



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**

**Emerging
Challenges**

In Primary Care: 2015

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

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.

The University of Miami Leonard M. Miller School of Medicine designates this live activity for a maximum of *2.25 AMA PRA Category 1 Credits*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.*

Commercial Support

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Clinical Management - Whether to Follow or Treat, and How
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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

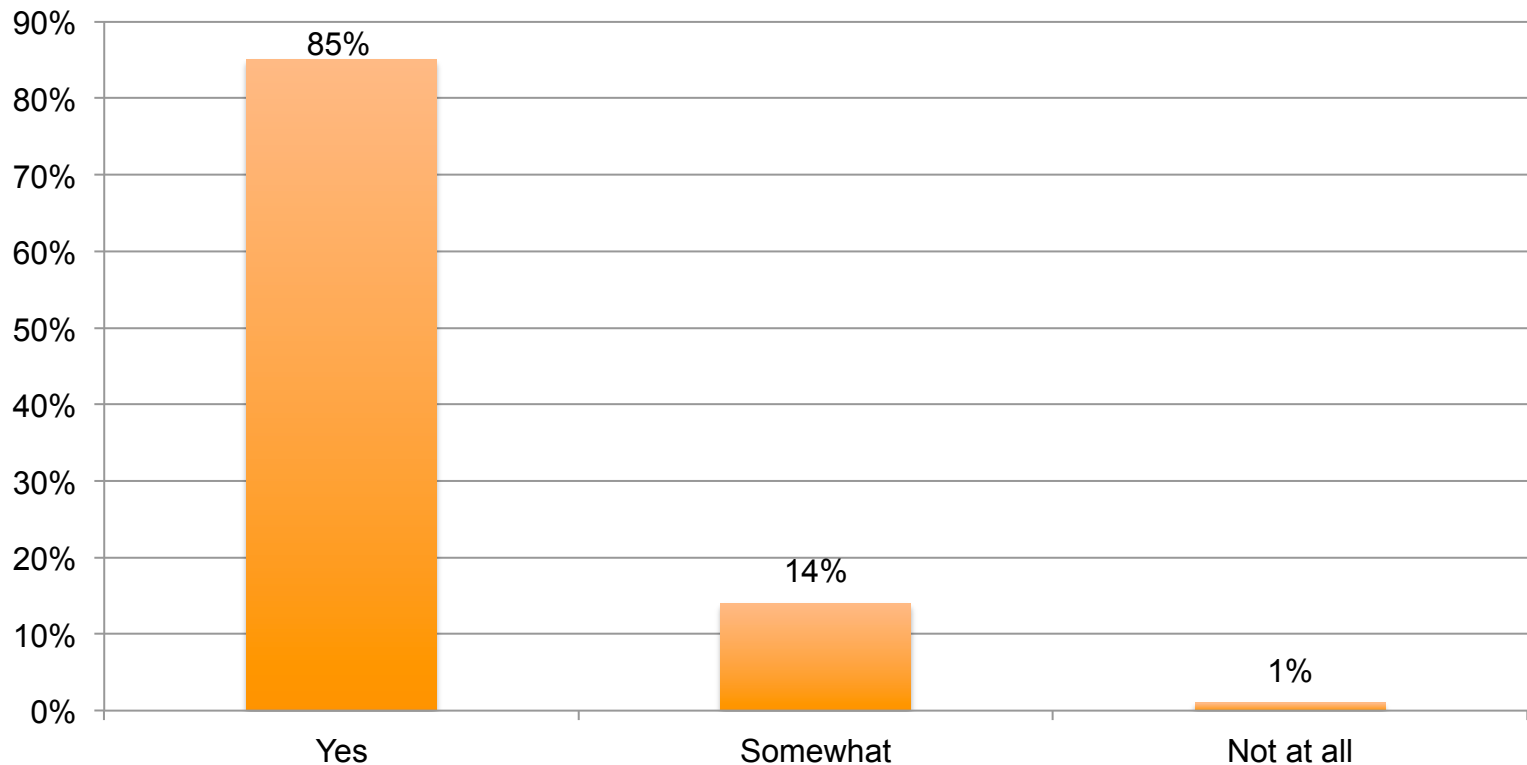
- 99% rated the activity as excellent
- 100% indicated the activity improved their knowledge
- 97% stated that they learned new and useful strategies for patient care
- 88% said they would implement new strategies that they learned in their practice
- 100% said the program was fair-balanced and unbiased

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 who should be screened for chronic hepatitis B and discuss appropriate testing for those patients; apply evidence-based strategies for the overall medical management of patients with chronic hepatitis B; determine which patients require medication for chronic hepatitis B and which should be monitored clinically; and discuss the medications available for treating chronic hepatitis B and associated resistance issues.



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

Faculty

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

Christopher O'Brien, MD, AGAF, FRCMI

Learning Objectives

1. Identify patients who should be screened for chronic hepatitis B and discuss appropriate testing for those patients.
2. Apply evidence-based strategies for the overall medical management of patients with chronic hepatitis B.
3. Determine which patients require medication for chronic hepatitis B and which should be monitored clinically.
4. Discuss the medications available for treating chronic hepatitis B and associated resistance issues.

Key Findings

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

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 B.
Confidence	Whereas the majority of learners rated themselves as having very low confidence in their treating patients with Chronic Hepatitis B before the education, most of the learners showed high gains in confidence after the program.
Intent to Perform	As a result of this program, 33% of learners who did not treat patients with Chronic Hepatitis B before this course, but as a result of attending this course are considering doing so, while 18% indicated that they will change their treatment methods.
Change of Practice Behavior	85% 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.

