



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

**Diagnosis and Management of Chronic
HCV and HBV in the Primary Care Setting :**

**Part I - Chronic Hepatitis C: Update on Screening, Diagnosis,
Management, and Promising New Treatments**

Part II - Chronic Hepatitis B: Guidelines for Screening,
Clinical Management - Whether to Follow or Treat, and How

**Final Outcome Report
for Hepatitis C in Four Cities**

**Emerging
Challenges**

In Primary Care: 2015

Report Date: October 9, 2015

Prepared By: NACE

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Course Accreditation

The University of Miami Leonard M. Miller School of Medicine is accredited by the Accreditation Council (ACCME) for Continuing Medical Education to provide continuing medical education for physicians.

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Commercial Support

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Cities and Dates

Emerging Challenges in Primary Care: Update 2015 Conference Schedule

May 2, 2015
Miami, FL

June 20 ,2015
Columbus, OH

September 19, 2015
Sacramento, CA

May 9, 2015
Baltimore, MD

June 27, 2015
Troy, MI

September 26, 2015
Ft. Lauderdale, FL

May 16, 2015
Tampa, FL

August 15, 2015
Denver, CO

October 3, 2015
San Antonio, TX

May 30, 2015
Atlanta, GA

August 22, 2015
St. Louis, MO

October 10, 2015
Uniondale, NY

June 6, 2015
Birmingham, AL

August 29, 2015
Houston, TX

October 17, 2015
San Diego, CA

June 13, 2015
Raleigh, NC

September 12, 2015
Anaheim, CA

October 24, 2015
Nashville, TN

Titles of Presentations

Cardiovascular Disease Update for Primary Care

Translating the Advances in Evidence Based Medicine into Better Health Outcomes for People with Heart Failure

Jan Basile, MD or Karol E. Watson, MD, PhD or Elizabeth Ofili, MD, MPH, FACC or Anekwe Onwuanyi, MD

Novel Pharmacologic Advances for the Treatment of Hypercholesterolemia to Reduce LDL levels in Patients Who are Responsive and Refractory to Statin Therapy

Jan Basile, MD or Karol E. Watson, MD, PhD or Elizabeth Ofili, MD, MPH, FACC or Anekwe Onwuanyi, MD

Diagnosis and Management of Chronic HCV and HBV in the Primary Care Setting

Part I - Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF,FAASLD or Christopher O'Brien, MD, AGAF, FRCMI

Part II - Chronic Hepatitis B: Guidelines for Screening, Clinical Management - Whether to Follow or Treat, and How

Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF,FAASLD or Christopher O'Brien, MD, AGAF, FRCMI

A Primary Care Approach to Prostate Cancer - The Role of Shared Decision Making in Screening and Treatment

Part I - Prevalence and Screening - Finding Those at Risk

Matt T. Rosenberg, MD and/or E. David Crawford, MD and/or Neal Shore, MD, FACS and/or Ronald Tutrone , MD, FACS

Part II - Shared Decision Making - Initial and Ongoing Treatment Strategies

Matt T. Rosenberg, MD and/or E. David Crawford, MD and/or Neal Shore, MD, FACS and/or Ronald Tutrone , MD, FACS

Levels of Evaluation

Consistent with the policies of the ACCME, NACE evaluates the effectiveness of all CME activities using a systematic process based on Moore's model. This outcome study reaches Level 5.

- Level 1: Participation
- Level 2: Satisfaction
- Level 3: Declarative and Procedural Knowledge
- Level 4: Competence
- Level 5: Performance
- Level 6: Patient Health
- Level 7: Community Health

Level 1: Participation

- 1073 attendees in 4 cities
- 66% Physicians; 28% NPs or PAs; 5% RNs; 1% Other
- 57% in community-based practice
- 71% PCPs, 3% Cardiologist; 2% Endocrinologist; 24% Other or did not respond
- 89% provide direct patient care

Did we reach the right audience? **Yes!**

Level 2: Satisfaction

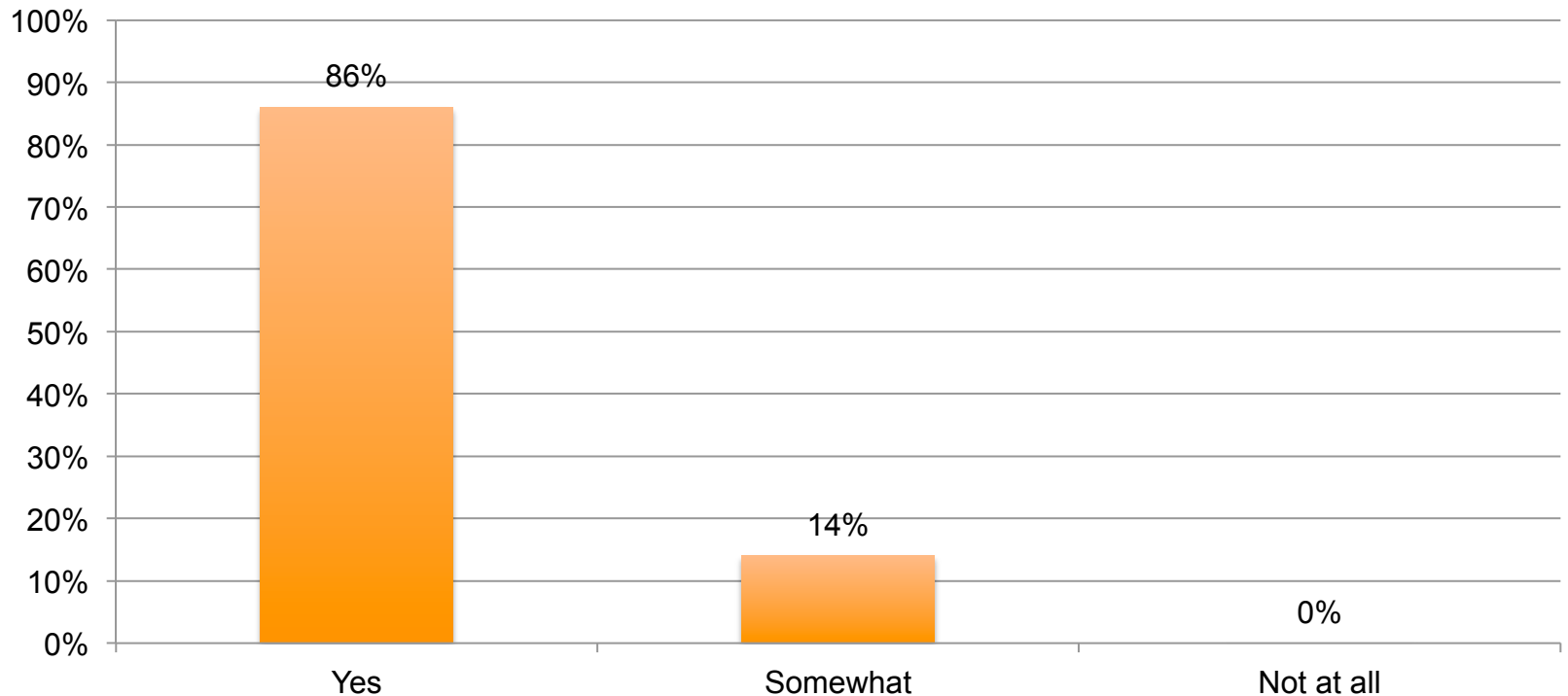
- 99% rated the activity as excellent
- 100% indicated the activity improved their knowledge
- 97% stated that they learned new and useful strategies for patient care
- 88% said they would implement new strategies that they learned in their practice
- 100% said the program was fair-balanced and unbiased

Sample Size: N = approximately 1073

Were our learners satisfied? **Yes! Data were collected across four cities for the Emerging Challenges in Primary Care program.**

Did Learners Say They Achieved Learning Objective?

