Treatment Naïve and Treatment Experienced

Liver Transplantation

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

Curry MP, et al. Gastroenterology. 2015;148:100-7.

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

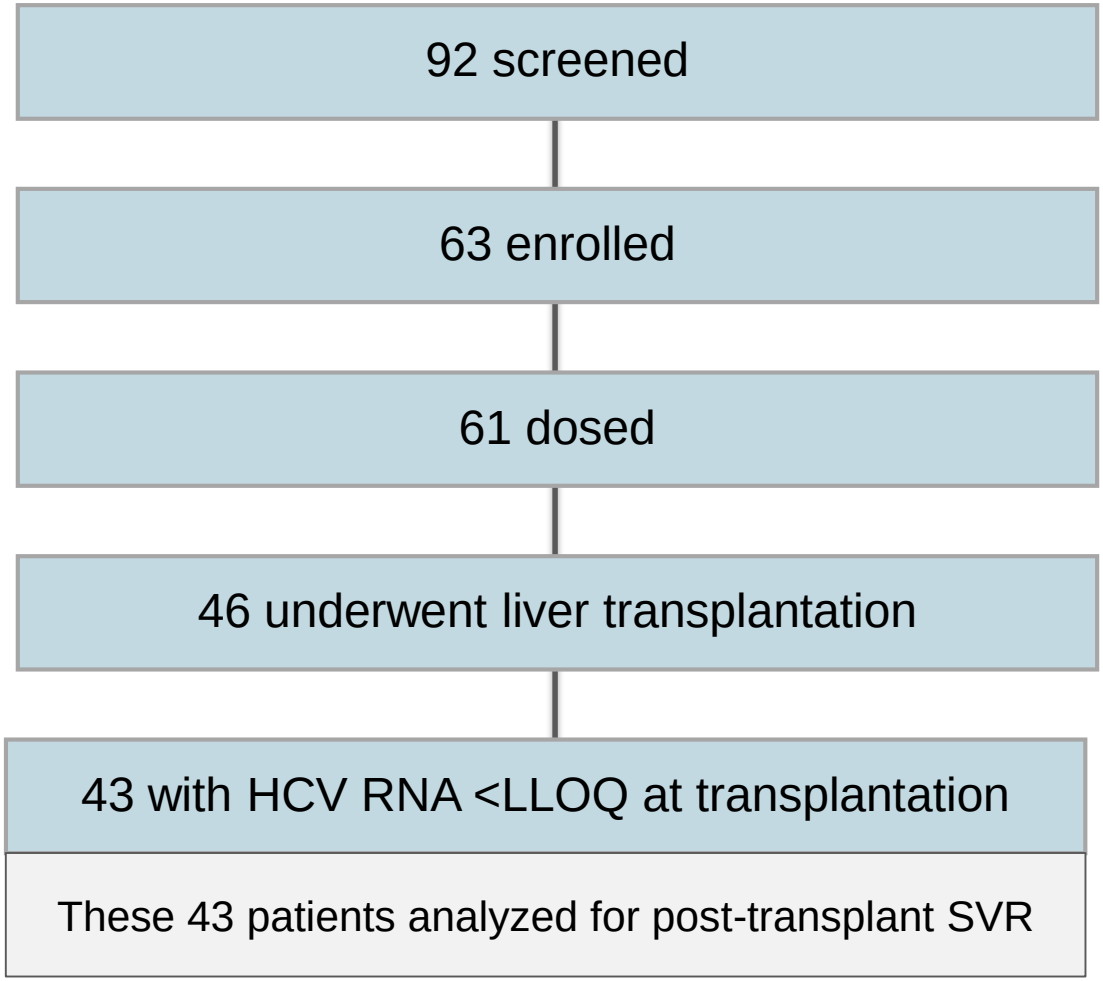
Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