N= 75

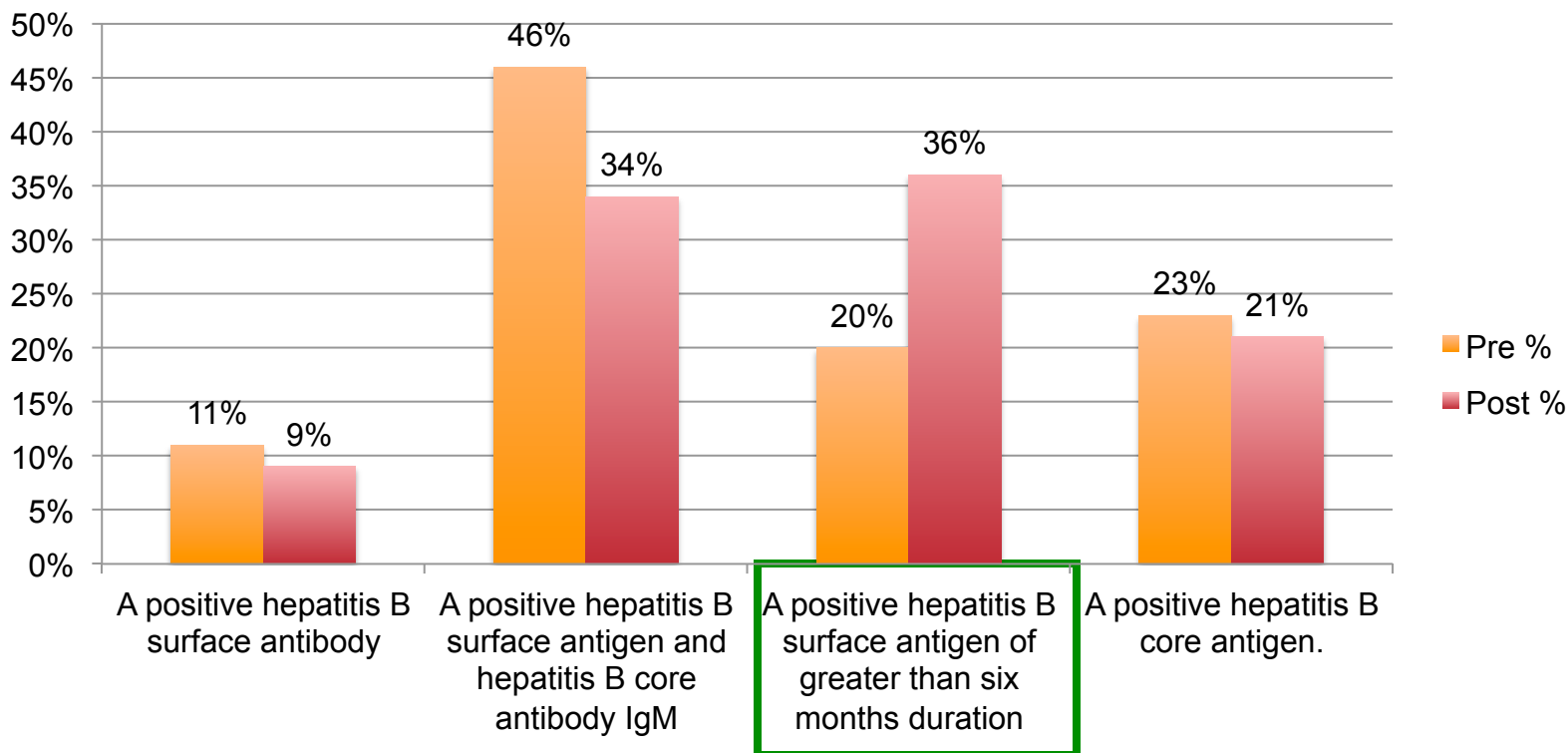
Case Vignette Knowledge and Competence Assessment Questions

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

The first case is 47-year-old woman born in Korea, who came to the United States at 35 years of age. She is HBsAg positive, has no previous history of jaundice or hepatitis, and no current symptoms, and her only notable medical history is mild hypertension. There is no known family history of hepatitis B or HCC. Her husband and 2 sons have not been tested for HBV and should be advised to do so. You decide to screen this patient for Hepatitis B.

Which laboratory test confirms the diagnosis of chronic hepatitis B? (Learning Objective 1)

P Value: <0.001 - Significant



Pre N= 534 Post N= 545

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)

Hepatitis serologies:

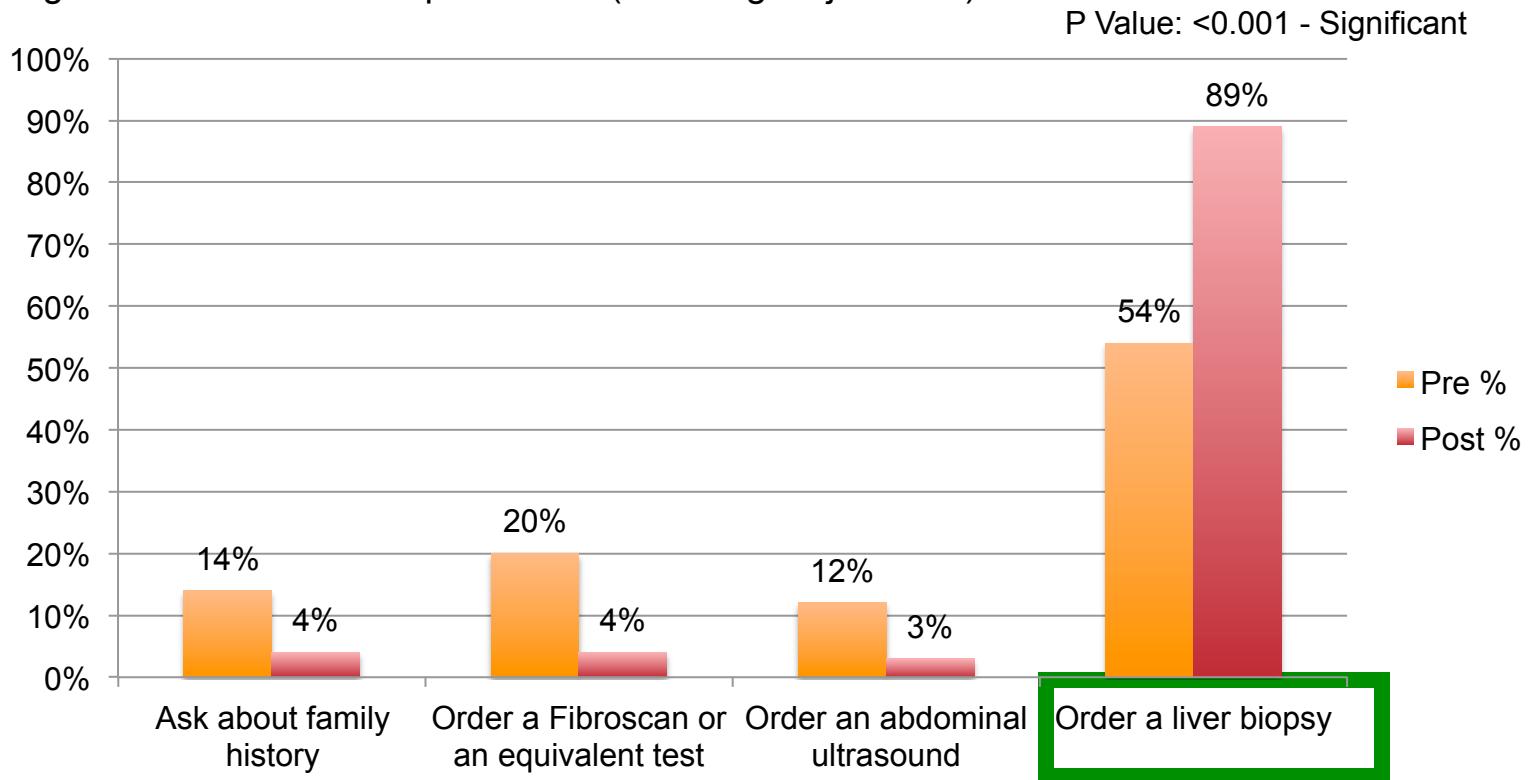
HBsAg positive, HBcAb positive, HBsAb negative

