

ABOUT THE PROGRAM

Program Description

This program has been designed to meet the needs of hepatologists, gastroenterologists and other physicians who regularly face the clinical issues and decisions that relate to the treatment of challenging patient populations infected with the hepatitis C virus.

Educational Objectives

This symposium has been designed to prepare the practicing physician to:

- Understand the diagnostic and clinical issues involved in the management of challenging patient populations infected with the hepatitis C virus, including patients with normal ALT levels, patients who relapse or fail to respond to first-line therapy, patients with decompensated cirrhosis, obese patients and patients with NASH, and patients with HCV/HIV coinfection
- Be aware of the most current approaches to diagnose and monitor the above-mentioned challenging patient populations with HCV
- Be familiar with the most current clinical trial results of therapy for these challenging patient populations with HCV

Accreditation

The Stanford University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Credit

The Stanford University School of Medicine designates this educational activity for a maximum of 2 category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the activity.

Policy on Faculty and Sponsor Disclosure

It is the policy of the Stanford University School of Medicine that the faculty and sponsor disclose real or apparent conflicts of interest relating to the topics of this educational activity, and also disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentation(s). Detailed disclosures are enclosed in the course handout materials.

Acknowledgment

The Department of Hepatology at Stanford University School of Medicine gratefully acknowledges the support of Roche Laboratories, Inc.

EMMET B. KEEFFE, MD

Dr. Emmet Keeffe obtained his MD degree from Creighton University in 1969. He completed his postgraduate clinical training in internal medicine and gastroenterology at the Oregon Health & Science University in 1974. He then was a staff physician at the Oakland Naval Regional Medical Center, followed by 2 years of research training in hepatology at the University of California, San Francisco. In 1979, he joined the faculty at the Oregon Health & Science University and rose to the rank of Professor of Medicine. In 1992 he moved to California Pacific Medical Center in San Francisco as Medical Director of the Liver Transplant Program and Chief of the Division of Gastroenterology and Hepatology. In 1995 Dr. Keeffe joined the faculty at Stanford University as Professor of Medicine and was appointed Medical Director of the Liver Transplant Program. He also served as Chief of Clinical Gastroenterology from 1995 to 2000. He is currently Chief of Hepatology and Co-Director of the Liver Transplant Program.

Dr. Keeffe has been very active in national organizations in his field and has held several leadership positions. He is currently serving as the President of the American Gastroenterological Association. In the past, Dr. Keeffe has served from 1991 to 1995 on the Board of Directors of the American Liver Foundation, and from 1994 to 2001 on the Board of Directors of the American Digestive Health Foundation, serving as the Vice Chair of Public Health Programs and Chair of the Digestive Health Initiative from 1997 to 2001. He was the 1995- 96 President of the American Society for Gastrointestinal Endoscopy. He held executive responsibility for Digestive Disease Week as Chair of Digestive Disease Week Council from 2000 to 2002. Since 2001, he has served as a member of the Subspeciality Board on Gastroenterology for the American Board of Internal Medicine.

Dr. Keeffe holds several editorial positions. He was an associate editor of *Liver Transplantation and Surgery* from 1995 to 1999, and is currently associate editor of *Digestive Health & Nutrition* and of *Reviews in Gastroenterological Disorders*, chair of the editorial boards of *Hepatology Watch*[®] and *HBV Watch*[®], section editor of Liver Transplantation for *Current Opinion in Organ Transplantation*, and executive editor of *GastroHep.com*. He also serves on the editorial boards of *Hepatology*, *Journal of Hepatology*, *American Journal of Gastroenterology*, and *Alimentary Pharmacology & Therapeutics* as well as several internet gastroenterology and hepatology editorial boards. His research interests have bridged general and transplant hepatology, with a focus on antiviral therapy of chronic hepatitis, use of hepatitis vaccines and liver transplant selection criteria and outcomes. He has published more than 400 papers, books, book chapters and miscellaneous publications.

