

B HEPATITIS B

INFORMED

INSIDE

HBV Clinical Endpoints p.3

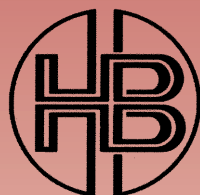
*Highlights from p.8
HepDART 2003*

*NIH Action Plan for p.9
Liver Disease Research*

*Andrew Lee Wise p.11
1978 - 2002*



*National Library of p.13
Medicine Tutorial
Goes Live Online!*



CAUSE FOR A CURE

We are a national non-profit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide.

TRADING IVY FOR PALM TREES

9th Annual Princeton Workshop Meets in Hawaii

Since 1995, the Hepatitis B Foundation (HBF) has sponsored the annual Princeton Workshop to stimulate scientific dialogue about critical issues in the development of therapies for chronic hepatitis B. The HBF invites 20 to 30 thought leaders in the field from academia, government and industry to gather for intense round table discussions.

Princeton, NJ, is certainly a good place for big thinking. However, when the offer came to host the Princeton Workshop in Hawaii every other year, there wasn't a lot of resistance. Everyone was happy to trade ivy-covered buildings for a tropical resort with swaying palm trees.

On December 16, 2003, the HBF's 9th annual Princeton Workshop was held as a special session for the second time at the HepDART conference in Kauai, Hawaii (page 8). The HBF sponsored session focused on surrogate markers used for evaluating the effectiveness of current and future hepatitis therapies.

The session began with an excellent overview by **Joan Block, RN**, HBF co-founder and senior advisor, about the HBF's expanding outreach efforts and the wave of cooperation between nonprofit organizations and public health agencies to create national initiatives highlighting hepatitis B and C, such as the Liver Disease Research Branch at the National Institutes of Health, National Viral Hepatitis Roundtable, National Task Force on Hepatitis B for Asian American and Pacific Islanders, and the American Liver Foundation's THINK Hepatitis B Campaign.

Scientific presentations about the proteomics of early disease detection and the surrogate markers used for evaluating the effectiveness of hepatitis treatments were given by a distinguished panel: **Timothy Block, PhD**, HBF president (Thomas Jefferson University);

W. Thomas London, MD, HBF board member (Fox Chase Cancer Ctr.); **Adrian DiBisceglie, MD** (St. Louis University of Health Sciences Center); and **Michael Fried, MD** (U. of North Carolina, Chapel Hill).

There was a lively discussion of how best to monitor people with viral hepatitis for signs of illness. This is of particular concern in evaluating the usefulness of new or experimental drugs and was the subject of last year's Princeton Workshop. Thus, this year's workshop session was an important follow-up with

new information discussed.

Historically, the liver biopsy has been considered to be the "gold standard" of treatment. However, this is expensive, comes with some risks to the patient, and inconveniences the patient for at least an entire day. The question is, in light of new information discussed at this year's Workshop, is a liver biopsy still necessary, or can other "surrogates" or substitutes be used instead?

There are currently two general categories of blood tests used to follow chronic hepatitis B infections. These blood tests monitor "markers" of liver function (i.e. ALT, AFP) or virologic function (i.e. sAg, eAg, HBV DNA).



Drs. Timothy Block (left) and Tom London co-chair Princeton Workshop session at the HepDART meeting in Hawaii (December 16, 2003)



Message from the President

Timothy M. Block, Ph.D.

Hepatitis B Can Be Solved

The Centers for Disease Control (CDC) recently announced that the incidence of hepatitis B infection has decreased dramatically in the U.S. over the past 10 years, as reported on page 7. That is very big news and was picked up by all the major broadcast and print media.

The decline in new hepatitis B infections is also good news because it will ultimately translate into thousands of lives being spared the untoward consequences of chronic hepatitis B disease. This decrease is a direct result of universal vaccine programs and underscores the effectiveness of immunization and awareness efforts. It makes clear, in a way little else can, that hepatitis B is a problem that can be solved.

Since most people who are infected with hepatitis B are unaware of their infection, it is difficult to identify and vaccinate everyone who may be at high risk. Therefore, universal vaccine programs are clearly very important to stopping the further spread of the hepatitis B virus.

The CDC and the Hepatitis B Foundation (HBF), as well as the other national nonprofit and public health organizations that have been campaigning relentlessly for prevention, can take great pride in this historic progress.

Of course, the vaccine remains of little use for the 400 million people who are already infected with hepatitis B. Offering current therapies, where appropriate, and discovery of more effective therapies must continue to be a priority. However, if people are unaware of their infection, it is almost impossible to reach them, and ultimately, help them.

Thus, the importance of reaching and helping those already infected must not be overlooked even as we celebrate the decline of new infections. This will require increased awareness and outreach efforts that are customized for different audiences and cultures. Initiatives such as the new Liver Disease Research Branch of the NIH and the National Viral Hepatitis Roundtable, with which the Hepatitis B Foundation is involved, are good starting points (page 9).

We remain passionate and committed to outreach to those who already infected, as well as to promoting universal vaccination against hepatitis B. We cannot leave anyone behind.

In The News



Killer In China Inspires Movement Against HBV Discrimination

Zhou Yichao, rejected for a public servant job in Jiaying because he tested positive for hepatitis B, killed one official who denied his application and seriously wounded another. The plight of Zhou, now on death row, has inspired a national movement against discriminatory hiring practices and lack of legal redress. More than 120 million people in China are chronic carriers of hepatitis B. Many, like Zhou, show no symptoms and should not pose a threat to co-workers. Zhang Xianzhu, another recent college graduate rejected by a state employer after his positive hepatitis B test, filed the country's first discrimination lawsuit against the government. "I did it because there are so many people like me locked out of jobs and rotting in their little dark corners of the world," Zhang said. "We are talking about people driven by the power of despair," said another hepatitis B carrier who would not reveal his name for fear of jeopardizing his job. "Without work, how can we survive? Society has to do something to reduce the social pressure and preserve our basic human rights." [CDC HIV/STD/ITB Prevention News Update, 1/16/04, www.cdcnpin.org]