HBeAg negative, anti-HBe positive

CBC: WBC 4200 cells/mm³, Hb 13 g/dL, platelets 182,000 cells/mm³

Liver Tests: AST 12 IU/L, ALT 16 IU/L

Which of the following is not essential for determining further management of patients newly diagnosed with chronic hepatitis B? (Learning Objective 2)



Pre N= 536

Post N= 540

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)

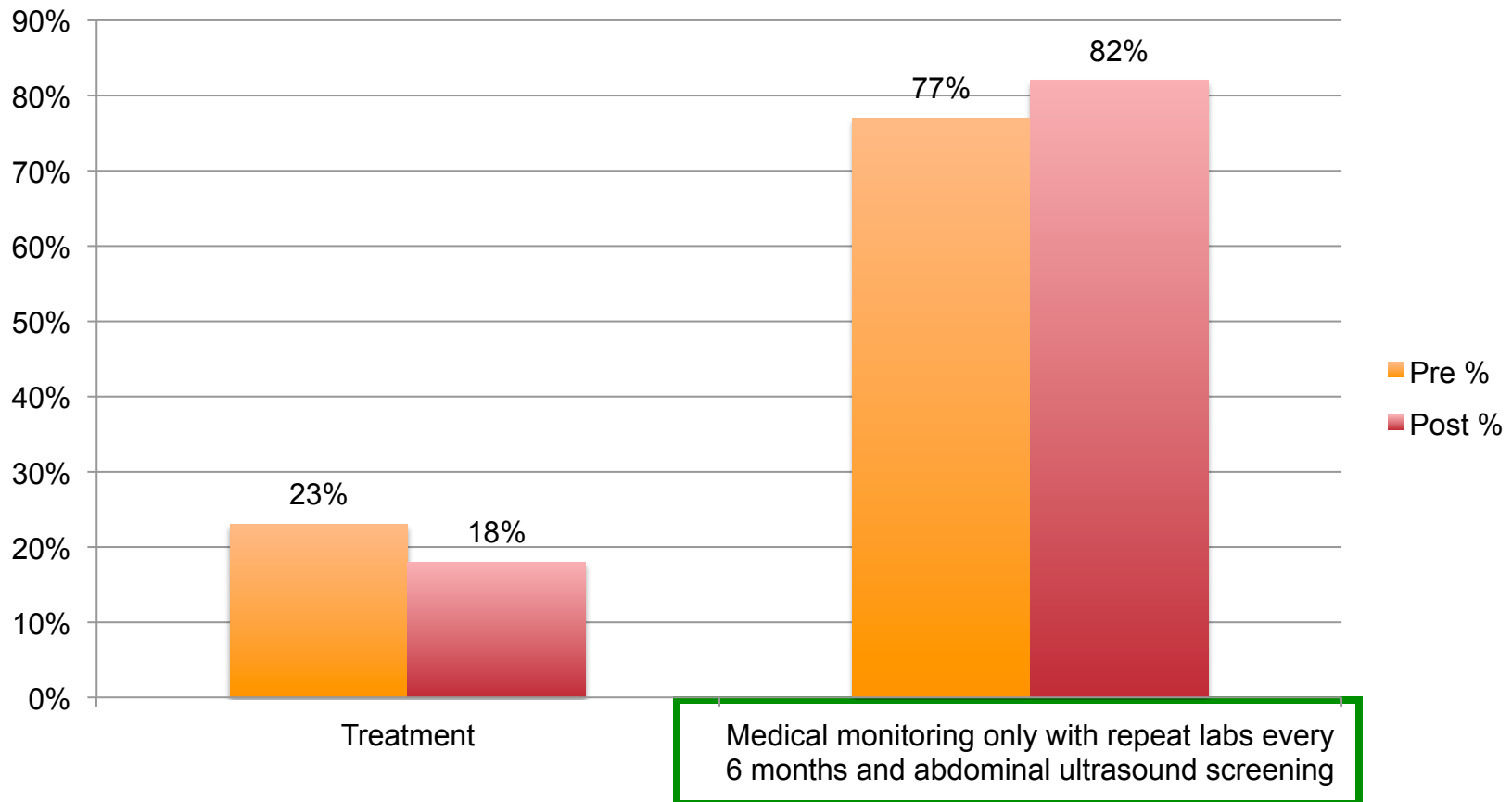
Fibroscan shows no fibrosis

- Ultrasound of the abdomen is normal
- Family history is negative for liver cancer
- HBV DNA 145 IU/mL

Does the Patient Require Treatment or Only Medical Monitoring?

(Learning Objective 3)