Upon completion of this activity, I can now – Identify patients at risk for hepatitis C and explain the approach to screening and confirmation of the diagnosis in these patients; discuss guidelines for the overall medical management of patients with hepatitis C; discuss patient and viral factors that determine the appropriate drug treatment for patients with chronic HC infection; and distinguish patients who may be treated in the primary care setting from those who require specialty referral.



Yes! 99% believed they did. Data was collected in 4 cities.

Sample Size: N = approximately 1073

Outcome Study Methodology

Goal

To determine the effect this CME activity had on learners with respect to competence to apply critical knowledge, confidence in treating patients with diseases or conditions discussed, and change in practice behavior.

Dependent Variables

1. Level 3-5: Knowledge, Competence, and Performance

Case-based vignettes and pre- and post-test knowledge questions were asked with each session in the CME activity. Identical questions were also asked to a sample of attendees 4 weeks after the program to assess retention of knowledge. Responses can demonstrate learning and competence in applying critical knowledge. The use of case vignettes for this purpose has considerable predictive value. Vignettes, or written case simulations, have been widely used as indicators of actual practice behavior.¹

2. Practitioner Confidence

Confidence with the information relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

3. Level 5: Self-Reported Change in Practice Behavior

Four weeks after CME activity, practitioners are asked if they changed practice behavior.

1. Peabody, J.W., J. Luck, P. Glassman, S. Jain, J. Hansen, M. Spell and M. Lee (2004). Measuring the quality of physician practice by using clinical vignettes: a prospective validation study. *Ann Intern Med*14(10): 771-80.

Outcome Study Methodology (Cont.)

4. Readiness to Change Behavior (Prochaska and DeClemente Model)

CME activities can motivate providers to move through different stages of change which can ultimately lead them to take action and modify their practice behavior in accordance with the objectives of the education. Movement through these stages of change is an important dependent variable to consider in evaluating the impact of CME. Participants were asked to evaluate their stage of change with respect to specific topics being presented.

- **Pre-contemplation stage:** I do not manage (XXX illness), nor do I plan to this year.
- **Contemplation stage:** I did not manage (XXX illness) before this course, but as a result of attending this course I'm thinking of managing it now.
- **Pre-contemplation/confirmation stage:** I do manage patients with (XXX Illness) and this course confirmed that I do **not** need to change my treatment methods.
- **Preparation for action stage:** I do manage patients with (XXX illness) and this course helped me change my treatment methods.

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

Faculty

Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF, FAASLD

Christopher O'Brien, MD, AGAF, FRCMI

Learning Objectives

1. Identify patients at risk for hepatitis C and explain the approach to screening and confirmation of the diagnosis in these patients.
2. Discuss guidelines for the overall medical management of patients with hepatitis C.
3. Discuss patient and viral factors that determine the appropriate drug treatment for patients with chronic HC infection.
4. Distinguish patients who may be treated in the primary care setting from those who require specialty referral.

Key Findings

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

| | |
|--|--|
| Knowledge/Competence | Learners demonstrated significant improvement from pre to post-testing in their answers to <i>four</i> out of <i>four</i> of the case-based questions regarding treating a patient with Chronic Hepatitis C. |
| Confidence | Whereas the majority of learners rated themselves as having very low confidence in their treating patients with Chronic Hepatitis C before the education, most of the learners showed high gains in confidence after the program. |
| Intent to Perform | As a result of this program, 31% of learners who did not treat patients with Chronic Hepatitis C before this course, but as a result of attending this course are considering doing so, while 14% indicated that they will change their treatment methods. |
| Change of Practice Behavior N= 56 | 88% of learners who responded to our four week survey indicated that they had changed their practice behavior to implement the learning objectives of this program within four weeks after they attended the activity. |

Case Vignette Knowledge and Competence Assessment Questions

(presented before and after lecture—boxed answer is correct)

A 55 year old Caucasian female presents with an upper GI bleed

Endoscopy demonstrated esophageal varices that were banded to obliteration

Routine labs revealed HCV Ab+

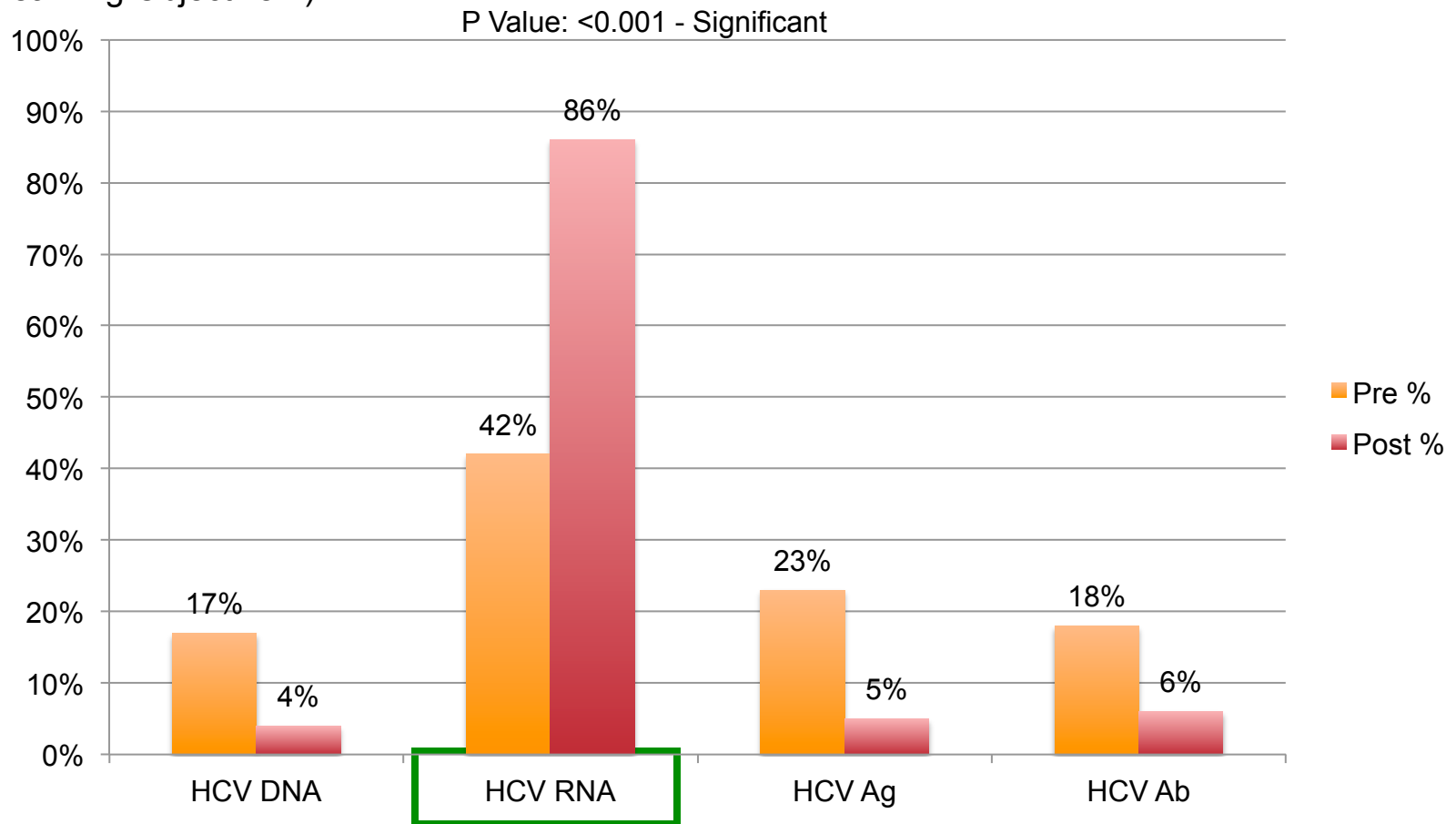
On further discussion she states that she:

Drinks wine daily

Has drastically reduced her work productivity due to debilitating fatigue

How would you confirm the diagnosis of Hepatitis C in this patient?