- **Design**: Open-label, pilot, phase 2 trial of up to 48 weeks of sofosbuvir + ribavirin in patients with HCV of any genotype and cirrhosis awaiting liver transplantation for hepatocellular cancer
- **Setting**: International Study in United States, New Zealand, and Spain
- **Entry Criteria**
  - N = 61 patients with chronic hepatitis C and cirrhosis and any genotype
  - Age: ≥ 18
  - HCV RNA ≥ 10^4 IU/mL
  - Treatment naïve and treatment experience
  - CTP score ≤ 7 and MELD score ≤ 17
  - Excluded if decompensated liver disease
- **Regimen Given Prior to Transplant (up to 48 weeks of therapy**)
  - Sofosbuvir + Ribavirin (weight based)
- **Primary End-Point**: SVR 12 weeks post transplant

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

Hepatitis web study

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence
Study Design



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Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence
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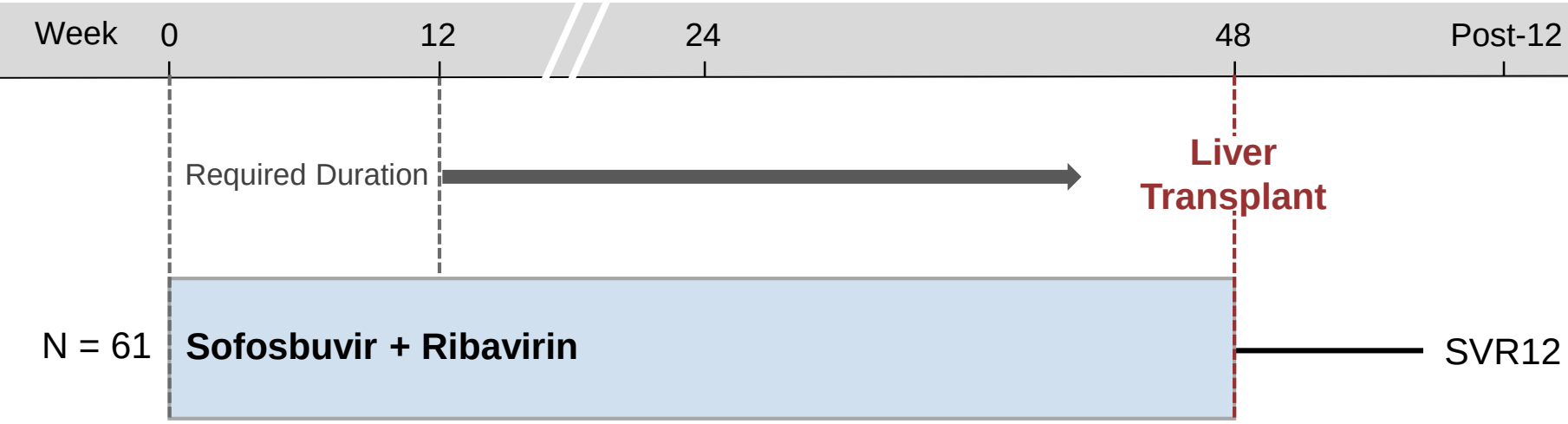


Treatment for 12 to 48 weeks while awaiting liver transplant
Dosing discontinued within 24 hours before transplantation

Drug Dosing
Sofosbuvir: 400 mg once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

