

Management of Hepatitis B: 2006

National Institutes of Health Workshop

April 6-8, 2006

**Natcher Auditorium
NIH Ca.m.pus
Bethesda, MD**

Organizers:

**Anna Lok, John Vierling, T. Jake Liang,
Russell Fleischer, Edward Doo, and Jay H. Hoofnagle**

Aims of the meeting: To assess current understanding of hepatitis B virus (HBV), the disease that it causes, and its optimal management; and to make recommendations for directions for future research, both basic and clinical. Topics will include HBV replication and mode of inducing chronicity, the immunology of hepatitis B, the virus-host interactions, the natural history of chronic infection, and up-to-date results of trials of antiviral therapies, including peginterferon, lamivudine, adefovir dipivoxil, tenofovir, entecavir, and LdT alone and in combination. Histological, clinical, and virological endpoints of therapy and the needs for future research will be discussed. The meeting will be sponsored by the Liver Disease Research Branch of the Division of Digestive Diseases and Nutrition of NIDDK in collaboration with the American Association for the Study of Liver Disease (AASLD), the American Liver Foundation, the Hepatitis B Foundation and Hepatitis Foundation International. A summary of the meeting and these recommendations will be submitted for publication.

In preparation for the meeting, the following documents will be prepared:

1. Standardized definitions of response and endpoints of therapy.
2. Guidelines for the format of presentation of results of clinical trials.

Day 1: Thursday, April 6, 2006

8:30 a.m. Welcome and Aims Jay Hoofnagle

Session 1: *Virology and Pathogenesis*: Moderators: Ed Doo and Jack Wands

8:40 a.m. HBV Replication William Mason
9:00 a.m. HBV Pathogenesis Stefan Wieland
9:20 a.m. HBV Immunology Barbara Rehermann
9:40 a.m. Discussion (30 minutes)

10:10 a.m. **Break (30 minutes)**

Session 2: *Natural History*: Moderators: Leonard Seeff and Patrick Marcellin

10:40 a.m. Natural History in Asian Cohorts Jia-Horng Kao
11:00 a.m. Natural History in European Countries Solko Schalm
11:20 a.m. Liver Histology Zachery Goodman
11:40 a.m. Fibrosis Markers Robert Fontana
12:00 noon Discussion (30 minutes)

12:30 p.m. Lunch (60 minutes)

Session 3: *Therapy and Mechanisms*: Moderators: Jenny Heathcote and Ray Chung

1:30 p.m. Overview of Therapy Anna Lok
1:50 p.m. Tests for HBV Jean-Michel Pawlotsky
2:10 p.m. The Woodchuck Model of HBV Brent Korba
2:30 p.m. Mechanisms of Action of Antivirals Loren Tyrrell
2:50 p.m. Discussion (20 minutes)

3:10 p.m. Break (20 minutes)

Session 4: *Monotherapy for Hepatitis B*: Moderators: Jay Hoofnagle and Norah Terrault

3:30 p.m. Peginterferon Alfredo Alberti
3:50 p.m. La.m.ivudine Marc Ghany
4:10 p.m. LdT Adrian Di Bisceglie
4:30 p.m. Adefovir dipivoxil Stephanos Hadziyannis
4:50 p.m. Tenofovir and FTC Marion Peters
5:10 p.m. Entecavir Eugene Schiff
5:30 p.m. Discussion (30 minutes)

6:00 p.m. Poster Review Reception (Natcher Auditorium Lobby)

Day 2: Friday, April 7, 2006

Session 5: *Viral Issues in Therapy*: Moderators: Anna Lok and Daryl Lau

8:30 a.m.	Viral Kinetics in HBV	Avidan Neumann
8:50 a.m.	Viral Resistance in HBV	Stephen Locarnini
9:10 a.m.	Clinical Issues in Viral Resistance	Fabien Zoulim
9:30 a.m.	HBV DNA, Genotypes and Responses	Harry Janssen
9:50 a.m.	Discussion (30 minutes)	

10:20 a.m. Break (30 minutes)

Session 6: *Combination Therapy of HBV*: Moderators: Jake Liang and John Vierling

10:50 a.m.	Overview of Combination Therapy	Jenny Heathcote
11:10 a.m.	Nucleoside Combinations	Robert Perrillo
11:30 a.m.	Peginterferon and Nucleosides	Patrick Marcellin
11:50 a.m.	Discussion (40 minutes)	

12:30 p.m. Lunch (60 minutes)

Session 7: *Special Populations and Special Issues*: Moderators: Jules Dienstag and Eugene Schiff

1:30 p.m.	Children with HBV	Jean Molleston
1:50 p.m.	Decompensated Liver Disease	Norah Terrault
2:10 p.m.	HBV/HIV Coinfection	Chloe Thio
2:30 p.m.	Chemotherapy and Immune Suppression	George Lau
2:50 p.m.	Discussion (25 minutes)	

3:15 p.m. Break (30 min)

Session 8: *Safety and Cost Issues*: Moderators: Russ Fleischer and Robert Fontana

3:45 p.m.	Prevention of Maternal-Infant Spread	Tony H.H. Chen
4:05 p.m.	Safety of Therapy During Pregnancy	Brenda Ross
4:25 p.m.	Costs of Therapy	John Wong
4:45 p.m.	Complications of Therapy	John Vierling
5:05 p.m.	Discussion (25 minutes)	

5:30 p.m. Adjournment

Day 3: Saturday, April 8, 2006

Session 9: *Special Situations and Future Therapy*: Moderators: Robert Perrillo and Tim Block

8:30 a.m.	Acute Hepatitis B	Jay Hoofnagle
8:50 a.m.	Prevention of HCC	Yun Fan Liaw
9:10 a.m.	Future Therapies	T. Jake Liang
9:30 a.m.	Design Issues in Future Studies	Russ Fleischer
9:50 a.m.	Discussion (30 minutes)	

10:20 a.m. Break (30 minutes)

Session 10: Conclusions and Recommendations

10:50 a.m. *Discussion: Indications for Therapy of Chronic Hepatitis B*: Moderators: Jay Hoofnagle, Jules Dienstag, Anna Lok, and John Vierling.

12:00 noon Adjournment