(Learning Objective 1)



Pre N= 518

Post N= 509

Green highlight indicates significant difference between pre and post testing.

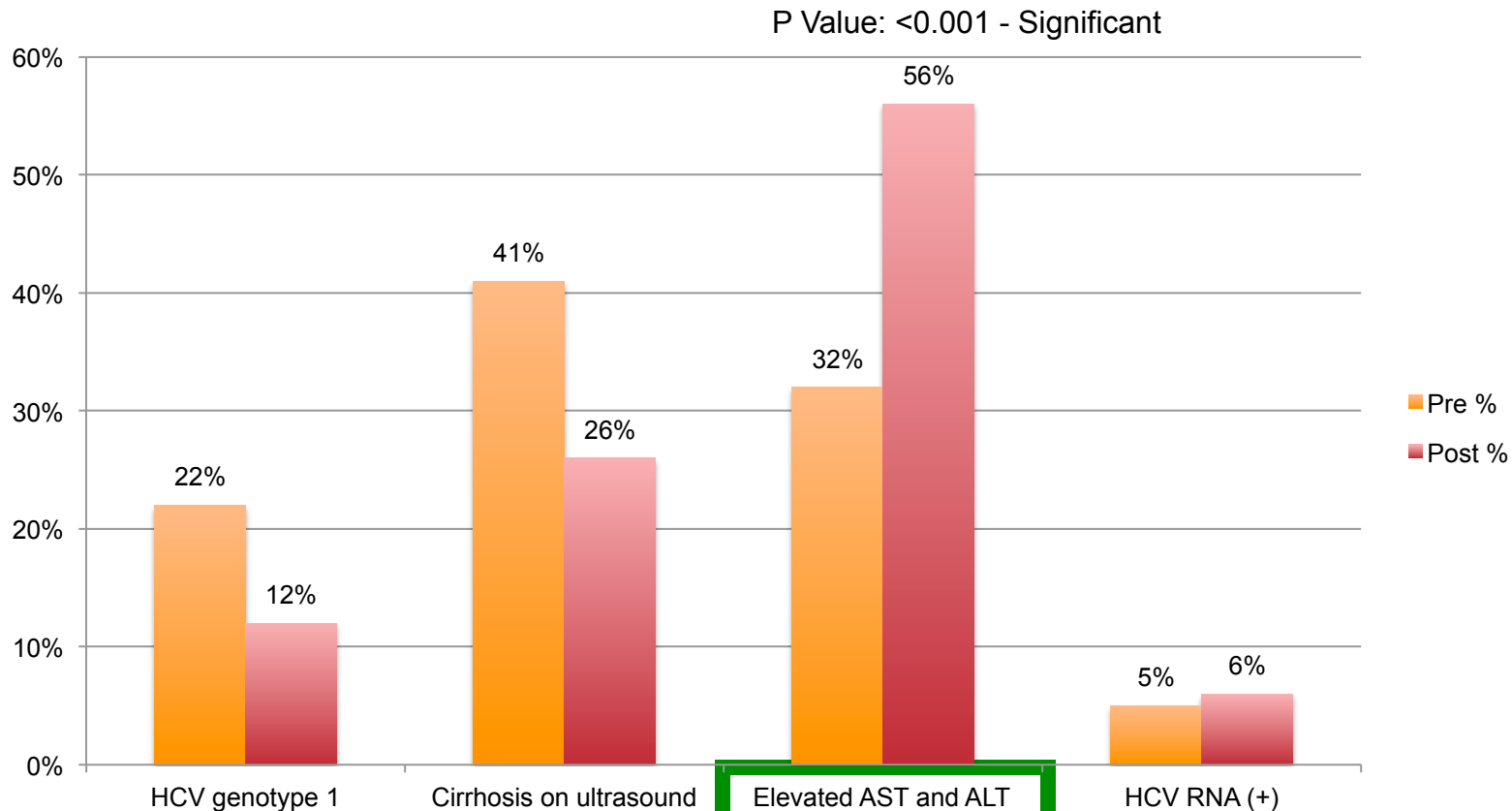
Case Vignette Knowledge and Competence Assessment Questions

(presented before and after lecture—boxed answer is correct)

- HCV RNA 6.1 million IU/mL
- Genotype 1
- AST; ALT 204 IU/L; 79 IU/L
- Platelets 99,000 cells/mm³
- Ultrasound Nodular surface

consistent with cirrhosis

What factor below is not required to qualify the patient for drug treatment? (Learning Objective 2)