P Value: 0.030 - Significant



Pre N= 545

Post N= 538

Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions

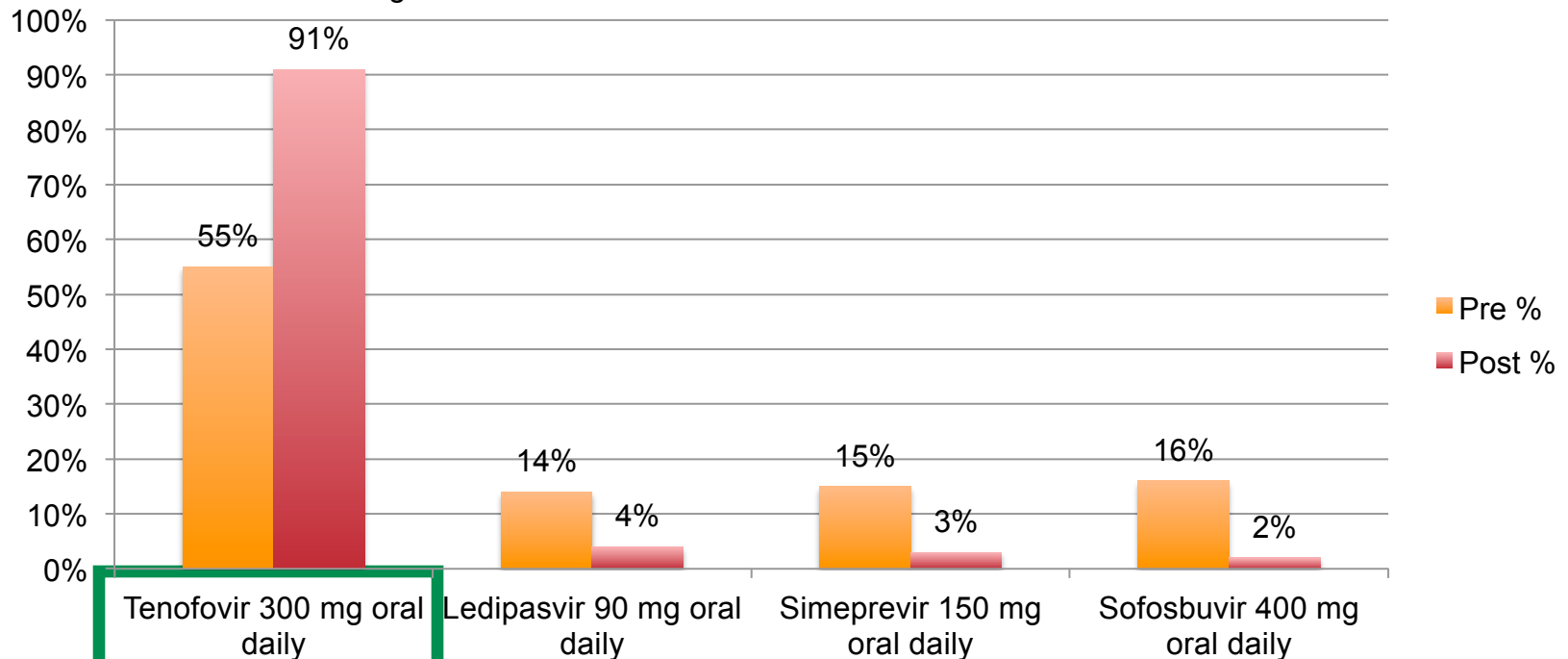
(presented before and after lecture—boxed answer is correct)

On screening of the family members for HBV

- Both sons have been vaccinated and are HBsAb (+)
- Husband, however, is found to be HBsAg (+), HBcAb (+), HBsAb (-), HBeAg (-), HBV DNA 79,000 IU/mL
A Fibroscan shows moderate fibrosis
A screening abdominal US is negative

What would be an appropriate treatment for the patient's husband? (Learning Objective 4)

P Value: <0.001 - Significant



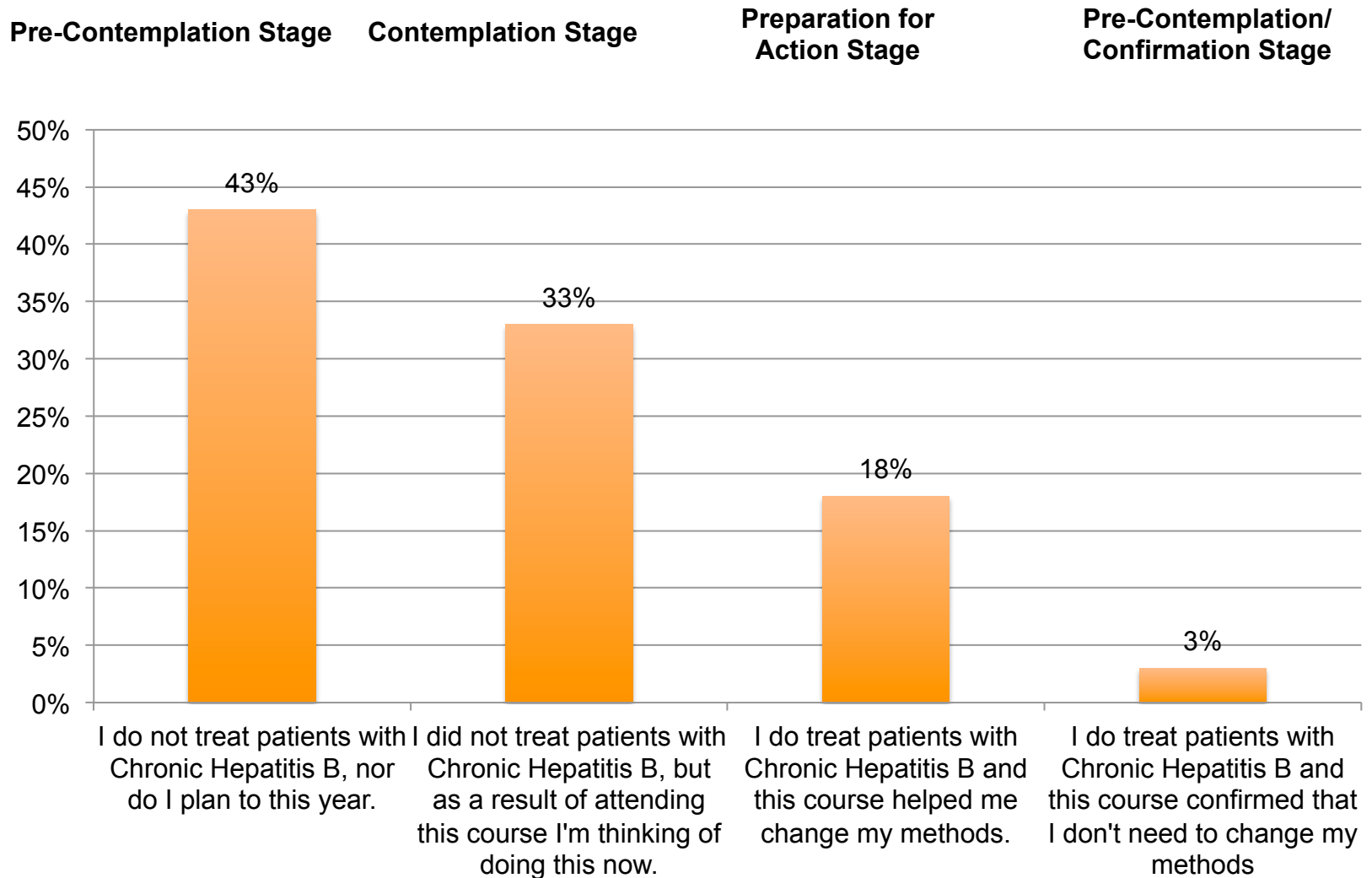
Pre N=455

Post N= 508

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 B ?