Hepatitis B Sufferers Compensated Millions

The Sapporo High Court in Japan ordered the government to pay a combined 16.5 million yen to three people who said they contracted the hepatitis B virus in their childhood through mandatory vaccinations. The high court supported the plaintiffs' claim that the government was negligent for allowing doctors to repeatedly use the same hypodermic needles when performing group vaccinations at public health centers. The plaintiffs said the inoculations must have caused their infections because they had never received blood transfusions and their families have no record of hepatitis. This was the first lawsuit in Japan involving hepatitis B infections claimed to have been contracted through inoculations. Prior to 1994, vaccinations against several diseases were mandated by the government, but following a number of lawsuits involving side effects from inoculations, such vaccinations are now only recommended. Currently, around 1.5 million people are infected with the hepatitis B virus in Japan. [The Japan Times, 1/17/04, www.japantimes.co]

Liver Cancer Still a Risk for Occult HBV Infections

Findings from a new study in Gastroenterology Jan. 2004 suggest that infection with the hepatitis B virus promotes oncogenesis [development of cancer] even in the absence of circulating surface antigen. Known as "occult" HBV infection, this type of hidden infection occurs when HBV is detectable in liver tissues but not in the blood. Whether occult infection, like standard infection, is associated with hepatocellular carcinoma (HCC) has been unclear. To investigate, researchers from the University of Messina in Italy tested for HBV in liver tissue obtained from 107 patients with HCC and 192 patients with chronic liver disease. All of the patients tested negative for hepatitis B surface antigen. "Our study definitively shows that HBV also maintains its oncogenic role in the case of occult infection," the researchers state. Therefore, surface antigen-negative patients with progressive liver disease should probably be tested for tissue HBV to assess their risk of liver cancer. [HBV Research List, 1/23/04, http://archive.mail-list.com/hbv_research]

As New Drugs Enter the Market, Clinical Endpoints Still Controversial

As new, more powerful anti-hepatitis B virus (HBV) drugs enter the marketplace, physicians are increasingly confronting the question, "What is the best way to tell if a drug is working?"

Because HBV infection-related diseases such as liver cancer or cirrhosis often takes years, if not decades, to develop, directly testing a drug's effectiveness in preventing or blunting illness is difficult if not impractical. As a result, substitute or "surrogate" markers and so-called "clinical endpoints" are used.

"The availability of new therapies makes it more important for doctors to know where their patients are in the continuum of the disease," said **Timothy Block, PhD**, professor and director of the Jefferson Center for Biomedical Research of Jefferson Medical College in Philadelphia. "Now patients ask, is it time [in the course of my infection] for me to be treated?"

The gold standard of surrogate markers is the liver biopsy, which looks for reductions in liver inflammation and fibrous tissue, two hallmarks of HBV infection. According to **W. Thomas London, MD**, a senior member at the Fox Chase Cancer Center in Philadelphia, a biopsy is usually taken before and after treatment, or at least approximately two years into treatment.

But liver biopsies are far from perfect. They are expensive, and may be painful and carry some health risks. Some clinicians and scientists claim that other markers and tests may be just as good, and many don't see the need for biopsy.

"This issue is coming to a head because there are now a handful of drugs approved for hepatitis B, and possibly more in the pipeline," said **Adrian Di Bisceglie, MD**, professor of internal medicine at St. Louis University. The U.S. Food and Drug Administration clearly favors biopsy, he said.

"Are there other valid markers in the blood or other clinical assessments that will satisfy the FDA," asked London. "While a goal of many researchers is to find valid biomarkers that can alleviate the need for biopsies, neither scientists nor the FDA can agree on good substitutes", he said.

Many clinicians, however, use several other markers to gauge drug effectiveness, including HBV DNA levels, HBV e-antigen and liver enzyme levels.

"The question of valid clinical endpoints – that is, how you know when a drug is working – has implications in a number of areas, including how expensive it is for a company to develop a drug and when the patient can stop taking it," Block said.

He noted that lamivudine and adefovir, two HBV drugs approved in recent years, were extensively – and expensively – tested on thousands of patients who received one,

sometimes two biopsies. He said there is "legitimate concern" over the ability to use other markers to tell if HBV liver disease is getting better or worse with treatment.

Block said many doctors argue that biopsies are proven and the best correlation with improved health. Others point to studies showing that lowering viral DNA levels also indicates clinical benefit.

Liver specialist **Hie-Won Hann, MD**, professor of medicine at Jefferson Medical College, favors blood tests indicating a drop in HBV DNA level or liver enzyme changes as clinical markers of drug effectiveness. "The FDA wants biopsies for trials, but patients are scared of them, and they are expensive," said Hann.

"While a goal of many researchers is to find valid biomarkers that can alleviate the need for biopsies, neither scientists nor the FDA can agree on good substitutes."

In the meantime, researchers continue to search for better biomarkers. Block, for example, is taking a proteomics approach to the problem, attempting to find proteins in the blood that are

signals for the early detection of liver cancer and which can monitor liver disease during treatment. He's tested one biomarker in patients with HBV and HCV, with promising results.

Block thinks the FDA will keep an open mind and eventually consider using surrogate markers in the HBV drug approval process. Di Bisceglie agrees.

Both drug companies, which want the quickest, most efficient path to drug approval, and patients, who want drugs approved as quickly as possible, want to avoid long protracted trials, he said.

"The FDA needs to show some leadership and a clear, consistent path for hepatitis B drug development," Di Bisceglie said. "Clinical endpoints is a big issue and it's not going away anytime soon."

Steve Benowitz is a science writer from Philadelphia, PA.

HBF Launches E-Newsletter "B-News ... You Can Use"

The HBF is pleased to launch our new e-newsletter, *B News...You Can Use*. Whether you or a family member are affected by hepatitis B, a health care professional or researcher, or a person interested in learning more about this liver infection, then this e-newsletter will provide you with the information you need to keep up to date on the latest prevention and treatment news.

B News...You Can Use is made possible through a grant from the NIH/National Library of Medicine. To subscribe to the only e-newsletter dedicated to hepatitis B, email us at info@hepb.org or visit www.hepb.org to learn more.