Pre N= 536

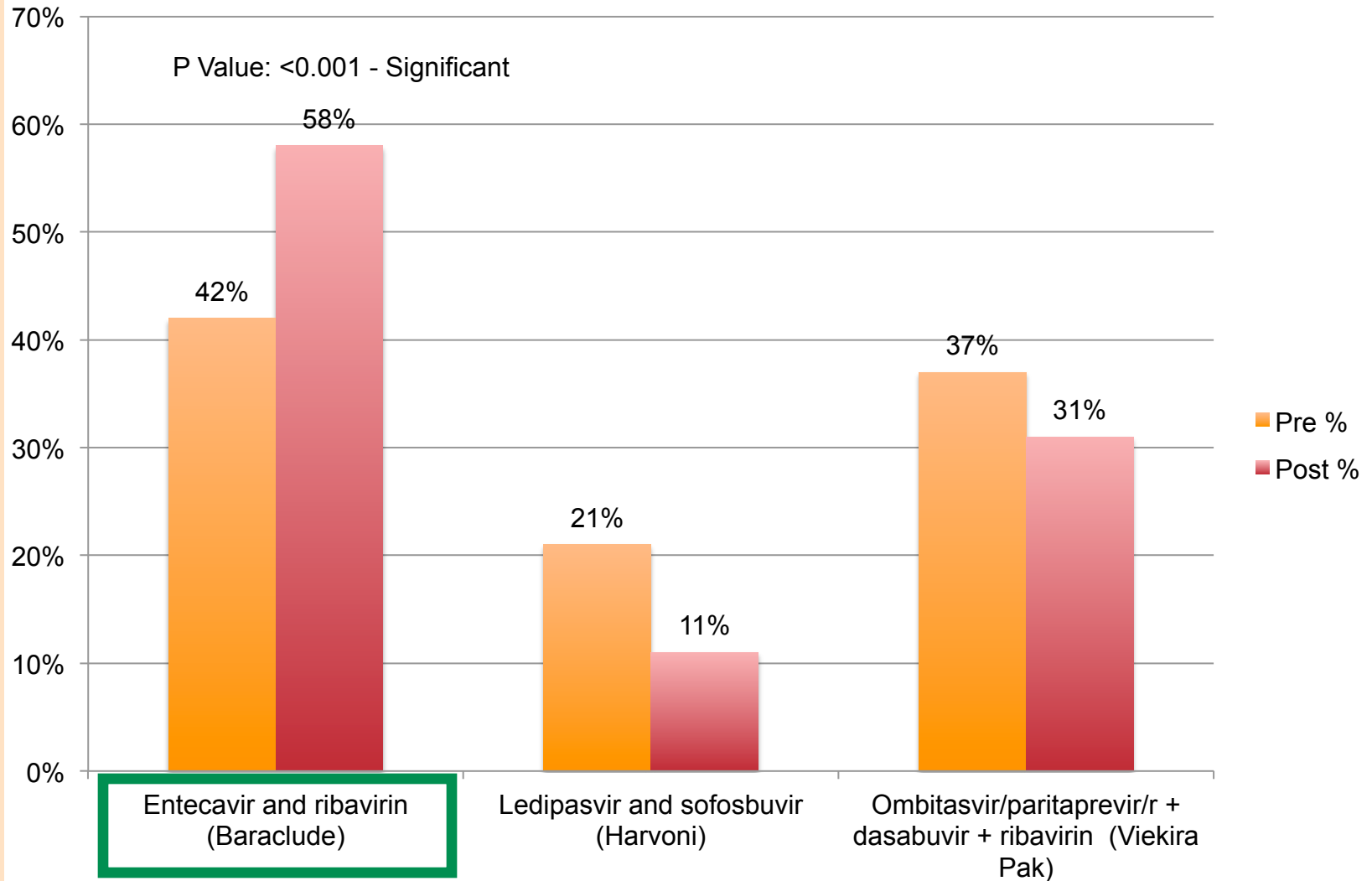
Post N= 517

Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions

(presented before and after lecture—boxed answer is correct)

You have decided to offer this patient treatment for HCV Type 1. Which treatment is not FDA approved for HCV Genotype 1? (Learning Objective 3)



Pre N=525

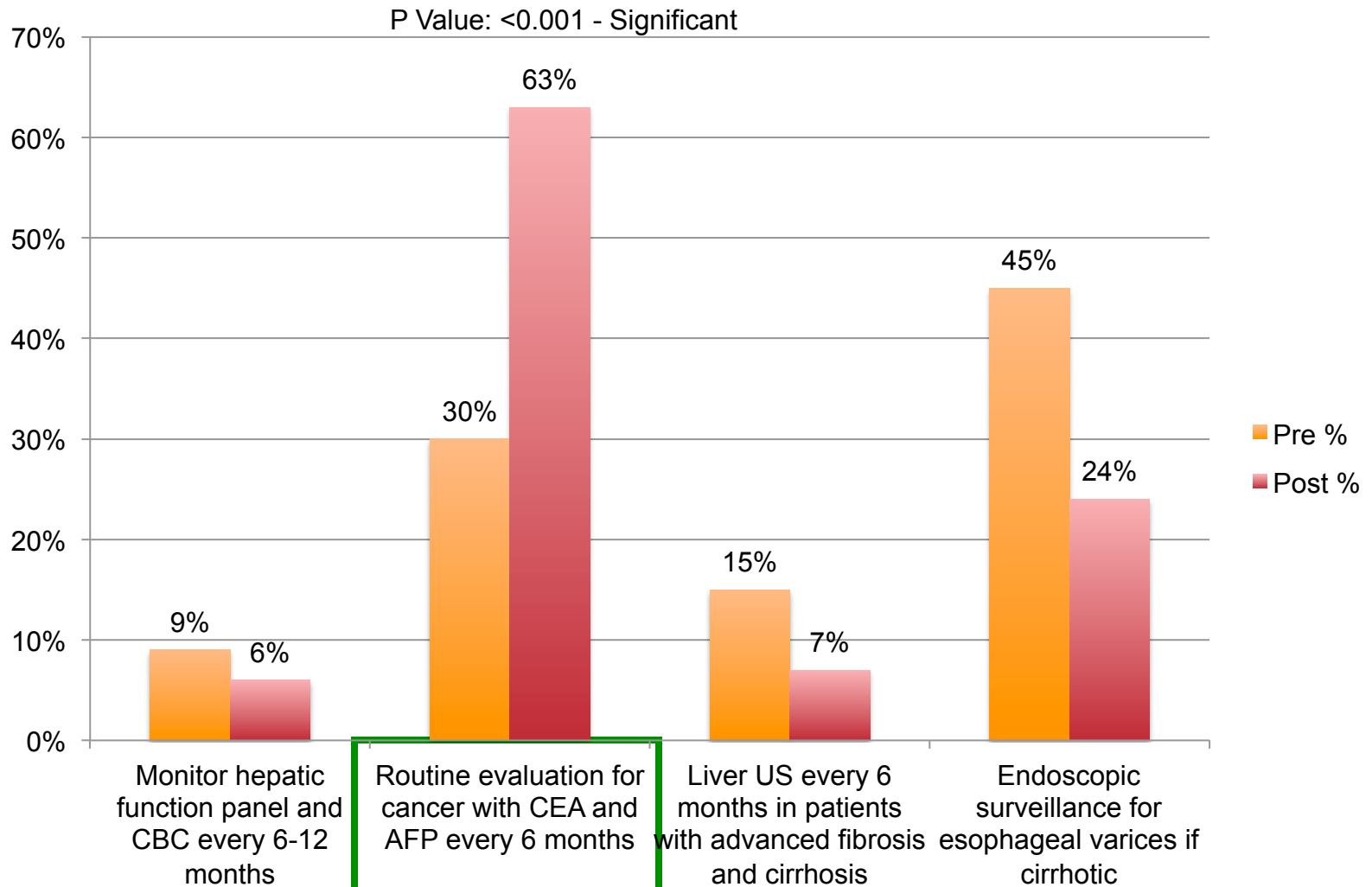
Post N= 513

Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions

(presented before and after lecture—boxed answer is correct)

All of the following strategies are required to monitor patients that have failed treatment for Hepatitis C except: (Learning Objective 4)

