseline labs and HCV viral load are conducted. Patients who had a positive HCV viral RNA test done are counselled and start treatment for 12 - 24 weeks depending on the stage of their disease as evidenced by the APRI score or clinical stigmata of cirrhosis with the regimen of sofosbuvir (400mg) and daclatasavir (60mg).

Patients were routinely monitored during the treatment regimen for side effects and any difficulties with adherence etc. Repeat viral loads were done twelve (12) weeks from the completed date of treatment to determine sustained virological response to assess means of treatment success or failure.

Study Population
The targeted population for this study was all patients enrolled (registered on treatment) in the hepatitis C clinic at NCTC.

Sample Size and Eligibility Criteria
The entire enrollment list of patients registered in the period September 2022 to September 2023 were eligible to be reviewed.

Inclusion Criteria
- All patients registered including children with confirmed hepatitis C antibody and positive HCV viral RNA test requiring treatment (>10,000 copies) results were analyzed.

Exclusion Criteria
- Any patient who tested positive for the hepatitis C antibody but negative viral load and did not receive the algorithmic treatment was not analyzed.

Methodology

Data Collection Procedure
All charts for patients enrolled in the Hepatitis Clinic for the period of September 2022-September 2023 were reviewed by the researcher. A template for data collection was used (See Appendix 1) which captured all required fields in the study. No names were collected in this study but each patient's chart according to a registration number was entered numerically, directly into an Excel data set in keeping with the template. The chart was perused for demographic, laboratory and treatment data.

Data Management and analysis
All data collected were stored on the researcher's personal laptop, which is password-protected, and backed up. Only the researcher had access to the data sets. The final data set was shared with the custodian of the records at the hepatitis C clinic after study analysis to improve data storage and records.

The data was analyzed using SPSS version 22 where both descriptive analysis (especially of the demographical make-up of the study population) and inferential statistics were conducted including the level of association with treatment success and receiving treatment.

Quality Assurance
All data was abstracted on the grounds of the hepatitis C clinic during clinic working hours. Patient chart records with missing information were left blank, leaving no room for the assumption of any data fields. A check was done for any outliers, and none was found.

Ethical Considerations

The research was conducted with approval from the Internal Review Board of the Ministry of Health, and further approval from the review committee of the Georgetown Public Hospital Corporation (GPHC).

Patient confidentiality was the pinnacle; hence the research was done with no patient name extracted. This research maintained its ethics of ensuring no patient nor staff were inconvenienced or harmed during the process. It also ensures that the beneficence factor extends beyond local patients but intends to publish results that will add knowledge of the treatment for Hepatitis C in Guyana.

Data Results & Analysis
A total of 74 patients with hepatitis C positive antibody tests were enrolled in the hepatitis C clinic at the National Care and Treatment Centre from September 2022 to September 2023 (n=74).

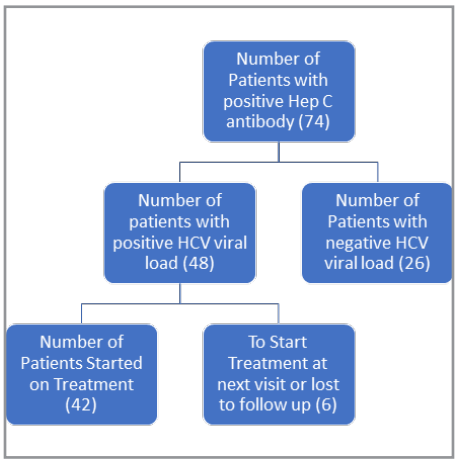

Figure 1: Flow Chart Depicting the Number of Patients Enrolled in the Hepatitis C Clinic During the Study Period and the Number of Patients Who Had a Positive or Negative HCV Viral Load. It also Depicts the Number of Patients Who Commenced Treatment for Hepatitis Among those with a Positive Hepatitis C Viral Load.

As per the inclusion criteria stated earlier in the manuscript, the data analysis and presentation will only include the forty-eight (48) patients who had a positive antibody and a positive viral load for HCV.