Dr. Keeffe has no information to disclose.

GREGORY T. EVERSON, MD, FACP

Dr. Everson received his medical degree from Cornell Medical College, NY, NY, in 1976. He is currently a Professor of Medicine and Director of Hepatology in the Division of Gastroenterology and Hepatology, Department of Internal Medicine, at the University of Colorado.

Dr. Everson is a recipient of both NIH- and industry-sponsored research grants and contracts to study liver disease, liver transplantation, and treat patients with hepatitis C. He is principal investigator of the NIH-sponsored HALT C trial and co-investigator of the NIH-sponsored A2ALL study of Living Donor Liver Transplantation at the University of Colorado Health Sciences Center.

He is an author and contributor to many scientific and clinical publications related to hepatitis C, liver transplantation, and liver disease. In conjunction with his co-author, Hedy Weinberg, he has authored 3 editions of *Living with Hepatitis C: A Survivor's Guide*, one edition of *My Mom has Hepatitis C*, one edition of *Living with Hepatitis B: A Survivor's Guide*, and one edition of *Living with Hemochromatosis: Answers to Your Questions*.

Dr. Everson is a member of the American College of Physicians (fellow), American Gastroenterologic Association, American Association for the Study of Liver Disease, International Liver Transplant Society, and the American Society of Transplantation. He is a former Associate Editor to *Liver Transplantation* as well as a former editor of *Journal of Lipid Research*, and currently serves as a reviewer for numerous scientific and medical journals.

Dr. Everson has disclosed the following:

- Has received grants/research support from Roche Laboratories, Inc., Schering-Plough Corporation, Ortho Biotech and InterMune Inc.
- Has acted as a consultant for Roche Laboratories, Inc., Schering-Plough Corporation, Ortho Biotech and InterMune Inc.
- Has served on the speaker's bureau for Roche Laboratories, Inc., Schering-Plough Corporation, Ortho Biotech and InterMune Inc.
- Intends to reference unlabeled/unapproved uses of drugs or products in his presentation.

STEPHEN A. HARRISON, MD

Stephen A. Harrison, MD received his medical degree from University of Mississippi School of Medicine in 1995. Previously, he earned his BA in biology from University of Mississippi in 1991.

Presently, Dr. Harrison is a Major in the United States Army and Chief of Hepatology, Brooke Army Medical Center in San Antonio, Texas. Dr. Harrison is also Assistant Professor, Department of Medicine, Division of Gastroenterology, at University of Texas Health Science Center in San Antonio.

Dr. Harrison completed his gastroenterology fellowship, residency in internal medicine, and internship in internal medicine at Brooke Army Medical Center in Fort Sam Houston, Texas 2002, 1998 and 1996, respectively.

Dr. Harrison is a Diplomat of the American Board of Internal Medicine and a Diplomat to the Subspecialty Board in Gastroenterology.

An accomplished author, Dr. Harrison has most recently published in *Hepatology*, *Clinics in Liver Disease*, the *American Journal of Gastroenterology*, *Drugs*, and *Journal of Hepatology*.

Dr. Harrison has no information to disclose.

WILLIAM M. LEE, MD

Since 1990, William M. Lee, MD has been a Professor of Internal Medicine and Director of the Clinical Center for Liver Diseases at the University of Texas Southwestern in Dallas, Texas. Additionally, Dr. Lee currently holds the position of the Meredith Mosle Chair in Liver Diseases.

In 1963, Dr. Lee earned his BA degree from Amherst College, and went on to earn his medical degree in 1967 from Columbia University College of Physicians and Surgeons.

From 2002 to 2003, Dr. Lee held the position of Meredith Mosle Distinguished Professor of Liver Diseases at University of Texas Southwestern Medical School. From 1980 to 1989, he was Assistant/Associate Professor at the Medical University of South Carolina. Prior to that, Dr. Lee was Assistant Professor of Clinical Medicine at Columbia University College of Physicians and Surgeons in New York from 1974 to 1980.