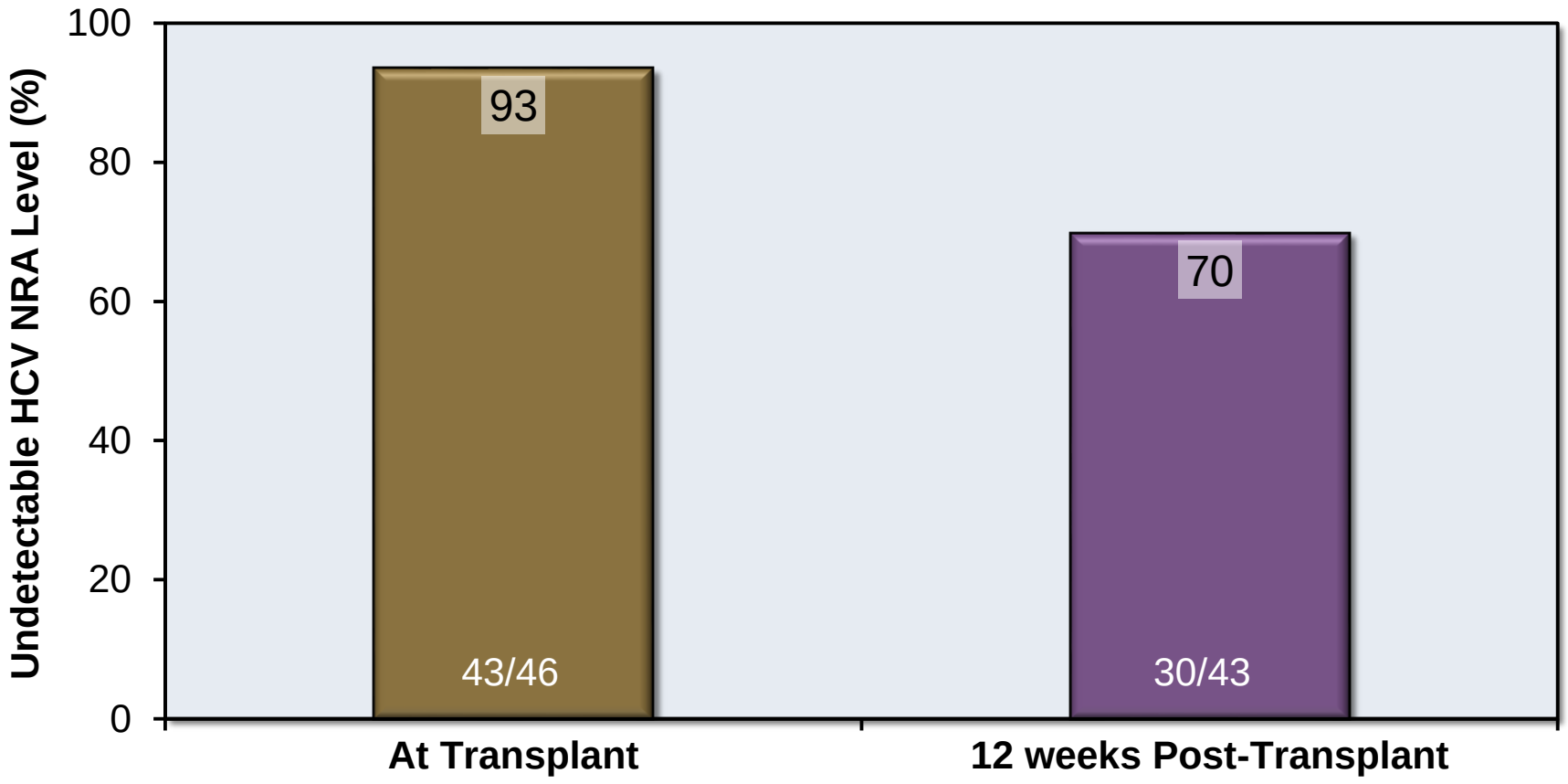
Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

Baseline Characteristic (n = 40)	All patients dosed (N=61)	Patients with HCV RNA <25 IU/mL at time of transplant (N=43)
Median Age, years	59	59
Male sex, %	80	74
White, %	90	93
Median Body Mass Index (BMI) kg/m^2	27.4	27.1
HCV genotype 1 (%)	73	72
IL28B genotype CC, (%)	22	23
Median baseline HCV RNA, log_{10} IU/ml	6.2	6.3
Previous HCV treatment, %	75	79