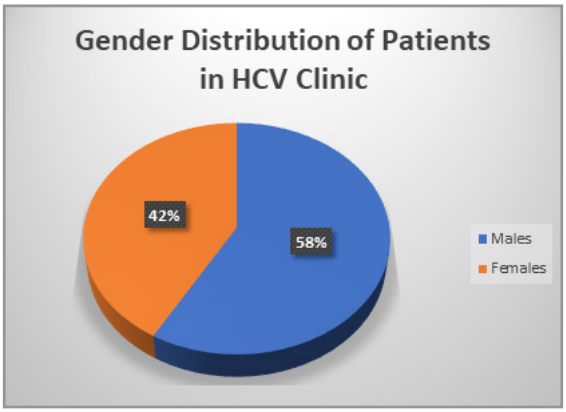

Figure 2: Showing a Pie-Chart Demonstrating the Gender Distribution of Patients Enrolled in the Clinic.

Of the total number of patients analyzed in this study (48) as represented in Figure 2, twenty-eight (28) were males representing a percentage of fifty-eight (58%) twenty (20) were females representing a percentage of forty-two (42%).

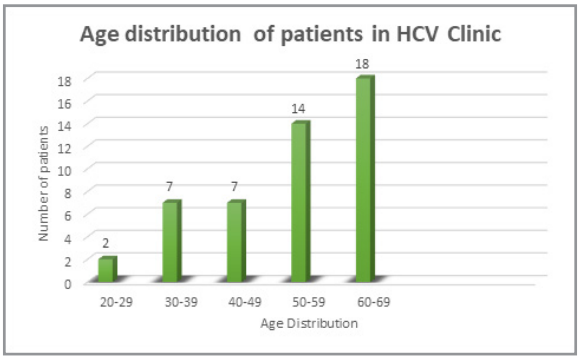

Figure 3: A Bar Graph Showing the Age Ranges of Patients Enrolled in the Clinic.

Figure three above demonstrates the age ranges of patients enrolled in the clinic. The ages ranged from the youngest patient at twenty-six years old to the oldest patient being sixty-nine years old. The majority (66.7%) were within the age range of 50-69 years old. The median age calculated was 52.8 years old with a standard deviation of 11.6.

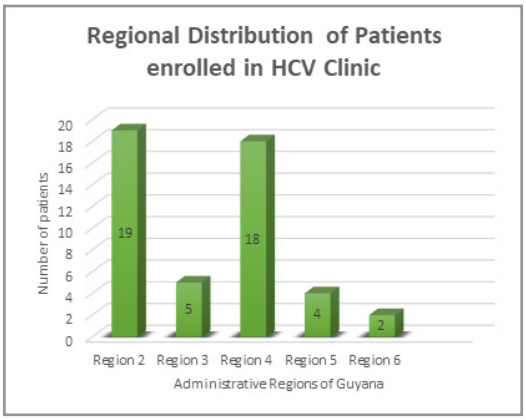

Figure 4: Bar Graph Showing the Administrative Region of the Patients Enrolled in the Clinic.

From the above graph, it can be observed that 39.6% of the patients enrolled in the clinic were from region 2 which is the Essequibo area of Guyana, while 37.5% were from region four. There were also small numbers from regions 3, 5 and 6 respectively as displayed on the above graph.

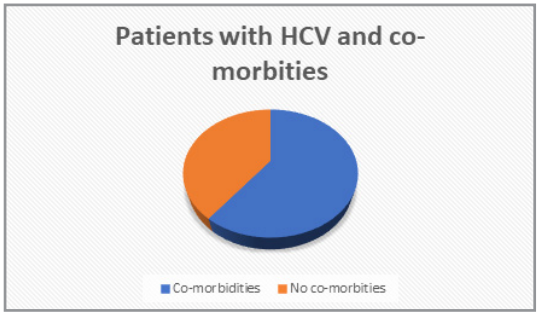

Figure 5: Pie chart Showing Patients Enrolled in the Clinic with or Without Comorbidities.

Patients who had co-morbidities represented 60% of the patients enrolled in the clinic along with hepatitis C These most common co-morbidities included chronic diseases such as Diabetes Mellitus, Hypertension, Hyperlipidemia and Human Immunodeficiency Virus (HIV). The co-infected population with HCV and HIV was 18.75%. Two of the patients also had a heart block and a mitral valve prolapse respectively. Of the total number of patients enrolled in the clinic with a positive hepatitis C antibody test (74), 64.9% (48) tested positive for a hepatitis C viral load greater than 10,000 viral copies.