HBV Drug Watch *HBV Compounds in Development* Winter 2004

FAMILY/DRUG NAME	MECHANISM	COMPANY	WEBSITE	STATUS, USA
INTERFERONS Mimic naturally occurring infection-fighting immune substances produced in the body				
Intron A (Interferon alpha-2b)	Immunomodulator	Schering-Plough, Madison, NJ	www.schering.com	FDA Approved 1991
Pegasys (PegInterferon alfa-2a)	Immunomodulator	Roche, Switzerland	www.roche.com	Phase III, outside USA
NUCLEOSIDE ANALOGUES Interfere with the viral DNA polymerase enzyme used for hepatitis B virus reproduction				
Epivir-HBV (Lamivudine)	Inhibits viral DNA polymerase	GlaxoSmithKline, RTP, NC	www.gsk.com	FDA Approved 1998
Hepsera (Adefovir Dipivoxil)	Inhibits viral DNA polymerase	Gilead Sciences, Foster City, CA	www.gilead.com	FDA Approved 2002
Emtricitabine (FTC)	Inhibits viral DNA polymerase	Gilead	www.gilead.com	Phase III / NDA Filed
Entecavir	Inhibits viral DNA polymerase	Bristol-Myers Squibb, Princeton, NJ	www.bms.com	Phase III / NDA Filed
Clevudine (L-FMAU)	Inhibits viral DNA polymerase	Bukwang, Seoul, Korea	www.bukwang.co.kr	Phase III, South Korea
Telbivudine (LdT)	Inhibits viral DNA polymerase	Idenix, Cambridge, MA	www.idenix.com	Phase III
Valtorcitabine (monoval LdC)	Inhibits viral DNA polymerase	Idenix	www.idenix.com	Phase II
Amdoxovir (DAPD)	Inhibits viral DNA polymerase	Gilead	www.gilead.com	Phase II
Elvucitabine (ACH-126,443)	Inhibits viral DNA polymerase	Achillion New Haven, CT	www.achillion.com	Phase II (Central & Eastern Europe)
RCV (Racivir)	Inhibits viral DNA polymerase	Pharmasset, Tucker, GA	www.pharmasset.com	Phase II, Europe
MIV-210	Inhibits viral DNA polymerase	Medivir, Sweden	www.medivir.com	Phase I, U.K.
Hepavir B	Inhibits viral DNA polymerase	Ribapharm, Costa Mesa, CA	www.ribapharm.com	Phase I, Europe, USA
Pentacept (L-3'-FD4C)	Inhibits viral DNA polymerase	Pharmasset	www.pharmasset.com	Preclinical
Robustaflavone (ALS-920)	Inhibits viral DNA polymerase	Advanced Life Sciences, Woodbridge, IL	www.advancedlifesciences.com	Preclinical
Hepavir B (ICN2001-3)	Inhibits viral DNA polymerase	Valeant, Costa Mesa, CA	www.valeant.com	Preclinical
LB80380	Inhibits viral DNA polymerase	LG Life Sciences, Seoul, Korea	www.lg.ic.kr/english	Preclinical
NON-NUCLEOSIDE ANTI-VIRALS				
BAM 205	"Small Molecule"	Novelos, Newton, MA	http://novelos.com	Phase II/III China
HepeX-B (XTL-001)	Human monoclonal antibodies	XTL Biopharm, Rehovot, Israel	www.xtlbio.com	Phase II, Israel & U.S.A. Orphan drug approval in US for liver transplants
UT 231 *Discovered by HBV scientists	Small Molecule	United Therapeutics Silver Spring, MD	www.unither.com	Preclinical HBV (Phase II HCV)
HepBzyme	Nuclease resistant ribozyme	Ribozyme, Boulder, Co	www.rpi.com	Preclinical
Bay 41-4109	Inhibits viral nucleocapsid	Bayer AG, Germany	www.bayer.com	Preclinical
NON-INTERFERON IMMUNE ENHANCERS Boost T-cell infection-fighting immune cells and the body's natural interferon production				
HE2000	Hollis-Eden	San Diego, CA	www.holliseden.com	Phase II, Singapore
Theradigm	Immune Stimulator	Epimmune, San Diego, CA	www.epimmune.com	Phase II
EHT899	Oral Viral Protein	Enzo Biochem, NY, NY	www.enzobio.com	Phase II, Israel
Zadaxin (Thymosin alpha-1)	Immune Stimulator	SciClone, San Mateo, CA	www.sciclone.com	Phase II w/lamivudine Orphan drug approval in US for liver cancer
HBV DNA Vaccine	Immune Stimulator	PowderJect, Oxford, U.K.	www.powderject.com	Phase I
SpecifEx-HepB	Immunological Cell Transfer	CellExSys, Seattle, WA	www.cellexsys.com	Preclinical/Phase I
HBV DNA Vaccine	Immune Stimulator	Jefferson Center, Doylestown, PA	Tel: 215-489-4949	Preclinical
POST-EXPOSURE AND/OR POST-LIVER TRANSPLANT TREATMENT				
BayHep B	HBV immunoglobulin	Bayer U.S., Pittsburgh, PA	www.bayer.com	FDA Approved 1977
Nabi-HB	HBV immunoglobulin	Nabi, Boca Raton, FL	www.nabi.com	FDA Approved 1999
Anti-hepatitis B	HBV immunoglobulin	Cangene, Ontario, Canada	www.cangene.com	FDA Filing 2001

NEW

Sincere thanks to Brent Korba, Ph.D. (Georgetown University Medical Center, Rockville, MD) and Raymond Schinazi, Ph.D. (Emory University Medical School, Atlanta, GA) for their regular review of the HBV Drug Watch Update.

Drug Notes

Oral Administration of Hepatitis B Proteins Continues to Show Promise

In patients with chronic hepatitis B virus (HBV) infection, oral administration of HBV envelope proteins improved the anti-HBV immune response and reduced immune-mediated liver damage, results of a new study indicate (American J. of Gastroenterology, Dec. 2003). There was a significant decrease in viral load and an improvement in the histological necroinflammatory score. Building on earlier research showing that antiviral immunity could be modulated through oral feeding of viral proteins, researchers from Hadassah-Hebrew University Medical Center in Jerusalem treated 42 chronic hepatitis B patients with HBV envelope proteins (HBsAg+preS1+preS2) three times per week for 20 to 30 weeks. They followed the subjects for another 20 weeks after the end of the treatment period. Treatment was well tolerated and 80% of those with elevated liver enzymes showed a favorable biochemical response. Treatment led to a significant decrease in viral load in 15 patients (35.7%), an improvement in HBsAg and HBeAg scores on liver biopsy in 41% and 57%, respectively, and in the histological necroinflammatory score in 30%. Five of 19 HBeAg positive patients (26.3%) became HBeAg negative. However, when treatment was halted, HBV DNA levels rebounded in roughly half of the responders. [HBV Research List, 12/30/03, http://archive.mail-list.com/hbv_research/]