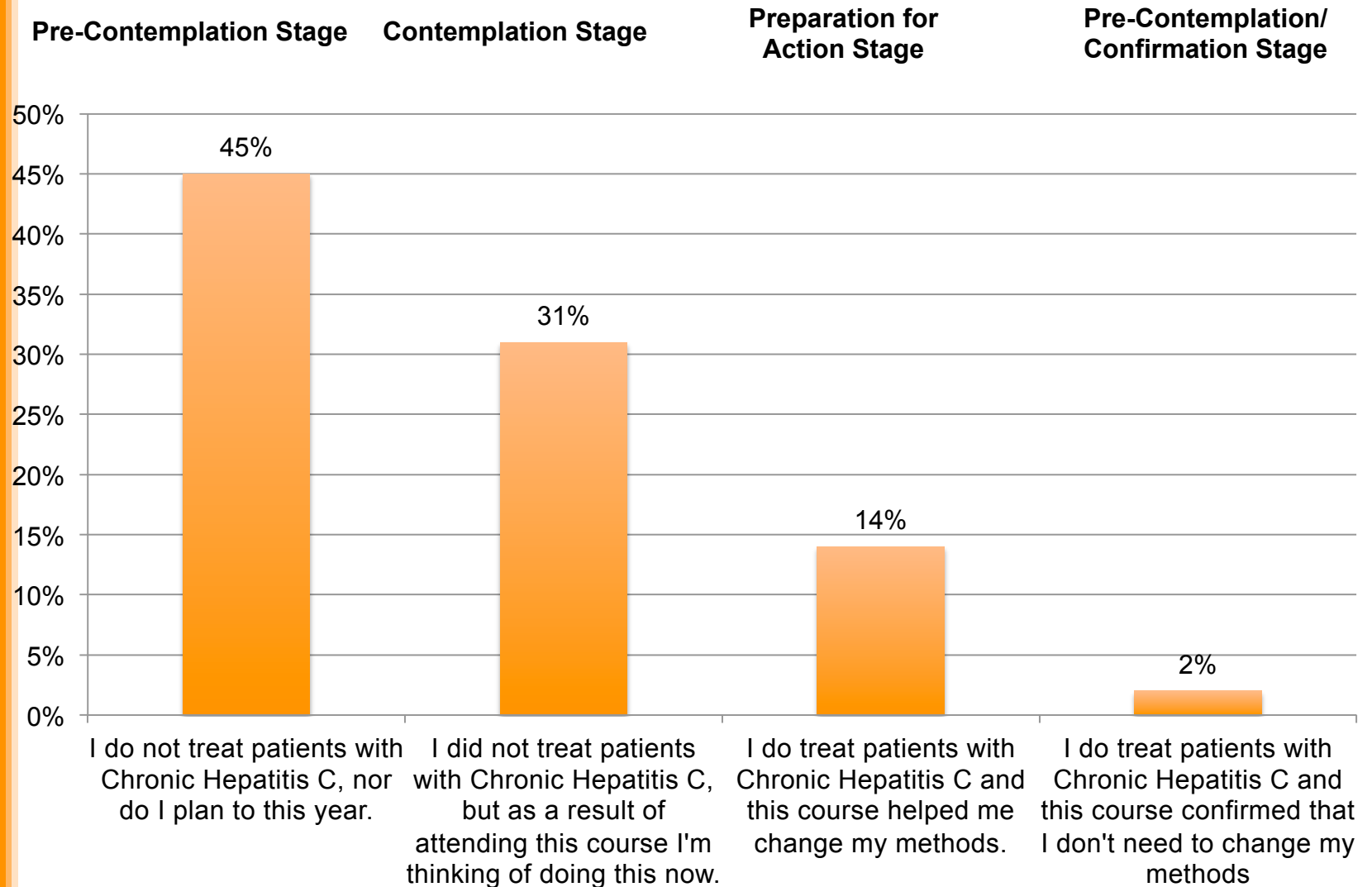


Pre N= 533 Post N= 518

Green highlight indicates significant difference between pre and post testing.

Change in Practice Behavior Question (presented after the lecture)

Which of the statements below describes your approach to treating Chronic Hepatitis C ?



N= 492

Four Week Case Study Questions

(boxed answer is correct)

A 55 year old Caucasian female presents with an upper GI bleed

Endoscopy demonstrated esophageal varices that were banded to obliteration

Routine labs revealed HCV Ab+

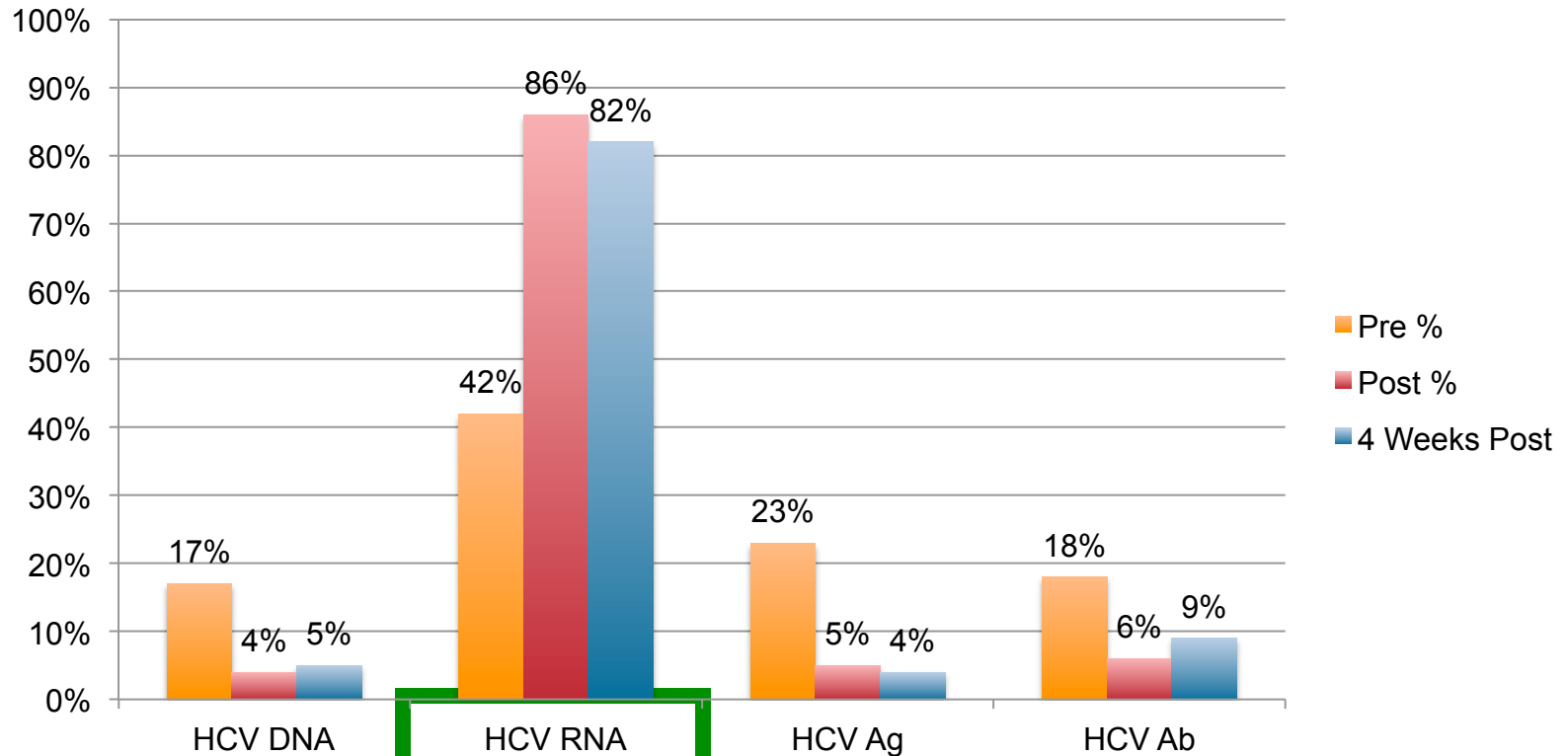
On further discussion she states that she:

Drinks wine daily

Has drastically reduced her work productivity due to debilitating fatigue

How would you confirm the diagnosis of Hepatitis C in this patient?

(Learning Objective 1)



Pre N= 518 Post N= 509

4 Week Post N = 56

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions

(boxed answer is correct)