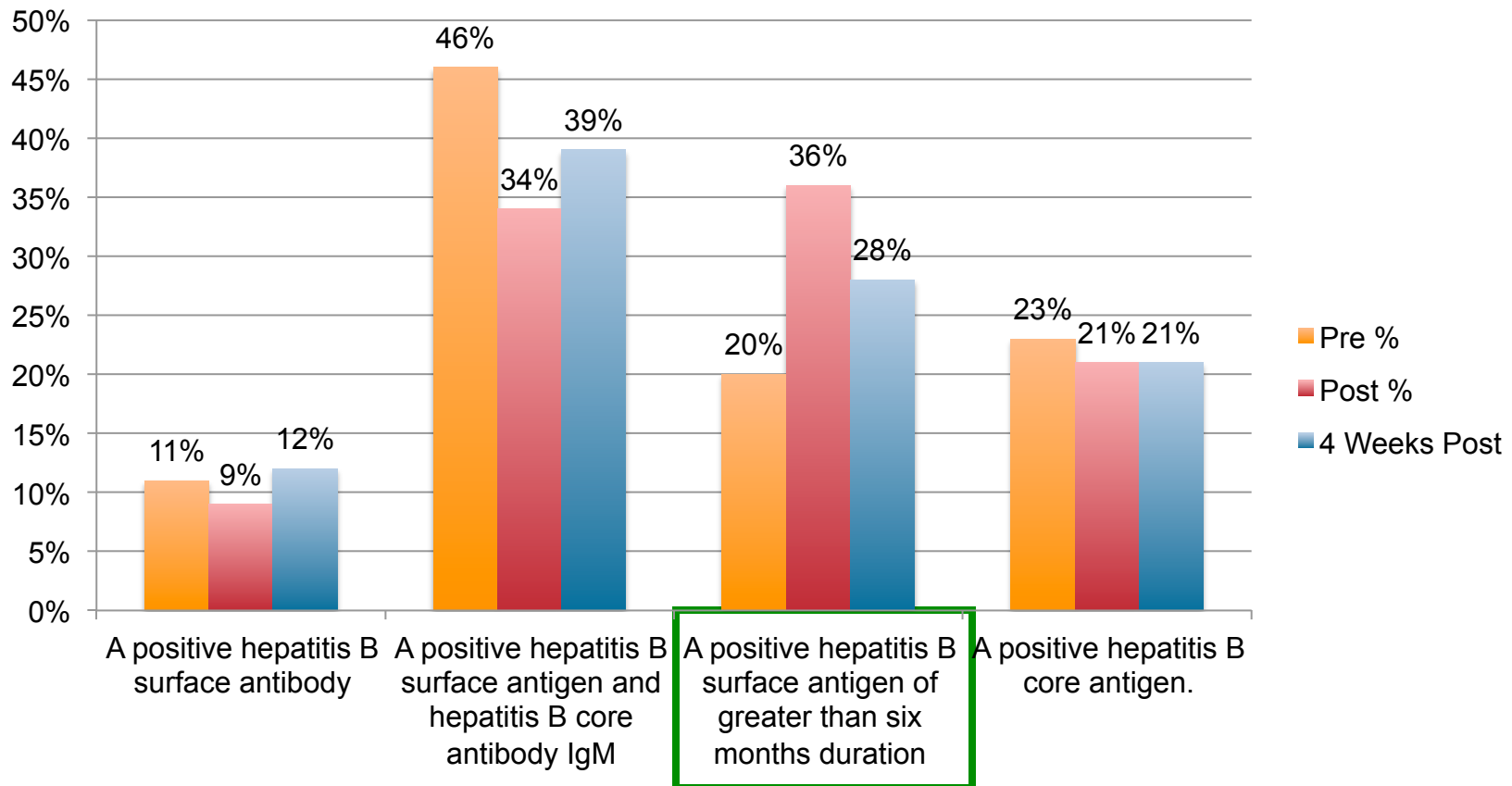
N= 446

Four Week Case Study Questions

(boxed answer is correct)

The first case is 47-year-old woman born in Korea, who came to the United States at 35 years of age. She is HBsAg positive, has no previous history of jaundice or hepatitis, and no current symptoms, and her only notable medical history is mild hypertension. There is no known family history of hepatitis B or HCC. Her husband and 2 sons have not been tested for HBV and should be advised to do so. You decide to screen this patient for Hepatitis B.

Which laboratory test confirms the diagnosis of chronic hepatitis B? (Learning Objective 1)



Pre N= 534 Post N= 545

4 Week Post N = 75

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions

(boxed answer is correct)

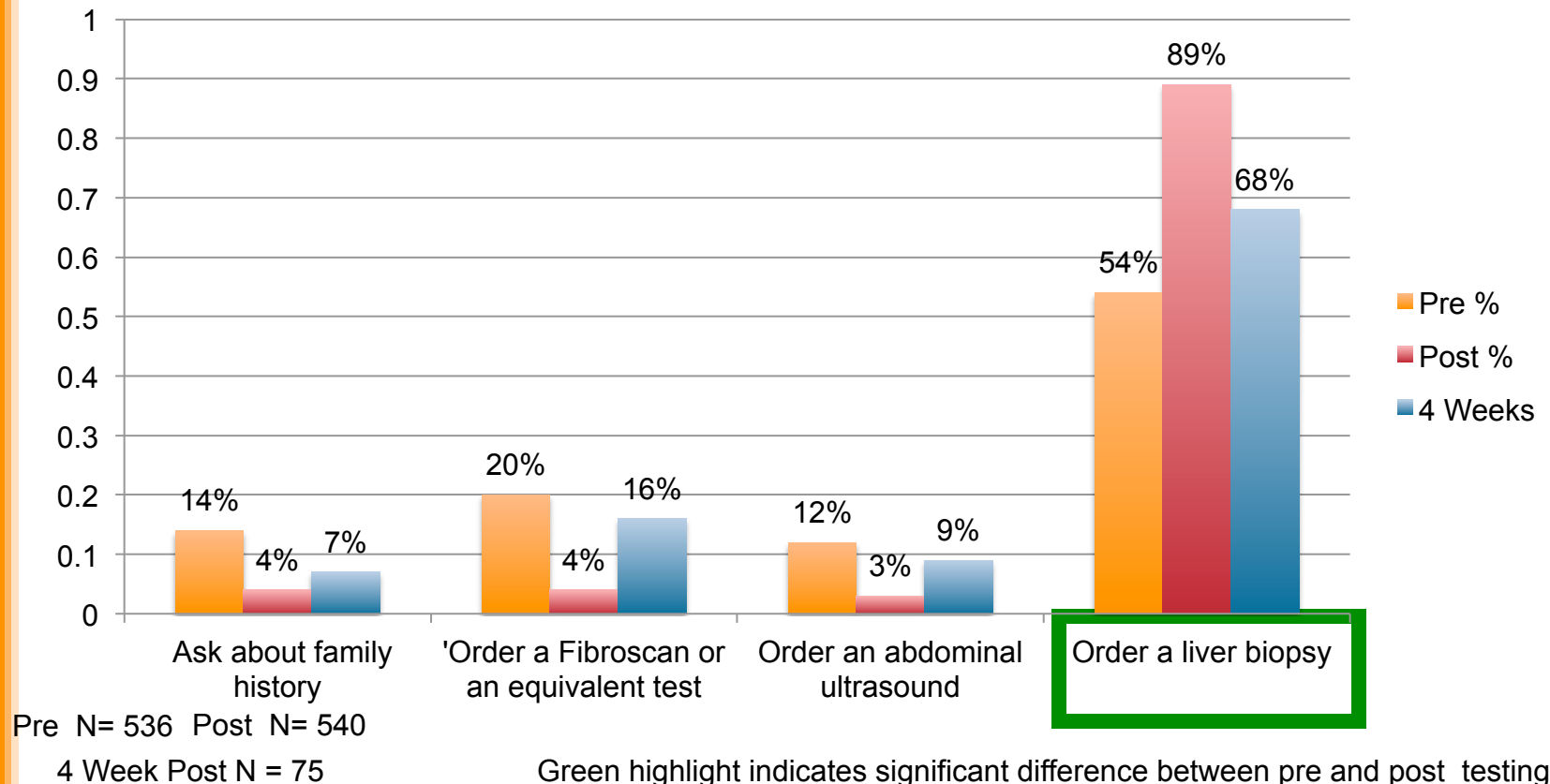
Hepatitis serologies:

HBsAg positive, HBcAb positive, HBsAb negative
HBeAg negative, anti-HBe positive

CBC: WBC 4200 cells/mm³, Hb 13 g/dL, platelets 182,000 cells/mm³

Liver Tests: AST 12 IU/L, ALT 16 IU/L

Which of the following is not essential for determining further management of patients newly diagnosed with chronic hepatitis B? (Learning Objective 2)



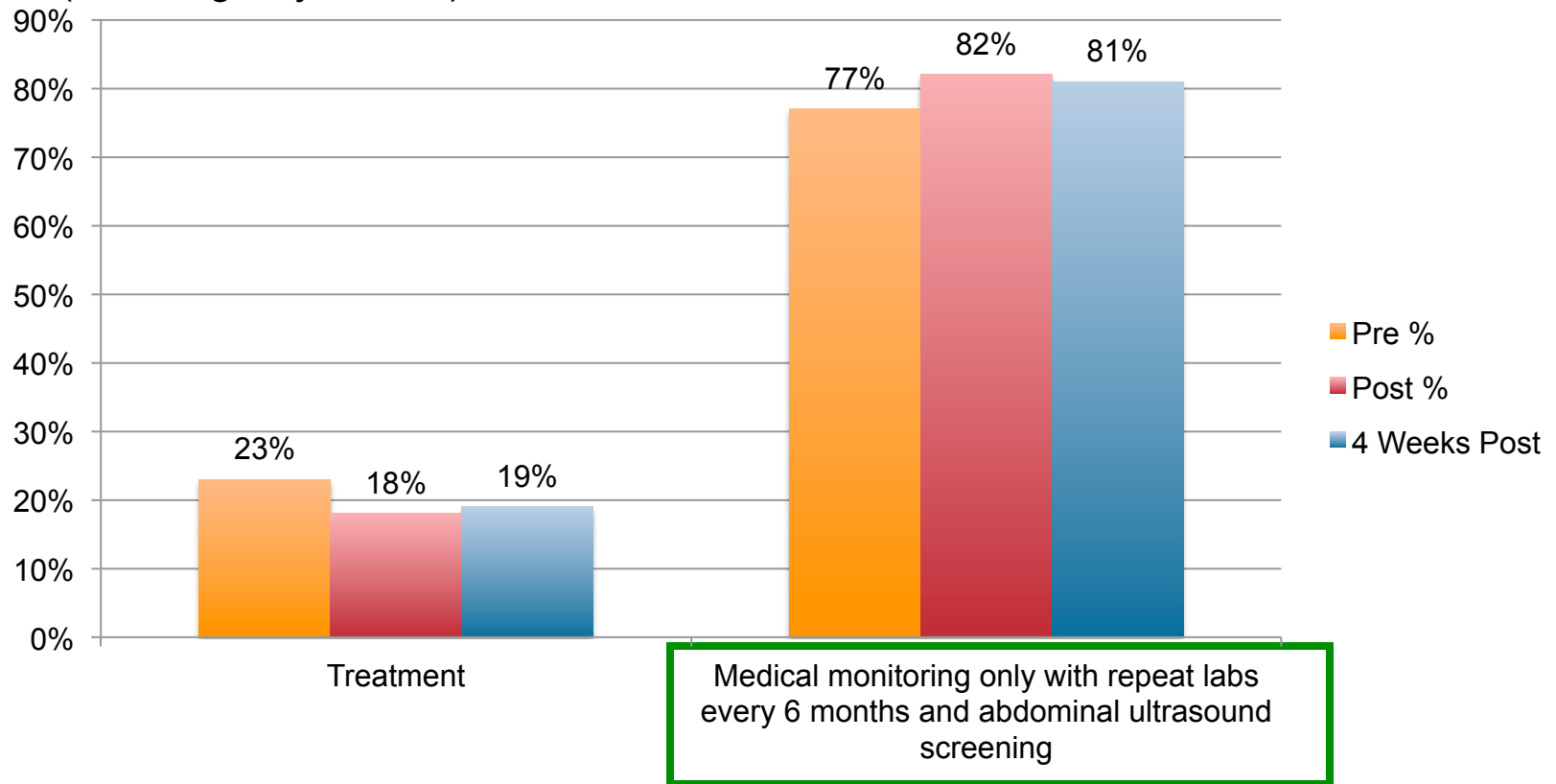
Four Week Case Study Questions

(boxed answer is correct)

Fibroscan shows no fibrosis

- Ultrasound of the abdomen is normal
- Family history is negative for liver cancer
- HBV DNA 145 IU/mL

Does the Patient Require Treatment or Only Medical Monitoring?
(Learning Objective 3)



Pre N= 545 Post N= 538

4 Week Post N = 75

Green highlight indicates significant difference between pre and post testing.