Phase II Trials Planned for Korean Drug LB80380

Recent clinical trials have shown that a new vaccine LB80380 developed by LG Life Sciences, S. Korea, effectively reduces the hepatitis B virus in patients and caused no apparent side effects even after large dosages, according to the makers. Early-stage phase II trials have been completed in Hong Kong and were presented in December at HepDART 2003 in Hawaii. The results indicate that the new vaccine is more than five times more effective, and is less toxic, than existing treatments. Furthermore, it effectively curbed the growth of resistant virus and prevented the recurrence of HBV after stopping medication. LG Life Sciences started developing the vaccine in 1998 and successfully completed first-phase clinical tests of the drug last October in England. The company plans to enter late-stage, second-phase clinical trials with chronic HBV patients around the world next year and hopes to launch the next-generation medicine in 2007 on foreign markets such as China. [The Korea Herald, 12/18/03, www.koreaherald.co.kr]

MBI-1313 Receives NIH Funding for Development

Spring Bank Technologies has acquired exclusive worldwide rights to MBI-1313, a nucleotide analogue under development as a treatment of hepatitis B virus chronic infections, from Micrologix Biotech. As part of the agreement, Spring Bank has received a \$2.6 million grant from the National Institutes of Health (NIH) to advance development of the compound. MBI-1313 is a compound originally discovered by Dr. Iyer and developed in collaboration with the NIH, Georgetown University (Dr. Brent Korba) and Utah State University (Dr. John Morrey). The molecule has shown high potency against HBV in vitro assays and has demonstrated efficacy in an established animal model of HBV infection. [FDA Drug World Daily, 12/10/03, www.fdanews.com/dailies/]

International Meeting of the Molecular Biology of Hepatitis B Viruses

The 2003 International HBV Meeting held Sept. 7-10 in Bergamo, Italy, was punctuated with many outstanding presentations, including those by **Dr. Anand Mehta**, HBF Bruce Witte Scholar, and **Dr. Timothy Block**, HBF president. The Hepatitis B Foundation is proud to be a sponsor of this annual scientific meeting.

Although it is impossible to review all the presentations, a few important themes ran throughout the meeting. These included the continued examination by several groups on the mechanism of action of cytokines against HBV. The understanding of how these agents inhibit HBV could be valuable in the development of potential new treatment options.



Another hot topic of the meeting was the existence of "occult" or hidden infections for both HBV and HCV. Although there appears to be some controversy over the existence of occult HCV infections, the existence of this sort of infection is becoming widely accepted in both woodchuck (the animal model used for many HBV studies) and human HBV infections.

On the antiviral front, several groups reported on attempts to stimulate a beneficial immune response in the host using a combination of a potent nucleoside analogue with a traditional vaccine. The idea of such an approach is to stimulate the body to fight and clear the virus, much like what happens in a self-limiting acute infection. Unfortunately, the results were disappointing. The idea, however, which has proved successful in the woodchuck model, has shown its appeal and is sure to be further developed.

Correction: Ms. Wendy Cuning, Gilead Sciences, wrote to the HBF on Dec. 12, 2003, to correct inaccurate statements about Hepsera that were reported in B-Informed Fall 2003 (page 9 - patient conference review). First, there is a pivotal study included in the package insert that demonstrates its efficacy in liver transplant patients who are lamivudine resistant. Second, she did not say that Tenofovir was an HIV drug and would stay that way. She reported that, "although tenofovir shows activity against HBV, it has not been approved for this indication and Gilead does not promote it as a treatment." The HBF apologizes to Ms. Cuning and Gilead for these inaccuracies.

The extent to which these “markers” accurately reflect true disease is the question.

Can early virological response be predictive of a beneficial outcome?

Early virological response refers to a rapid reduction in the amount of hepatitis B virus (HBV) or more specifically, the virological markers described above. Here is where hepatitis B and hepatitis C treatment responses may differ.

It appears that “early virological response” to interferon therapy in hepatitis C virus (HCV) patients is a good predictor of whether or not the interferon will be effective. Thus, decent reductions in the amount of HCV RNA (within weeks of starting interferon treatment) may forecast who will benefit from this treatment. Since this is not true for everyone taking interferon, the sense of the meeting, however, was that even for HCV, individual treatment decisions cannot yet be based entirely on early response.

With chronic hepatitis B infections, the results appear to be different. Early virological response (within weeks of starting interferon therapy) does not appear to correlate very well with predicting who will benefit.

Early virological response vs. Sustained virological response with polymerase inhibitors

For HBV-infected individuals, response to therapy (as measured over a longer period of time), it appears blood tests are useful. Reduction of HBV DNA in the blood as a result of treatment correlated favorably to clinical outcomes (including biopsy information) in those with elevated ALTs at the beginning of treatment. The situation for eAg-negative patients was less striking.

Nevertheless, a fairly consistent pattern was seen (as reported by Dr. London) in which sustained reductions of viral DNA from “baseline” (the amount of virus in a person immediately before treatment) by at least 10 fold are accompanied by reduced liver disease (as measured by biopsy).

Although early virological response was not enormously informative in HBV-infected individuals, “sustained virological response” did correlate well with reduced disease. That is, if the levels of viral DNA remain reduced over several years - even after a drug is stopped - the likelihood of benefit (i.e. less liver disease) is the greatest.

Alternatives to liver biopsy for measuring a drug’s benefit?

Serological (blood) assays are being studied that appear to offer alternatives to a liver biopsy and correlate with biopsy

information. It is important to note, however, that drugs with different mechanisms of action may require different surrogate markers.

Proteomics, a systematic examination of the complete protein profiles of the blood of HBV infected people, is being used and several promising, but as yet, unproved, protein markers have been discovered by HBF scientists and reported in scholarly journals. One of the most exciting results has been a “biomarker” that may help predict who is at greatest risk for liver cancer (in both HBV and HCV), which is under investigation by the National Cancer Institute.

Other possible surrogate markers to consider for HBV are quantitative (amount of) and qualitative (type of) surface antigen (sAg) levels in the blood. These are easy things to measure and it certainly can be imagined that they would correlate with disease activity in the liver. Dr. DiBicesglie has already done work in this area and the work is encouraging.