Dr. Lee was a Research Fellow and Honorary Registrar in the Liver Unit at Kings College Hospital Medical School from 1973 to 1974 and was Chief Resident in Medicine at Presbyterian Hospital, New York from 1972 to 1973.

Currently, Dr. Lee is a consultant to the Food and Drug Administration Nonprescription Drug Advisory Committee and the White House Office of Narcotic Drug Control Policy.

An accomplished author, Dr. Lee has written and published over 140 peer-reviewed articles, as well as books, chapters, editorials and review articles. Some of his most recently published articles appeared in *Hepatology*, *Gastroenterology*, *Journal of Infectious Disease* and *Annals of Internal Medicine*.

Dr. Lee is a recipient of both NIH and industry-sponsored research grants to study liver disease and hepatitis, and is involved in numerous ongoing trials.

Dr. Lee has disclosed the following:

- Has received grants/research support from Amgen, GlaxoSmithKline, Gilead Sciences, Roche Laboratories, Inc., Schering-Plough Corporation, Bristol-Myers Squibb Company, AKROS Pharma Inc. and Vertex Pharmaceuticals Incorporated.
- Intends to reference unlabeled/unapproved uses of drugs or products in his presentation.

KENNETH E. SHERMAN, MD, PhD

Kenneth E. Sherman, MD, PhD received his BS & PhD from Rutgers University and his MD from George Washington University. He holds an endowed chair as the Gould Professor of Medicine and serves as the Director of the Division of Digestive Diseases at the University of Cincinnati College Of Medicine. Dr. Sherman is the author of numerous articles, abstracts and book chapters on viral hepatitis. Recent credits include articles in the *New England Journal of Medicine*, *Archives of Internal Medicine*, *Clinical Infectious Diseases*, *Gastroenterology*, *Hepatology*, *Journal of Acquired Immune Deficiency Syndrome*, and the *Journal of Infectious Diseases*.

His research focus involves the pathogenesis, evaluation and treatment of liver disease in immunosuppressed patients, including those with HIV. He serves as a member of the FDA Antiviral Advisory Committee, the AGA Ethics Committee, the AASLD Membership Committee and is a member of the Editorial Board of the American Journal of Gastroenterology, Current Hepatitis Reports, and Chinese Hepatology.

Dr. Sherman has disclosed the following:

- Has received grants/research support from Roche Laboratories Inc., Schering-Plough Corporation, SciClone Pharmaceuticals, Inc. and InterMune Inc.
- Has acted as a consultant for SciClone Pharmaceuticals, Inc.
- Has served on the speaker's bureau for Roche Laboratories Inc. and Schering-Plough Corporation.
- Intends to reference unlabeled/unapproved uses of drugs or products in his presentation.

STEFAN ZEUZEM, MD

Stefan Zeuzem, MD, is Professor of Internal Medicine and Director and Chairman of the Department of Internal Medicine, Gastroenterology, Hepatology, and Endocrinology at Saarland University Hospital in Homburg/Saar, Germany.

Dr. Zeuzem received his medical training at the Johann Wolfgang Goethe University in Frankfurt am Main, Germany, the University of Cambridge School of Clinical Medicine, and the University of Newcastle upon Tyne Medical School, both in the United Kingdom. After graduating, he completed his fellowships in endocrinology and gastroenterology at University Hospital in Frankfurt. He conducted research sabbaticals at the Royal Victorian Infirmary Department of Medicine and Clinical Biochemistry in Newcastle upon Tyne, the Max Planck Institute of Biophysics in Frankfurt, and Yale University School of Medicine Howard Hughes Medical Institute and Boyer Center for Molecular Medicine in New Haven, Connecticut.