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

Virologic Response at Transplant and Post-Transplant



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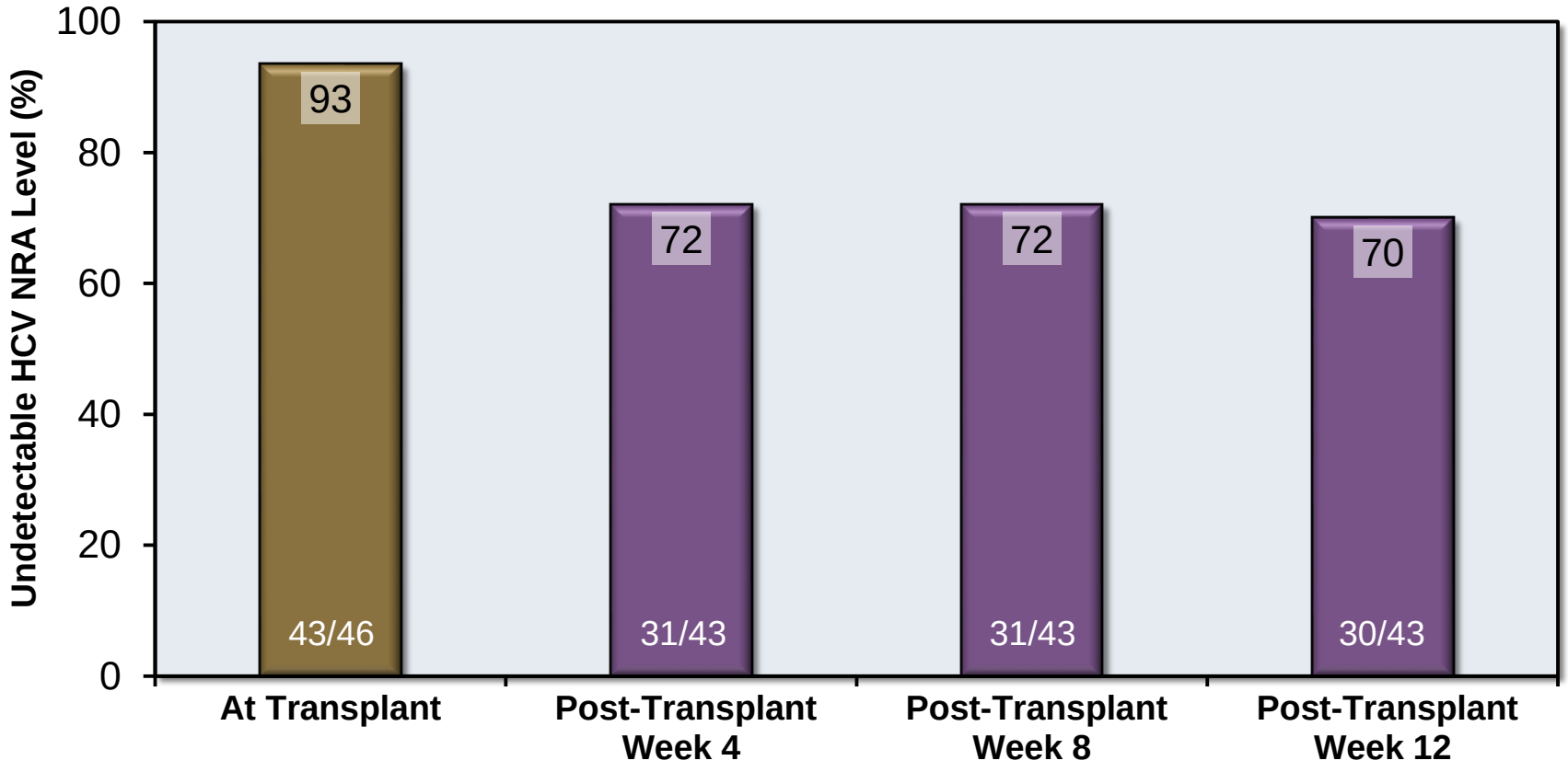
Virologic Response at Transplant and Post-Transplant