Finally, the type of viral DNA in the blood (not just amount) can probably be used as a surrogate marker. This includes detection of viral “cccDNA” (which is usually locked in the infected liver cell), viral mutants, and others.

Conclusions

The current consensus appears to be that for individual patients, clinicians usually prefer to base a treatment decision on a liver biopsy. Nevertheless, there is hope and a clear momentum for the use of surrogate markers as a substitute for liver biopsy in the evaluation of a drug’s efficacy (or effectiveness). It may now be possible to make compelling associations with clinical outcome for groups of patients based on a blood test.

Developing surrogate markers is critical in reducing the hassle and cost of getting a viral hepatitis drug approved by the U.S. Food and Drug Administration (FDA). Expediting the FDA drug approval process would be of enormous benefit to the entire hepatitis B community.

Fast Fact

Over the next five years, investors forecast that hepatitis B drug therapies will exceed \$1 billion, possibly even \$2 billion in worldwide sales.

NAME	TYPE VACCINE	COMPANY	WEBSITE	STATUS
Hepatitis B Vaccines - Recommended for those at risk and patients with chronic HCV				
Engerix B	Recombinant HBV	GlaxoSmithKline Phila, PA	www.gskvaccines.com	Market, USA
Recombivax HB	Recombinant HBV	Merck West Point, PA	www.merck.com	Market, USA
Gen Hevac B	Recombinant HBV	Aventis Pasteur Lyons, France	www.aventispasteur.com	Market, Europe
Hepacare (formerly, Hepagene)	HBV preS1, preS2	PowderJect Oxford, U.K	www.powderject.com	Market, Europe
Bio-Hep B	HBV S, preS1, PreS2	Biotech. Gen. Corp	www.btgc.com	Market, Israel
Hepavax Gene	Recombinant HBV	Berna Biotech, Switzerland	www.bernabiotech.com	Market, Europe
Hepatitis A Vaccines - Recommended for those at risk and patients with chronic HBV and HCV				
Havrix	Inactivated HAV	GlaxoSmithKline	www.gskvaccines.com	Market, USA
VAQTA	Inactivated HAV	Merck	www.merck.com	Market, USA
Avaxim	Inactivated HAV	Aventis Pasteur	www.aventispasteur.com	Market, Europe
Combination Hepatitis Vaccines				
TwinRix (Adult)	HBV and HAV	GlaxoSmithKline	www.gskvaccines.com	Market, USA
Comvax (Pediatric)	HBV and HiB	Merck	www.merck.com	Market, USA
Pediarix (Pediatric)	HBV, Polio, DTP	GlaxoSmithKline	www.gskvaccines.com	Market, USA
Hexavac (Pediatric)	HBV, DTP, HiB, Polio	Aventis Pasteur	www.aventispasteur.com	Market, Europe
Hepatitis Vaccines In Development				
Extra Strength Hep B (for poor or nonresponders)	Recombinant	GlaxoSmithKline (with Corixia)	www.gskvaccines.com www.corixia.com	Phase III
Hep B Vaccine	ISS-linked to HBsAg	Dynavax Technology Berkeley, CA	www.dynavax.com	Phase I/II
Hep B DNA Vaccine Px	HBV DNA Vaccine	PowderJect	www.powderject.com	Phase I

Vaccine News

Hepatitis B Declines 67% in U.S.

The year 2004 was ushered in with good news - the incidence of acute hepatitis B in the U.S. has declined 67% over the past decade. This confirms the effectiveness of a universal vaccination program for infants and children that was initiated in 1991.

On January 2, the Centers for Disease Control (CDC) published a report of their analysis of data from 1990 - 2002, which showed that the greatest decline of acute hepatitis B occurred among children and adolescents. According to the CDC, "The incidence of acute hepatitis B has declined steadily during the preceding decade, in part because of successful vaccination and other prevention programs... The decline in acute hepatitis B among children indicates that successful hepatitis B vaccination programs are possible."

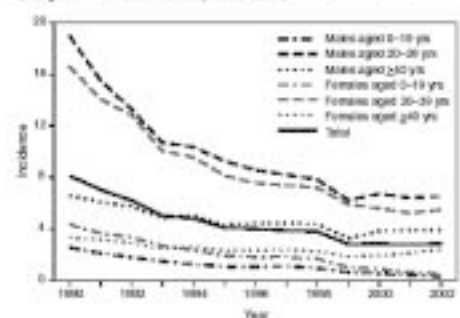
Unfortunately, the decline was lowest among adults, who accounted for the majority of cases, with actual increases noted among adults in some age groups. As a result, the

CDC is turning its attention to adults at high risk in order to further reduce the incidence of hepatitis B among all Americans.

The CDC report concludes, "No national adult hepatitis B program exists that is similar to those that have proven successful for children and adolescents. Components of a national adult vaccination program must include policies for vaccination, including methods for achieving higher vaccination rates among adults at greatest risk and appropriate resources to support implementation."

Read the full CDC report *M M W R Weekly*, January 2, 2004, visit www.cdc.gov/mmwr/html/mm5251a3.htm

FIGURE. Incidence* of acute hepatitis B, by age group, sex, and year — United States, 1990–2002





Highlights of HepDART 2003

Frontiers in Drug Development for Viral Hepatitis December 14 - 18, 2003, Kauai, Hawaii

HepDART 2003 is the fifth in this series of meetings dedicated to viral hepatitis, which is co-chaired by Drs. Raymond Schinazi, Jean-Pierre Sommadossi, and Charles Rice. This bi-annual meeting has rapidly emerged as one of the premiere conferences in the field with a world-class faculty and hundreds of distinguished participants from around the world. Of course, flying to a resort hotel in Hawaii during the cold month of December also makes this meeting highly attractive.

In addition to the usual clinical and scientific presentations, a unique session that reviewed the global antiviral drug market from an investors' perspective was presented. According to Helix Management, HIV therapeutics accounts for \$6 billion, hepatitis C for \$3 billion, and hepatitis B for \$600 million in worldwide drug sales. Over the next five years, it is forecasted that hepatitis C drug therapies will exceed \$9 billion and hepatitis B will exceed \$1 billion, possibly even \$2 billion. Mr. David Franklin, Idenix Pharmaceuticals, reported that the bulk of hepatitis B drug sales are outside of the U.S. with approximately \$500 million in China, \$50 million in Korea, and \$20 million in Taiwan (no U.S. figures were given).