Dr. Zeuzem's research interests include cellular physiology, the molecular biology of hepatitis viruses, viral kinetics, the role of hepatitis C in hepatocarcinogenesis, and the stratification and optimization of antiviral treatment. He has authored or coauthored articles concerning these and other related topics in internal medicine. His articles are published in prestigious scientific journals such as the *New England Journal of Medicine*, *The Lancet*, *Gastroenterology*, *Hepatology*, *Journal of Virology*, *Journal of Biological Chemistry*, and *Oncogene*. Dr. Zeuzem is the recipient of the Thannhauser Award of the German Association of Digestive and Metabolic Diseases (DGVS).

Dr. Zeuzem has disclosed the following:

- Has acted as a consultant for Schering-Plough Corporation and Hoffman La-Roche, Inc.
- Has served on the speaker's bureau for Schering-Plough Corporation and Hoffman La-Roche, Inc.

**Stanford University School of Medicine
Department of Hepatology**

“HCV: Optimizing Treatment of Challenging Patient Populations”

***An Educational CD from a Satellite Symposium Held During the
2004 AASLD Annual Meeting***

CD--CME Activity – Quiz

To receive the 2.0 category I credits of CME credit, you must complete the following quiz satisfactorily (70% correct answers) and MAIL to:

**Stanford University
Attn: Kari Costa
251 Campus Drive
MSOB X-3C35
Stanford, CA**

***Please circle the correct response**

1. Based on a prospective cohort study among 94,533 men and 47,522 women, the serum aminotransferase concentration is directly associated with mortality from liver disease, even within the current normal range. This statement is:
 - a. True
 - b. False
2. The updated upper limit of normal ALT level for males is 30 U/L, and for females is 19 U/L. This statement is:
 - a. True
 - b. False
3. Predictors of favorable response to antiviral therapy of HCV include all of the following EXCEPT:
 - a. HCV RNA: <800,000 IU/mL
 - b. Ethnicity: Caucasian vs African American
 - c. Genotype: 1 or 4
 - d. Presence of an EVR at week 12 of therapy
4. Based on the results of the lead-in phase of the HALT-C Trial among 1045 patients, the following conclusions can be drawn:
 - a. Dose reduction has a negative impact in the first 24 weeks of therapy
 - b. Reducing the dose of peginterferon alfa-2a to ≤60% adversely affected SVR
 - c. Ribavirin dose can be reduced to ≤60% without affecting SVR as long as ribavirin is not discontinued
 - d. All of the above

5. In patients with compensated cirrhosis, antiviral therapy is effective and has the potential for major benefit, including:
 - a. Halt disease progression
 - b. Reduce need for transplantation
 - c. Potentially reduce the risk of HCC
 - d. All of the above

6. Host factors associated with co-existent HCV and steatosis include all of the following except:
 - a. Obesity
 - b. Diabetes mellitus
 - c. Lack of regular exercise
 - d. Insulin resistance

7. In patients with hepatitis C, steatosis and steatohepatitis decrease SVR rates. This statement is:
 - a. True
 - b. False

8. Factors supporting a decision to treat a patients with HIV/HCV coinfection include all of the following EXCEPT:
 - a. Increased rate of disease progression with coinfection
 - b. Potential drug interactions between anti-HCV and anti-HIV agents
 - c. Increased liver-associated morbidity with coinfection
 - d. Ability to achieve viral clearance in some patients

9. Key treatment response factors in HIV/HCV coinfection include HCV viral load, HCV genotype and quasispecies, CD4+ cell count, presence of cirrhosis and adherence to regimen. This statement is:
 - a. True
 - b. False

10. The largest multi-center, randomized, controlled clinical trial of peginterferon plus ribavirin therapy in HIV/HCV coinfection is:
 - a. The ACTG5071 Study
 - b. The RIBAVIC Study
 - c. THE APRICOT Study

PLEASE PRINT

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

I claim _____ category 1 credits (up to 2.0 AMA/PRA credits)

Signature