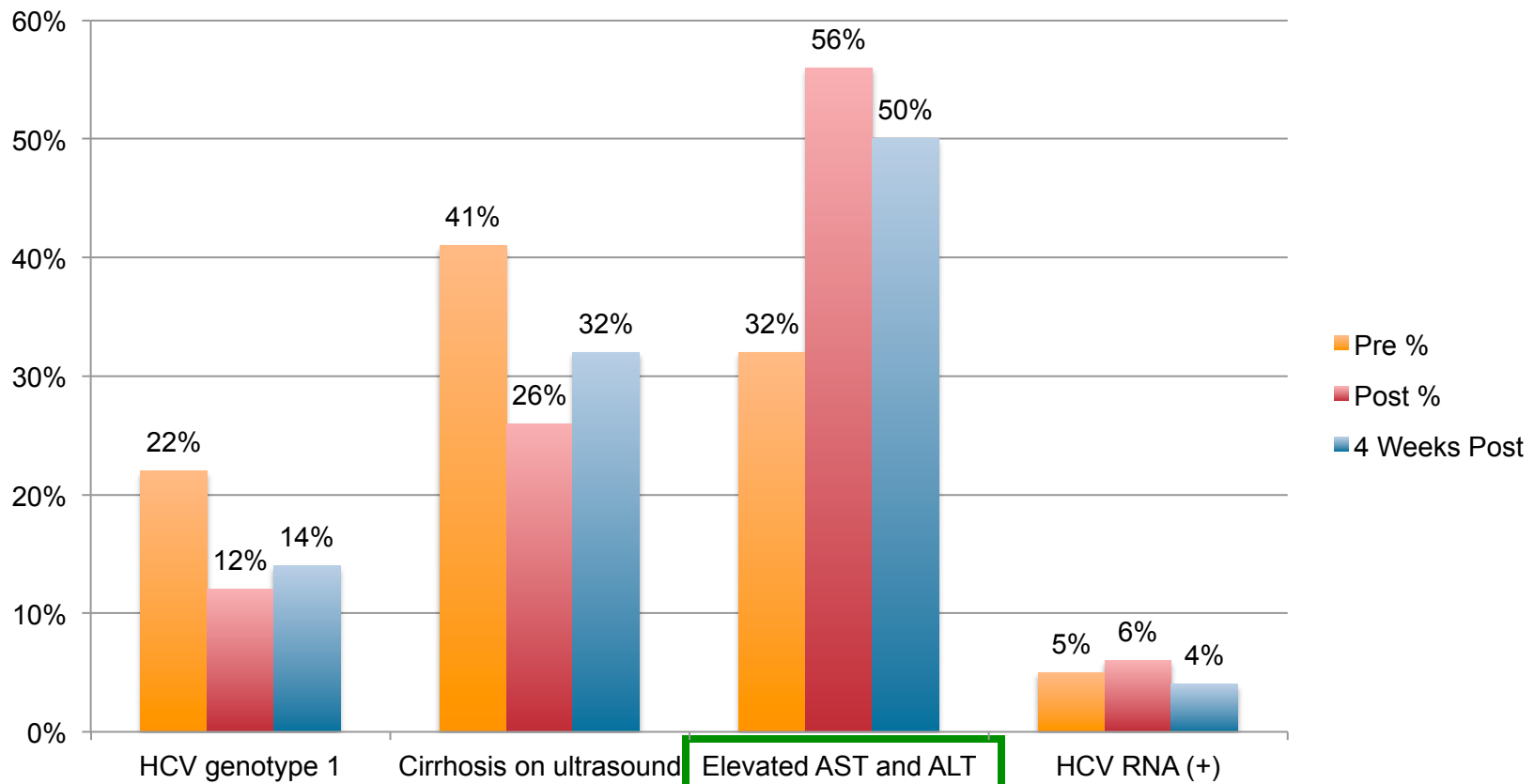
HCV RNA

6.1 million IU/mL

- Genotype 1
- AST; ALT 204 IU/L; 79 IU/L
- Platelets 99,000 cells/mm³
- Ultrasound Nodular surface consistent with cirrhosis

What factor below is not required to qualify the patient for drug treatment?

(Learning Objective 2)



Pre N= 536 Post N= 517

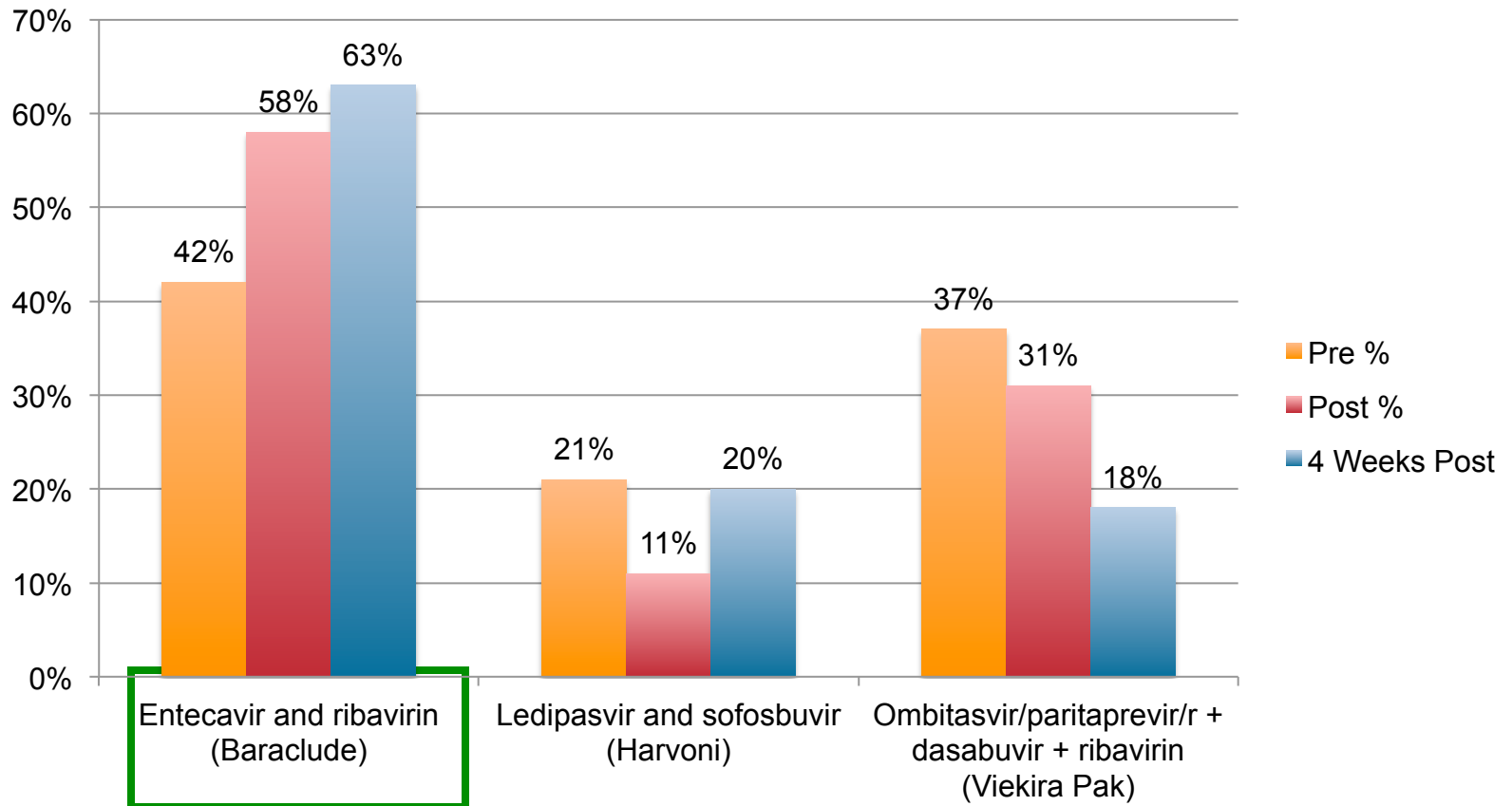
4 Week Post N = 56

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions

(boxed answer is correct)

You have decided to offer this patient treatment for HCV Type 1. Which treatment is not FDA approved for HCV Genotype 1? (Learning Objective 3)