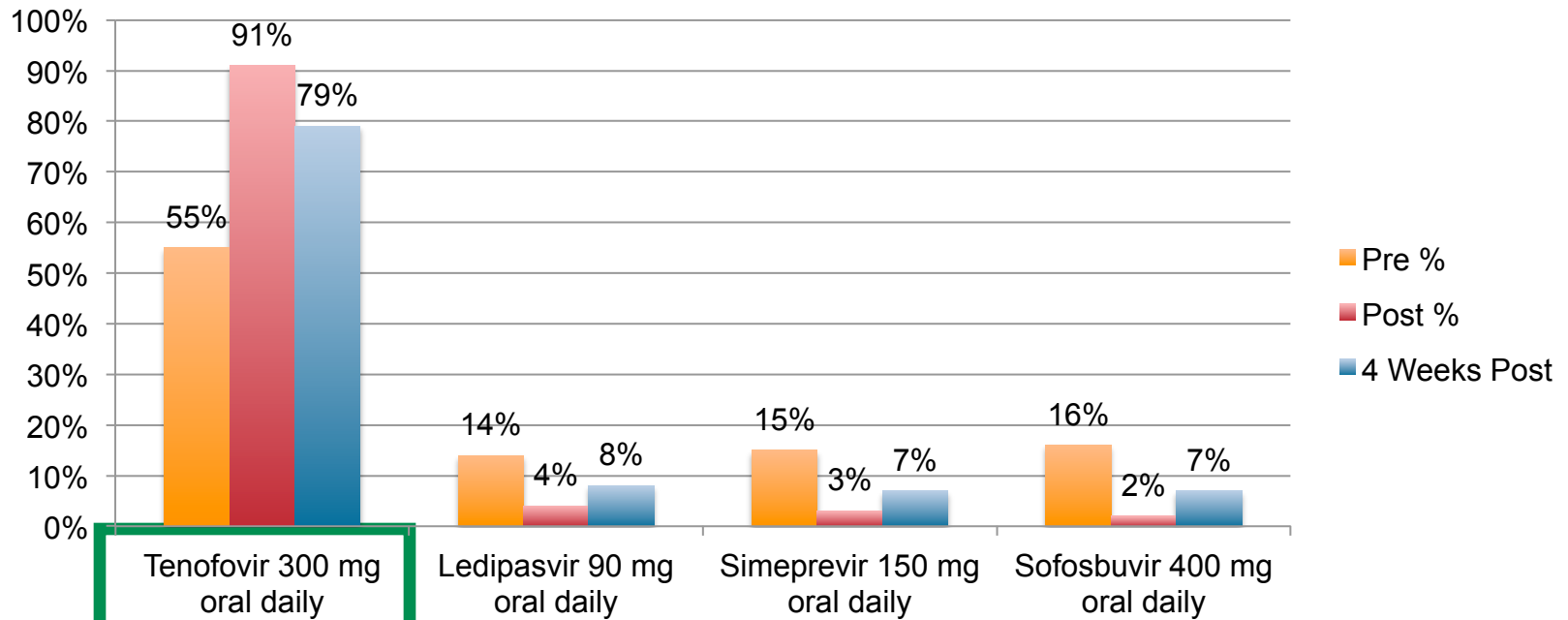
Four Week Case Study Questions

(boxed answer is correct)

On screening of the family members for HBV

- Both sons have been vaccinated and are HBsAb (+)
- Husband, however, is found to be HBsAg (+), HBcAb (+), HBsAb (-), HBeAg (-), HBV DNA 79,000 IU/mL. A Fibroscan shows moderate fibrosis. A screening abdominal US is negative.

What would be an appropriate treatment for the patient's husband? (Learning Objective 4)



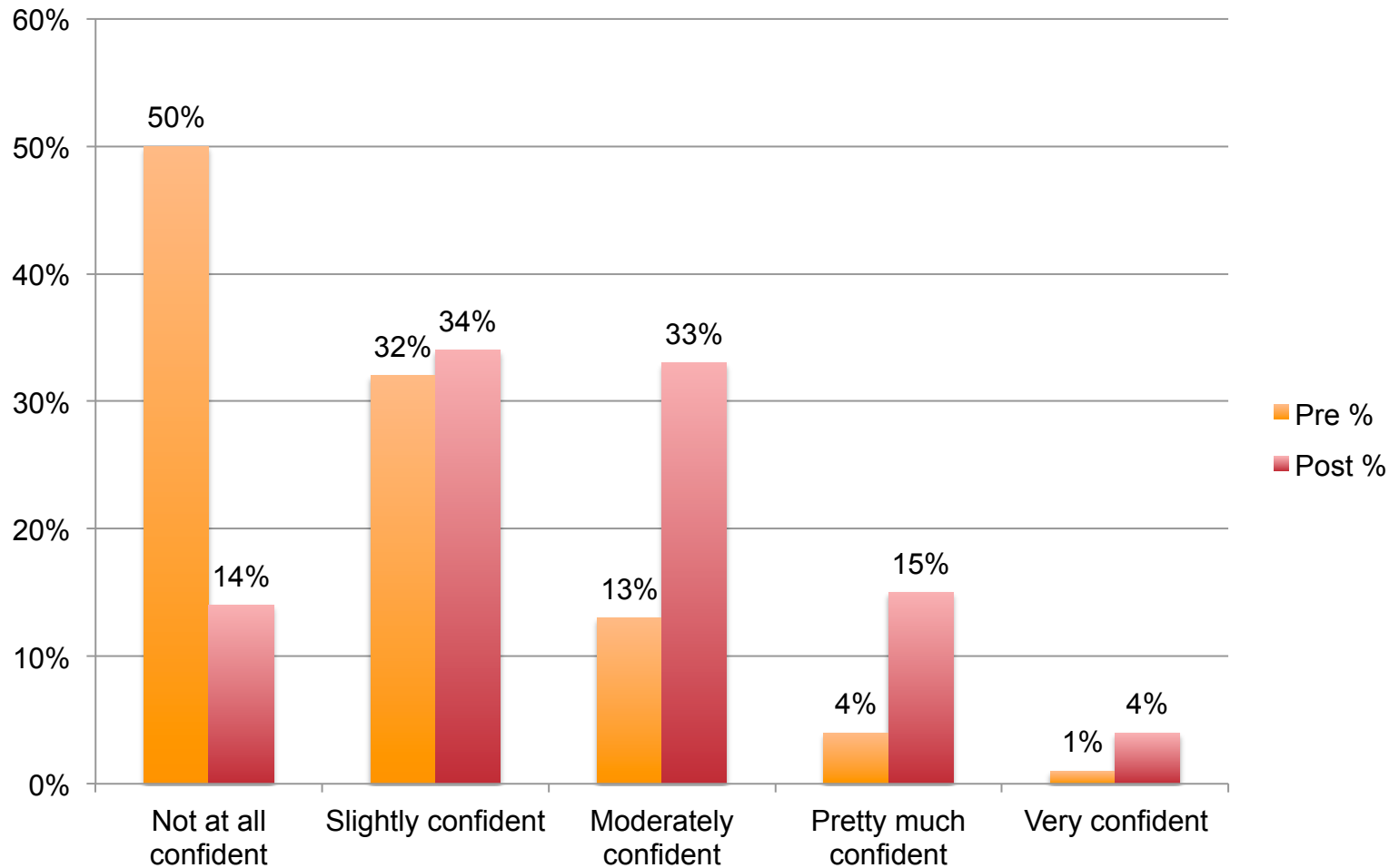
Pre N= 455 Post N= 508

4 Week Post N = 75

Green highlight indicates significant difference between pre and post testing.