Treatment was initiated on forty-two (42) of the forty-eight (48) patients with a positive Hepatitis C viral load representing 87.5% of that population. Treatment was initiated with a sofosbuvir/daclatasvir combination (400mg/60mg). The remaining six (6) patients who tested positive will be initiated on treatment at the next clinic visit which was out of the study period for this research with 2 being lost to follow up.

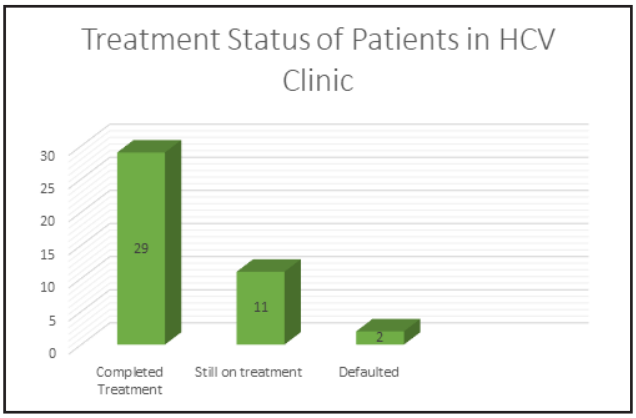

Figure 6: Showing a Bar Graph Depicting the Patients Who Have Completed Treatment, are Still on Treatment, and Lost to Follow-Up/Defaulted.

Twenty-nine (29) of the forty-two patients that started treatment for hepatitis C, completed treatment at the end of the study period representing 69% of the patients. Eleven patients or 26% are currently still on treatment while two patients were lost to follow-up despite numerous efforts to contact the patient via telephone.

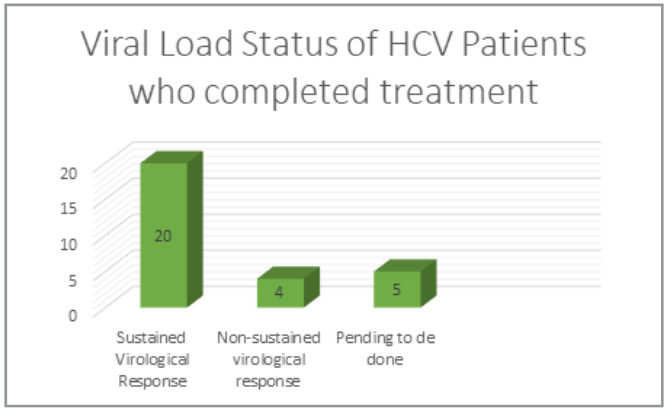

Figure 7: Shows the Status of the Viral Load for Patients Who Have Completed Treatment.

As represented on the graph twenty (20) of the twenty-nine patients who completed treatment had a sustained virologic response 12 weeks after the treatment would have been completed. Five patients are pending to be done at the end of this research study period. This represents 83% sustained virologic response of the twenty-four patients that completed treatment and had post viral load testing done while 17% still had a positive viral load for reasons that will have to be explored.

Discussion

Hepatitis C poses a global health challenge, even more so prevalent in the Caribbean and Guyana. This is mainly due to the lack of screening protocols, knowledge provided to these populations, and resources available to treat the disease. In Guyana, most of the cases were detected coincidentally mainly through blood donation drives and the screening protocols within that process. Due to the Ministry of Health of Guyana's collaboration with the Pan American Health Organization (PAHO), Guyana is the first country within the Caribbean to offer treatment of hepatitis C with direct-acting antiviral agents free of cost to the general public.

Hepatitis C as depicted in Figure 3 in the data analysis section has no age barrier. It affects all ages with the eldest patient enrolled in the clinic at 69 years old while the youngest being 26 years old with a mean age of 52.8 years old. This is in keeping with other countries in the region where the most predominantly affected age group is older than 50 years old. No universal screening protocol for Hepatitis C exists in Guyana therefore the true prevalence of the disease remains unknown. It can also be noted that it can affect both males and females as depicted in figure 2.