Pre N= 525 Post N= 513

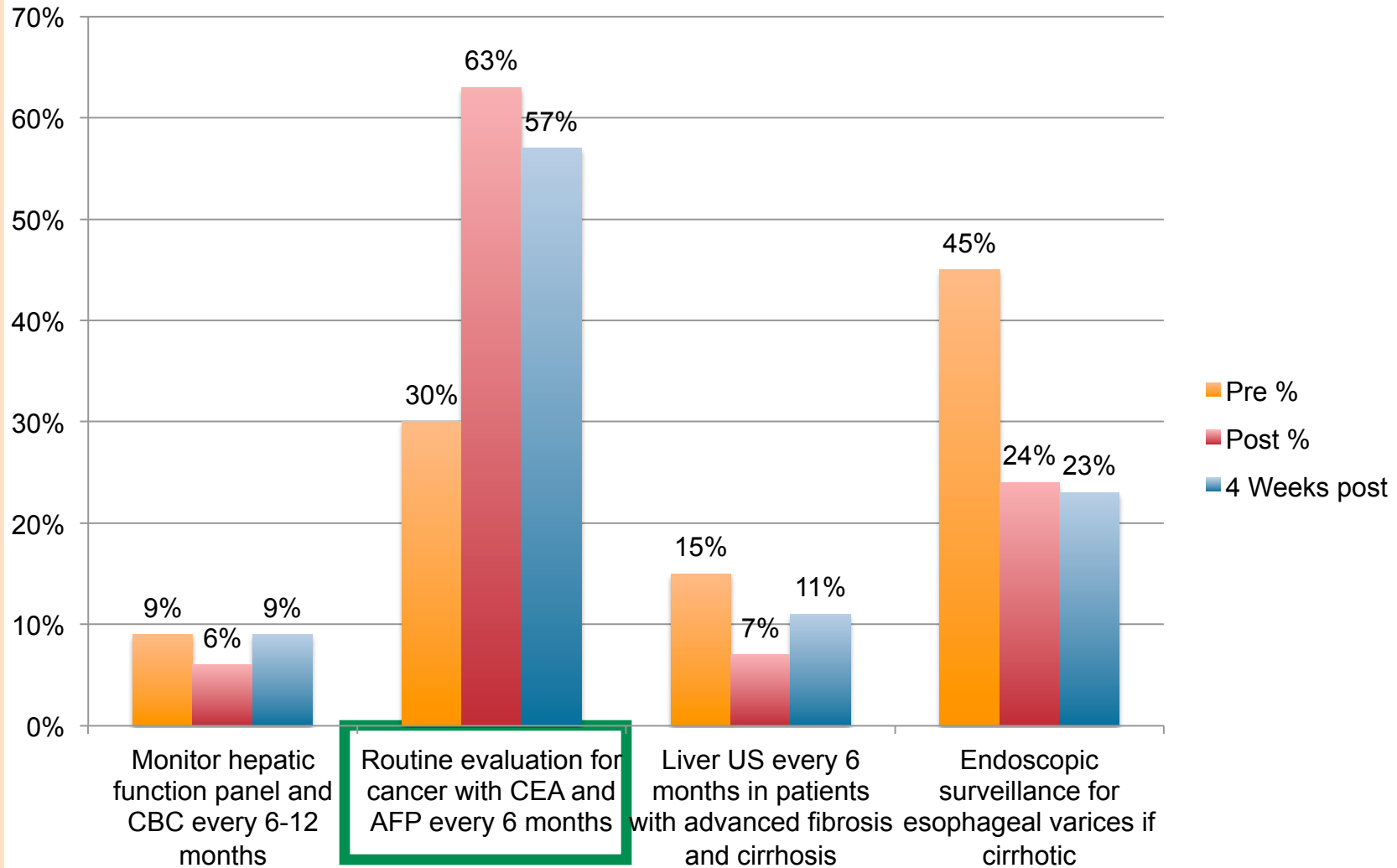
4 Week Post N = 56

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions

(boxed answer is correct)

All of the following strategies are required to monitor patients that have failed treatment for Hepatitis C except: (Learning Objective 4)



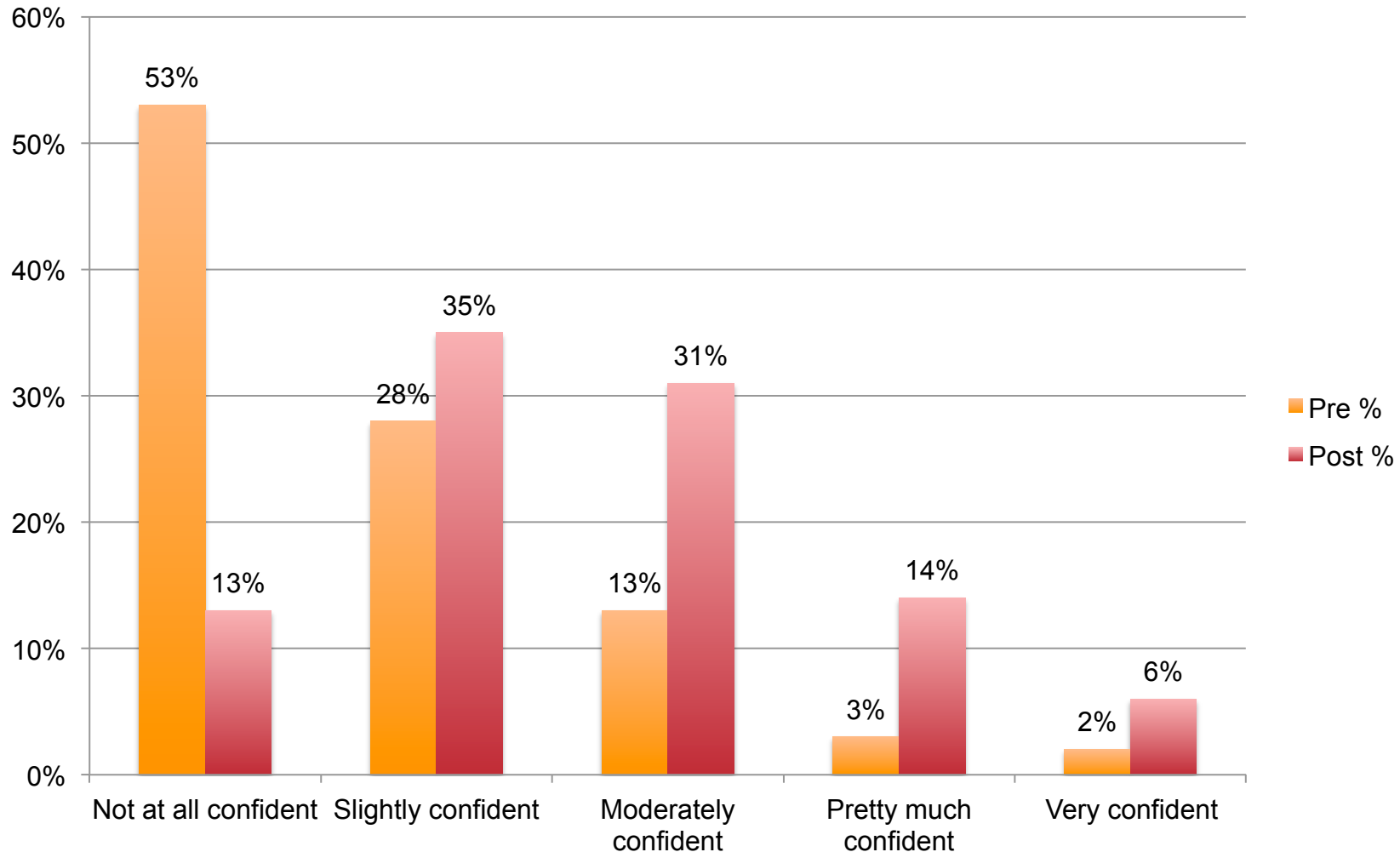
Pre N= 533 Post N= 518

4 Week Post N = 56

Green highlight indicates significant difference between pre and post testing.