Data for the 43 patients with HCV RNA <25 IU/mL at time of transplant

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

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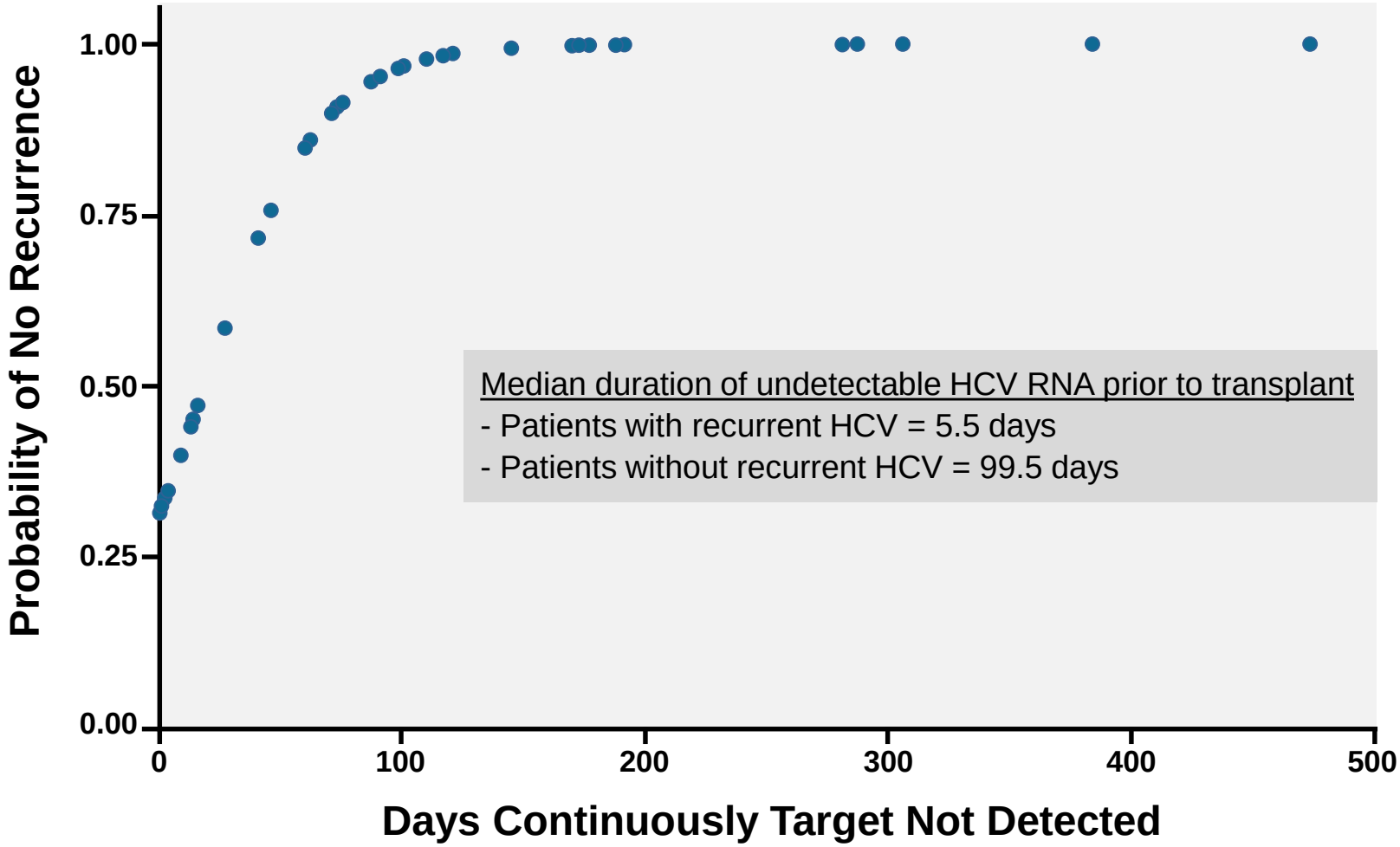
Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

Duration of Undetectable HCV RNA and Risk of Recurrence



Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

Event	**Sofosbuvir + Ribavirin** (N=61)
Any adverse event (%)	54 (8%)
Any serious adverse event	11 (18%)
Hemoglobin decrease to <10 g/dL	18 (30%)
Hemoglobin decrease to <8.5 g/dL	3 (5%)
Adverse event occurring in >10% of patients	
Fatigue	23 (38%)
Headache	14 (23%)
Nausea	10 (16%)
Rash	9 (15%)
Cough	7 (11%)
Dyspnea	7 (11%)
Insomnia	7 (11%)

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence Conclusions

Conclusions: “Administration of sofosbuvir and ribavirin before liver transplantation can prevent post-transplant HCV recurrence.”

Source: Curry MP, et al. Gastroenterology. 2015;148:100-7.

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

http://depts.washington.edu/hepstudy/

Funded by a grant from the Centers for Disease Control and Prevention.

Hepatitis web study