One of the important areas highlighted in figure 4 represents the regional distribution of the patients affected with Hepatitis C. Even though the clinic is primarily located in region four (4), the majority of the enrolled patients are from region two with a few from region five and six. This highlights the need for the establishment of satellite clinics in these areas with resources available to screen patients for this disease now with the ability of a sustained virological response treatment modality available in the public health sector.

All patients enrolled in the clinic had a positive Hepatitis C antibody test. The HCV RNA levels were further tested for these patients and those with levels >10,000 viral copies (Fig 1) were then started on the treatment protocol of sofusbovir (400mg) and daclatasvir (60mg) once daily for twelve weeks and monitored for side effects. Forty-two patients of the forty-eight patients that met this criterion were commenced on treatment with the remaining six to be commenced at the next clinic visit which was beyond the study period of this research representing 87.5% of that population.

At the end of the study period, twenty-nine patients had completed treatment. The remaining eleven were still on the treatment regimen. Of the twenty-nine, twenty-four were retested to determine sustained virological response while the other five were waiting for the timeframe to re-test. Eighty Three percent (83%) of the patients had a sustained virological response twelve weeks after the last treatment date which is in keeping with prior studies done in Pakistan and Egypt quoted above in the literature review.

Four patients did not have sustained virological response. Reasons for these are currently being investigated as they relate to compliance or a need for genotypic testing to determine if the subtype of hepatitis C virus these patients have may not have responded to the available direct-acting antiviral agent used in this research. There is also consideration based on the clinical presentation of the patient for a longer treatment course. Future research to also consider the patient's clinical characteristics before treatment initiation.

Even though the sample size was small, this study demonstrated the effectiveness of the direct acting anti-viral agent sofosbuvir/daclatasvir in treating hepatitis C patients by the high percentage of sustained virological response and tolerability of the regimen to patients. This will serve as a foundation to implement this clinic to satellite areas, improved screening to detect undiagnosed cases with a bride to treatment and potential cure to improve the quality of life of patients affected with hepatitis C not only in Guyana but throughout the Caribbean.

Limitations and Key Findings

1. Compliance with treatment is a difficulty encountered in this study. Patients were prescribed the appropriate treatment regimen and sent home to self-administer. Even though regular follow-up appointments were made with patients there was no way to prove the drug was administered as instructed especially for the treatment failure patients.
2. One limitation faced is the sample size used in this study does not represent all cases of HCV in Guyana, this is because of the lack of screening and treatment centers in far

reached communities and the lack of knowledge provided to the entire population of the country on risk factors and importance of screening.

3. Availability of re-agents to do viral load testing to initiate treatment as well as determine success of treatment which also could have increased the sample size and power of the study.

Conclusion

Forty-eight (48) patients were included in this retrospective study to determine the Outcome of hepatitis C patients treated with sofosbuvir/daclatasvir in the Hepatitis Clinic at Georgetown Public Hospital Corporation September 2022 - September 2023. Forty-two (42) of these patients had a positive HCV RNA viral load of more than 10,000 copies and were started on treatment with sofosbuvir/daclatasvir for 12 weeks. At the end of the study period, twenty-four patients completed treatment with 83% of those patients achieving a sustained virological response.

It can be concluded that the treatment regimen is effective at treating chronic HCV and therefore should become more available to outlying communities along with establishing more screening and treatment centers throughout the various administrative regions of Guyana. This research serves to provide data to prospective studies on HCV in Guyana and the Caribbean and to aid in the design of screening strategies to be integrated into primary health care.

Definition of Terms

Sustained Virological Response: the hepatitis C virus is not detected in the blood after more than or equal to twelve weeks after completing the treatment regimen.

Completed Treatment: refers to patients who would have completed twelve weeks of treatment using the direct acting antiviral agents available for hepatitis C. N.B. There are other regimens such as 24 weeks for cirrhotic patients. Non-Sofosbuvir/Daclatasvir regimens also have different duration.

Positive HCV viral load test: refers to patients who would have had a positive serum hepatitis antibody test and who also has a high viral load representing infectivity.

Treatment Success: refers to patients with a sustained virological response after completing hepatitis C treatment.

Treatment Failure: refers to patient with a sustained or high positive HCV viral load test twelve weeks or more after completing hepatitis C treatment.

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