With the growing sales of hepatitis B drugs, there appears to be a concomitant increase of drugs in the research pipeline. Clearly, there is a positive synergy between market demand and drug development. This is good news for those living with chronic hepatitis B.

There should be at least two new anti-hepatitis B drugs available within the next two years. These new drugs, however, are very similar in action, so the advantage will go to those that work most effectively against lamivudine resistance.

The next real new wave to make a big difference will be drugs that work on a target other than the viral polymerase. That's a much tougher goal. Stay tuned. Next year the Princeton Workshop is back on land, in Princeton, NJ, and HepDART 2005 will be meeting again in Hawaii.

Drug Highlights

Approved Drugs

- **Adefovir dipivoxil** (Hepsera, Gilead Sciences) deserves mention, since it continues to be a great success story with excellent activity against lamivudine-resistant mutants. The FDA approved this oral drug in 2002.

Drugs in Clinical Trials

- **Entecavir** (Bristol-Myers Squibb) is in Phase III trials and is likely to be the next hepatitis B drug that will be approved. It is met with great anticipation since it is so potent, achieves the expected clinical milestones, and works against most lamivudine-resistant strains. One concern is that people who develop lamivudine resistance may be pre-disposed to developing the rare entecavir-resistant mutant.

- **LdT** (Telbivudine, Idenix Pharm) has also successfully jumped through the hoops of a phase II trial, is enrolling for Phase III trials, and could be an excellent addition to the formulary.

- **L-FMAU** (Clevudine, Bukwang Pharm) continues to raise interest because of its extraordinary potency in woodchuck studies. A small study in people was consistent with good antiviral activity and even appeared to suggest rapid ALT normalizations.

Drugs in Preclinical Development

- **New acyclic pyrimidines** have been tested in the duck model, by Dr. Lorne Tyrell's group in Edmonton, Canada. Dr. Tyrell is also involved with a clever, off-beat approach using viral protein derivatives to activate important immune cells called "dendritic cells" to recognize the hepatitis B virus.

- **Interleukins 28 and 29** (Zymogenetics, Seattle, WA) are "cytokines" (as are "interferons") and may be another unconventional therapeutic approach to hepatitis therapy.



Drs. Schinazi (left) and Sommadossi, meeting co-chairs, at the gala luau.

Under Construction: NIH Action Plan for Liver Disease Research

This past fall, **Dr. Timothy Block**, HBF president, was invited to join the National Institutes of Health (NIH) initial planning meeting for the construction of an Action Plan for Liver Disease Research, which will identify scientific opportunities and challenges for future research in liver disease. This one-day workshop was held on November 25, 2003, in Bethesda, MD.

Dr. Jay Hoofnagle, founding director of the new Liver Disease Research Branch, told the planning committee that the "HBV Research Priorities", identified at the HBF's Princeton Workshop 2000, will be very useful in laying the groundwork for the action plan (see sidebar).

He also told the HBF, "One of the crushing issues is whether the research being funded is going to really result in improvement in health of Americans. For this reason I believe that the focus of the Action Plan should be to stabilize research in liver disease, improve its quality as much as possible, and find ways to bridge results from laboratory science to practical means of affecting health."

With this strong sense of purpose, Dr. Hoofnagle successfully chaired the first planning meeting. The morning sessions were dedicated to presentations on the current burden of liver disease in the U.S. and existing NIH-led initiatives to support liver disease research. In the afternoon, the overall structure for the Plan, topic areas, timeline, and the working groups in charge of drafting the Plan were finalized.

The NIH welcomes any comments on its Action Plan. Most helpful would be comments on what the most important goals are for liver disease research, gap areas that must be addressed, and initiatives that might best advance the field.

Send your comments to liverplan@mail.nih.gov and visit the Liver Disease Research Branch at www.niddk.nih.gov

The Hepatitis B Foundation's "HBV Research Priorities"

A brief summary of the research priorities that were identified at the Hepatitis B Foundation's Princeton Workshop 2000 is offered below.

1. Early Detection of Disease

Promote research to evaluate and make further use of current clinical information to better predict outcomes of chronic HBV carriers who have been treated or remain untreated.

2. Therapeutics

Support the development of new antivirals that either target virus functions or modulate host functions.

3. Evaluation of the Efficacy of a Therapeutic

Research into the development of predictive, surrogate intermediate markers of clinical disease endpoints should be pursued.

4. Virology

The role of viral mutants in causing resistance to therapies in new or recurrent disease should be explored.

5. Standardization of HBV DNA Determinations

This is not so much a research question as an implementation issue.

6. Theoretical studies

Fundamental research plays a broader role than as a tool for troubleshooting practical problems. Its role is to provide a framework for understanding what is possible or not possible in developing new therapies.

**Please note that the numerical ordering of these items should not be construed as a ranking of their priority.*

For a full report, please visit "Researchers & Scientists" at www.hepb.org, and click on "Princeton Workshop".

National Viral Hepatitis Roundtable Launched

After a year of intensive planning, the National Viral Hepatitis Roundtable (NVHR) was officially launched Dec. 7 - 9, 2003. More than 140 people representing 114 organizations participated in the inaugural meeting held in Washington, DC.

"This conference is a major step towards achieving our goal of developing a national strategy for viral hepatitis", said **Ms. Mollie Conti**, HBF vice-president. She added, "By working together, we can coordinate our efforts to help reduce the burden of viral hepatitis nationwide."

Day one of the NVHR launch began with dinner and presentations about the organization's mission, goals, and history. On day two, **Dr. Harold Margolis** (Centers for Disease Control) presented an epidemiological overview of

viral hepatitis. After some additional team-building exercises, participants were divided into facilitator-led workgroups (Prevention and Screening, Education, Policy and Legislation, Care and Treatment, and Research) to address issues that would potentially influence the development of the National Viral Hepatitis Strategy.

As a charter member of the NVHR steering committee, Ms. Conti is clear about her priorities - "The critical role of the Hepatitis B Foundation is to ensure that the patients and families who are struggling with this disease not be forgotten in the development of a national strategy to eliminate viral hepatitis."

Read more about the NVHR on their new website at www.nvhr.org



Still Lucky Parents

Helen Wise

Excerpted with permission from "One Family's Story: Coping with Hepatitis B" by Helen Wise in Hi Families Magazine (Jan/Feb 2004), published by Holt International Children's Services at www.holtintl.org.