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

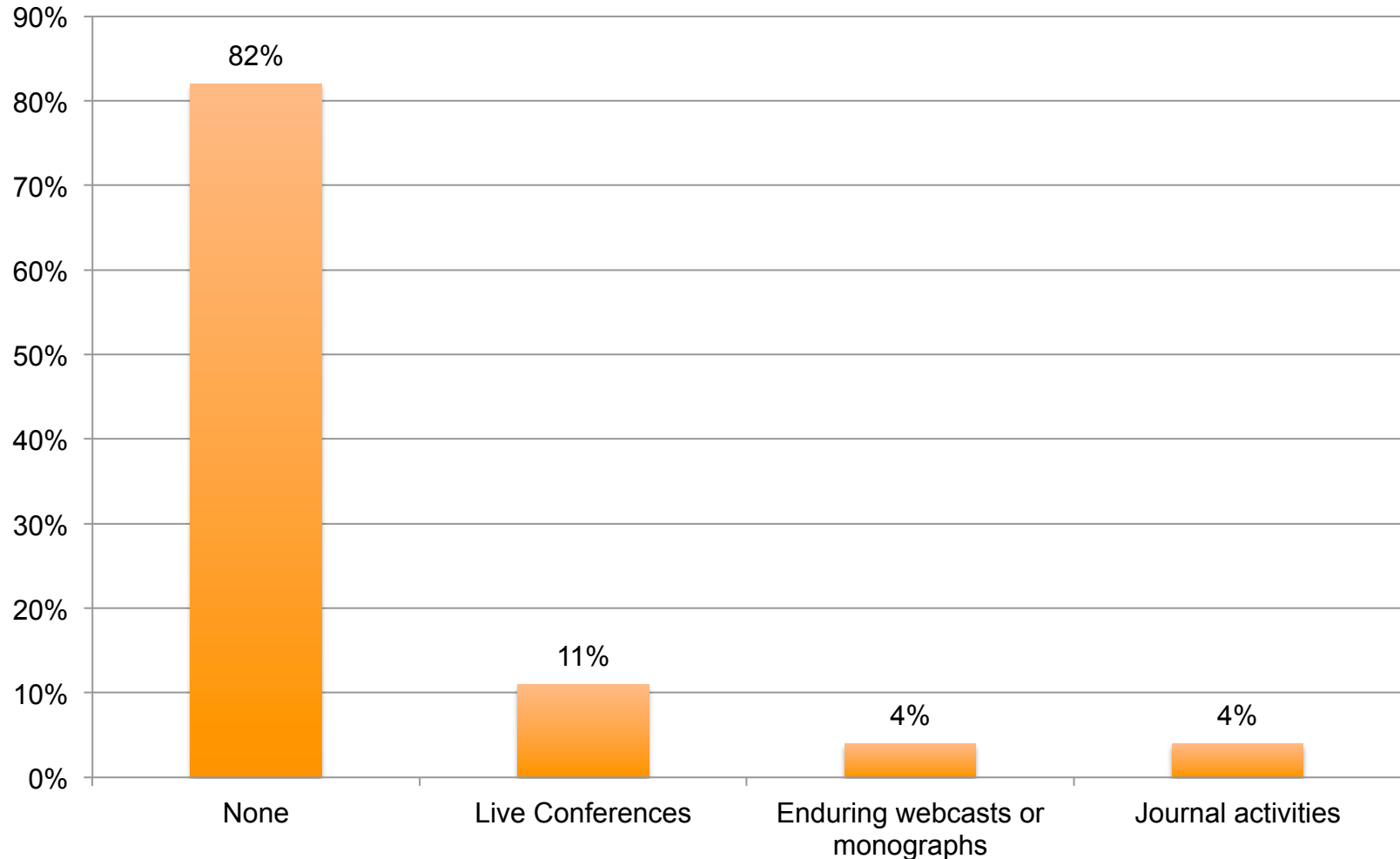
On a scale of 1 to 5, Please rate how confident you would be treating a patient with Chronic Hepatitis C ?



Pre N= 488 Post N= 515

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

Describe/list any other educational activities that you attended in the last month concerning the treatment of Chronic Hepatitis C ?



Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

What specific skills or practice behaviors have you implemented for patients with Chronic Hepatitis C since this CME activity?

(Comments received from attendees at 4 week follow up)

- More aware of treatment for hepatitis C
- Following up patients of Hep C
- Will continue to refer to specialty clinic for treatment
- Ordering appropriate labs
- Screening patients more often
- Recognize available advanced testing and monitoring
- Better awareness
- Recognize approved meds
- Screening more patients
- Inform patients with Hep C about available treatments
- Discussed treatment options with colleagues
- Identifying patients at risk and check for Hep C antibody

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with Chronic Hepatitis C since this CME activity?

(Comments received from attendees at 4 week follow up)

- Number of patients with Chronic Hepatitis C
- Need more knowledge and practice
- Insurance & time restrictions, patient compliance
- Lack of consensus among physicians
- Lack of research in this area
- Financial barriers in a free clinic
- Insurance coverage and sometime patient's compliance and understanding
- Patient compliance
- Lack of patients
- Staffing
- Cost of drugs
- Insurance coverage

Discussion and Implications

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

The need for continued education in the screening, diagnosis and treatment of Hepatitis C was demonstrated based on literature reviews and surveys completed prior to the conference series. Attendee knowledge was assessed at 3 points for this program: prior to the lecture, immediately following the lecture and again at 4 weeks after the conference. The results indicate a statistically significant improvement in knowledge in all 4 of the areas tested. Specifically, as a result of this lecture, participants: understand that HCV RNA is the appropriate test to confirm a diagnosis of HCV; recognize that abnormal liver function tests is not a requirement to initiate drug treatment for HCV; are more aware that the combination of Entacavir and ribavirin are not FDA approved for treatment of HCV genotype type 1; understand that both CEA and AFP are not required for evaluating a patient with HCV for cancer.

Data obtained from participants 4 weeks after the program demonstrated some decline in learning from the post-test scores but still significant improvement from the pre-test scores. Persistent gaps in knowledge exist: 18% of learners are still unclear that HCV RNA is the confirmatory test of choice; 50% still believe that abnormal LFT's are required to begin treatment; 38% are not clear on the FDA approved treatments for HCV; and 43% believe that routine screening for cancer includes CEA and AFP levels every 6 months.

Discussion and Implications

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments

Participants indicated a significant overall increase in self-reported confidence levels in the screening for and management of a patient with Hepatitis C. Moderate to very confident levels rose from 18% to 51% by the end of the program. 31% of learners that were not involved with the management of patients with Hepatitis C are now thinking of it and 14% are planning on changing what they do as a result of this course. 45% of learners remain uncomfortable with actually treating patients with Hepatitis C but the large majority of responses on behavior changes indicated they are much more likely to screen patients at risk. After the program, 88% of participants indicated that they are likely to utilize information learned from this presentation in their practice and 88% indicated that they had made changes 4 weeks after the program.

Attendees indicated multiple new, specific, practice behaviors they implemented as a result of this program that included greater awareness of FDA approved treatment options for Hepatitis C, more consistent screening of patients at risk, and more comfort in appropriate lab evaluation to screen and confirm a diagnosis. 82% of respondents indicated that they had not participated in any other educational activities suggesting that their behavior changes were most likely a result of this program. Barriers to care included lack of patients with Hepatitis C, need for greater knowledge on the subject, financial barriers, patient compliance and medication costs.

The notable changes in post test scores signify a clear gap in knowledge and an unmet need among primary care clinicians. Persistent gaps in knowledge persist across all areas indicating that additional education on Hepatitis C screening and management is necessary for primary care clinicians.