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

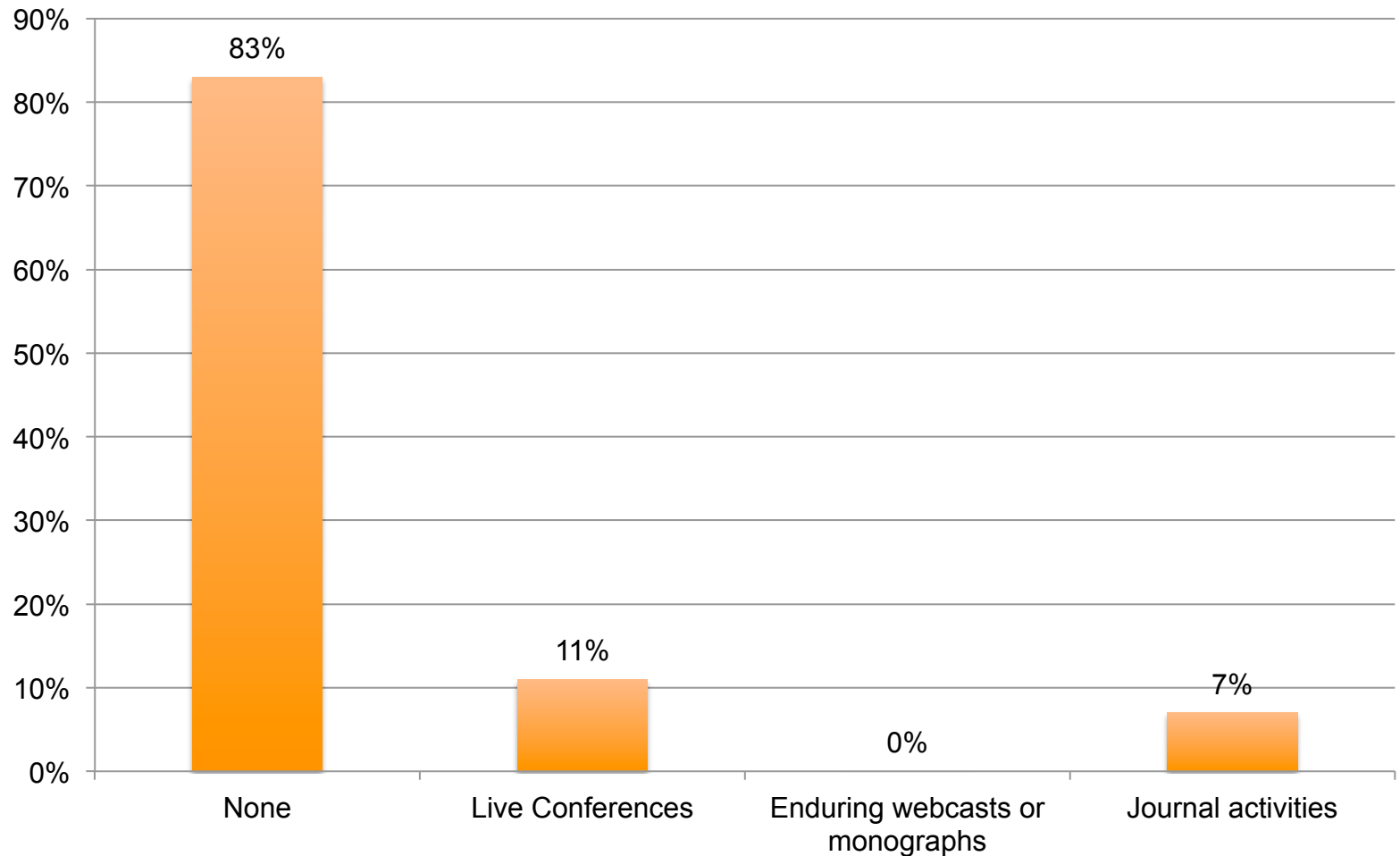
On a scale of 1 to 5, Please rate how confident you would be treating a patient with Chronic Hepatitis B ?



Pre N= 521 Post N= 500

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

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



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

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

(Comments received from attendees at 4 week follow up)

- Understand treatment regimen for hepatitis B
- Know how to follow up patients with Hep B
- Will continue to refer to specialty clinic for treatment
- Ordering appropriate labs
- Screening more often
- More comfortable with advanced testing and monitoring
- Better awareness of condition
- Recognize approved meds
- Informing patients with Hep B about available treatments
- Discussed treatment options with colleagues
- Identify patients at risk and check for Hep C antibody

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

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

(Comments received from attendees at 4 week follow up)

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

Discussion and Implications

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

The need for continued education in the screening, diagnosis and treatment of Hepatitis B 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: are more aware that a positive Hepatitis B surface antigen of 6 months duration is required for a diagnosis of chronic Hepatitis B; understand that a liver biopsy is not required for determining management strategies for a newly diagnosed patient with Hepatitis B; are more likely to recommend monitoring instead of treatment for a patient with low levels of HBV DNA, a normal Fibroscan, negative abdominal ultrasound and negative family history for Liver Cancer; recognize FDA approved treatments for Hepatitis B.

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: 72% of learners are still unclear on lab requirements to make a diagnosis of chronic Hepatitis B; 32% still think they need a liver biopsy to determine appropriate management strategies in a newly diagnosed patient; 19% will recommend drug therapy inappropriately to a low risk patient; and 20% of learners are still not sure what the FDA approved treatments for HBV are.

Discussion and Implications

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

Participants indicated a significant overall increase in self-reported confidence levels in the screening for and management of a patient with Hepatitis B. Moderate to very confident levels rose from 18% to 52% by the end of the program. 33% of learners that were not involved with the management of patients with Hepatitis B are now thinking of it and 18% are planning on changing what they do as a result of this course. 43% of learners remain uncomfortable with actually treating patients with Hepatitis B but the large majority of responses on behavior changes indicated they are much more likely to screen patients at risk. After the program, 85% 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 B, more consistent screening of patients at risk, and more comfort in appropriate lab evaluation to screen and confirm a diagnosis. 83% of attendees had no other exposure to educational materials on this topic 1 month after this program. Barriers to care included lack of patients with Hepatitis B, need for greater knowledge on the subject, insurance coverage, financial barriers, patient compliance and medication costs. 83% 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.

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 B screening and management is necessary for primary care clinicians.