How could it possibly happen? Every precaution and care was taken. Matt, our only child with hepatitis B, had been monitored since he was two and a half months old. Three generations in our family had been tested and vaccinated for the virus. Then, suddenly and without warning, our middle son Andrew was diagnosed with hepatitis B related liver cancer. How? How? How?

We had felt so lucky. Matt, born in Korea, joined our family in 1984. Soon after he came home, he was diagnosed as a hepatitis B carrier. At that time hepatitis B was a fairly new phenomenon on the American pediatric scene and there were many unknowns. By the time Matt started school, we had found the Hepatitis B Foundation and the Liver Cancer Prevention Center at Fox Chase Cancer Center...where he was given [each year] a physical exam, and blood was drawn to monitor for liver involvement.

In 1985 our family grew again. Andrew, 7, and his sister Jenny, 6, arrived from Korea, and the same pediatrician tested for hepatitis B. We were happy to hear their tests were negative, and both Andrew and Jenny were vaccinated. We thought nothing more of it.

A son-in-law and two grandchildren joined our family and were all vaccinated. Matthew turned 20, still showing no hepatitis B side effects. All was well. We were so lucky.

Then on Sept. 2, 2002, Andrew, woke complaining of abdominal pain. By then I had six children and had been a mother for over 30 years. Stomachaches were routine. I suggested he get dressed and go to work; maybe he would feel better. But by the time breakfast was over, Andrew was in such pain that his sister took him to the emergency room. By the afternoon he was admitted to the hospital. I was stunned when two doctors came to tell us Andrew tested positive for hepatitis B.

A biopsy confirmed a diagnosis of stage IV hepatocellular carcinoma [liver cancer] metastasized to the lungs. An earlier diagnosis could have meant surgery or a transplant, but now chemotherapy was our only option, and even then it only shrank the tumor in a small percentage of patients. Our best chance was a clinical trial and a miracle.

Neither was to be. By the time Andrew qualified for a trial, his liver function was so low he was rejected. Andrew Lee Wise died at home on Dec. 11, 2002. He was only 24 years old.

But that is not the end of our story.

After Andrew's cancer diagnosis, I called our former pediatric group to see the results of all the original hepatitis B tests. Their office said the lab's records before 1992 were no longer available. One doctor gave me a handwritten copy of their file reports and said, "See! Their tests were negative. Matthew's was positive."

I read it for myself: "Hep B Surface Antibody Negative." Just surface antibody negative means nothing! It is the combination of results from the surface antibody, core antibody, and surface antigen tests that determines a person's hepatitis B status. I felt and still feel like screaming. How could a leading pediatric group in a university town get it right in 1984 and so wrong in 1985 and 2002? How? How? How?

Our family has been devastated by Andrew's death. We are weary and wary, and painfully aware his life could have been prolonged, and might have been saved had his pediatricians recognized he was a hepatitis B carrier. The lessons we learned were painful and need to be passed on, but the experience is rare.

What advice do we have? Older adoptees and their families should re-test for the virus. Be sure you see and understand the tests and results [and ask for copies]. Vaccinate the entire family. Stay informed about the latest research on hepatitis B. And enjoy life.

When our youngest daughter Mary was in high school, our youth minister asked, "What was the best gift you ever got?" Mary replied, "Andrew, Jenny and Matthew." We are still very lucky parents.

Editor's Note: The Wise family has graciously shared their story so that other families can avoid a similar tragedy. Adoptive parents must be absolutely certain of their child's hepatitis B status. Re-testing may be necessary. Ask for copies of all hepatitis B blood tests and confirm the results with your doctor or contact the Hepatitis B Foundation for assistance.

Helen can be contacted at helen_wise@juno.com



The Wise Children on Christmas day 1995

A Profile in Courage: Andrew Lee Wise 1978 - 2002

Excerpted with permission from "Through Death to Life" by John Aeby in *Hi Families Magazine* (May/June 2003), published by Holt International Children's Services at www.holtintl.org.

Lee, Seung-hoon was born March 4, 1978 in Seoul, Korea. Andrew, as he is now known, and his sister Jenny joined the Wise family in Princeton, N.J., in December 1985. These excerpts from his journals, conversations, and e-mails chronicle his struggle with ... the news in late 2002 that he had liver cancer. Andrew Lee Wise died Dec. 11, 2002, at the age of 24.

Sept. 22, 2002—I wanted to send this letter, personally, to let each and every one of you know [my] biopsy confirmed liver cancer. If you are bewildered, shocked, upset, concerned, scared, anything at all, let me assure you that I am too. However, I have come to realize that this is just a battle and a battle that I can win and will win with God, my family and my friends.

Oct. 6—I have good news: I was accepted to the Cancer Institute of New Jersey (RWJUH) for treatment Oct. 9.

Oct. 25—I went into RWJUH October 7, two days earlier than expected [for] chemoembolization of the right lobe of my liver. I was pretty drugged up and cannot remember anything. Once I got home...extreme amount of pain...really tough...a high temperature.

Nov. 14—I hope that everyone is able to enjoy the few beautiful autumn days that have come around recently. However, a bit of bad news—the three spots originally seen in the scans on my lungs—they have grown since the first treatment...

Nov. 2—This treatment [chemoembolization of the left liver lobe] was a bit rougher and there were a few more complications but I am "done" (supposedly) until after Thanksgiving. I am quite concerned about what the next treatment will be. I have been told not to think about these things and focus on the here and now, but it is really hard to do. My typical day has two lows: the morning, when I first wake up and my body feels as if it has been through a thorough beating... and the evening, when everything is quiet and dark, and I am left to my wandering thoughts and self-pity. But, once I am up and have eaten my breakfast and taken my 9 or 10 pills, I begin to be progressively better

as the day goes on. I am quite excited for Thanksgiving with my family... It will be the first time [most] of my siblings will have seen me post-treatment. I am a bit shocking to look at now.

Nov. 23—I need to have hope, keep faith and believe God is with me always. I need to ... let myself be flooded by the enormous embrace of love from all those around me, and even around the country.

Nov. 26 (first day of Hospice)—Living each day to its fullest potential, that is the goal. Sleeping, eating, exercising and engaging in merry fellowship is how I'll do this. I can do this with the will of God.

Thanksgiving 2002—Last Sunday morning, I was taken up to RWJUH after waking with pains in my liver. The doctor informed my parents and me the tumors in my liver and lungs were growing. This was obviously a shock to us but what was revealed next was heart-shattering. I was given an expected time frame of six months to live...I believe in miracles and continue to have faith. I will not let six months be the definitive! I pray that each of you will continue to be positive and to live life to its fullest.

Dec. 9—Dearest Friends and Family, as the Holiday season starts to take off, my health has turned somewhat sour. My nurse comes over more often, and eating, talking, listening, reading and writing are far more taxing than I ever imagined. I will try and remain as strong as I can for this holiday season as it signifies so much more to me this season than ever before...Thank you all for your love and support...I love you all so much! God bless you all!

Dec. 10 (Christmas list)—I want something very sentimental, such as a necklace with "mother" in English on one side and "mother" in Korean on the other, just to let [Mom] know she has and always will be my one and only mother.

Dec. 10—Death is not an evil at all, just a different blessing that requires a more positive frame of mind and good reminiscence....

Editor's Note:

The Hepatitis B Foundation sincerely extends its sympathies and gratitude to Helen Wise and her family for sharing Andrew's story with us. The loss of such a beautiful, articulate, and generous young man is heartbreaking for all who knew him.



Andrew Lee Wise 1978 - 2002

"We are...painfully aware [Andrew's] life could have been prolonged, and might have been saved had his pediatricians recognized he was a hepatitis B carrier."

Foundation at the Forefront

Dr. Hie-Won L. Hann, HBF Medical Advisor Honored as Distinguished Daughter of PA



Hie-Won L. Hann, MD, professor of Medicine, Division of Gastroenterology and Hepatology, Jefferson Medical College of Thomas Jefferson University, was honored as a Distinguished Daughter of Pennsylvania for 2003. She received the award at a formal luncheon at the Governor's Residence this past October. The coveted 2003 award was given to eight women within the Commonwealth in recognition

of outstanding accomplishments of state and national importance.

A member of more than 24 medical and scientific societies, Dr. Hann has authored more than 200 publications and has been the principal investigator on more than 17 research grants. As director of the Liver Disease Prevention Center at Jefferson, Dr. Hann also treats patients from around the world who have hepatitis B. In addition, Dr. Hann makes weekend visits to churches to screen and test immigrants at high risk for hepatitis B infection.

Since the first group of Daughters was named in 1949, there have been 395 women recognized as Distinguished Daughters of Pennsylvania. There are 154 women still living. Previous honorees include Pearl Buck, Grace Kelly, Mamie Eisenhower, Marian Anderson, and Julie Nixon Eisenhower.

The HBF is proud to congratulate Dr. Hann on this prestigious award in recognition of her outstanding work as a scientist and physician in the field of hepatitis B!

PKIDs Sponsors Summer Camp for Kids – Again!

PKIDs, the national non-profit organization for "Parents of Kids with Infectious Diseases", is offering a summer camp experience for 6 – 16 year old children with hepatitis B and C for the second year in a row.

PKIDs and the Association of Hole in the Wall Camps are generously offering to cover all transportation and camps costs for each child. The Hepatitis B Foundation is also pleased to provide a grant in support of this program.

Call PKIDs at 1-877-557-5437 or email pkids@pkids.org for more information. Donations are also welcome.

HBF Patient Conference Goes West!

This summer, the HBF's 4th annual *B-Informed* patient conference will be held in Stanford, California (near San Francisco). We just couldn't pass up an invitation from Dr. Samuel So (last year's hit keynote speaker at the conference) to travel west and partner with his organization, the Asian Liver Center at Stanford University, of which he is founder and director.

Fortunately, the Hepatitis B Information & Support List co-owners are willing to make the change with us! Now all of the people who have been unable to make it to the east coast for the past three years will finally have a chance to participate in this unique gathering of friends on the west coast.

B-Informed 2004 A Gathering of Friends June 25 - 27 Stanford, California

Please join the Hepatitis B Foundation and the Hepatitis B Information & Support List in collaboration with the Asian Liver Center at Stanford University for a lively two-day conference focusing on the care and treatment of those living with chronic hepatitis B.

Patients, families and all those concerned about hepatitis B are invited to participate! Learn from each other and the experts in a relaxed and supportive environment.

Venue: Asian Liver Center, Stanford, California
Formal sessions begin Saturday June 26 and end Sunday June 27

Cost: This year there will be no registration fee. Instead, participants will be responsible for covering the modest cost of their own lodging. Meals will be provided during the meeting.

Lodging: Lodging will be available on Friday and Saturday evenings only.

All participants will be required to make their own reservations at the Stanford Guest House, which is located on the campus of Stanford University.

Call (650) 926-2800 or visit their website at www.stanford.edu/dept/hds/SLAC

Registration: Hepatitis B Foundation
Register Online at www.hepb.org
(215) 489-4900 or
email info@hepb.org

Space is limited, so sign up early!

Visit Our New Features at www.hepb.org

Two New Foreign Language Chapters Added

More than a brochure and less than a book, the HBF's unique foreign "Language Chapters" are a condensation of important hepatitis B information for ethnic communities in the U.S. and abroad. We just added two new chapters (and more will be added as funds allow):

- **NEW! Simplified Chinese**
www.hepb.org/simplifiedchinese
- **NEW! Spanish**
www.hepb.org/spanish

Be sure to read our other foreign Language Chapters in Traditional Chinese, Korean and Vietnamese. Each language chapter has an English companion. All versions are available in text, html, and PDF format.

Visit our FAQ Section

Need information quickly and easily? Then be sure to visit our new FAQ section throughout our website, which includes many of the "frequently asked questions" about hepatitis B. These FAQs can be printed in text, html or PDF format to share with others.

In addition, the HBF has prepared Information Sheets about specific topics (i.e. the liver, the vaccine, living with chronic hepatitis B, and more) that can be easily downloaded in PDF format.

A special thanks to **Fonta Reilly**, outreach coordinator and grants manager, who initiated and completed the FAQ project (which also served as the basis for our new Spanish Language Chapter – see above) and to **Chari Cohen**, program coordinator who wrote the Information Sheets.

Keeping up with Hepatitis B News

Tired of sifting through multiple news websites or articles to find one about hepatitis B? Then visit the "What's New in Hepatitis B" link on our homepage to find regular postings of hepatitis B news items. With one click, you can find timely and relevant information.

A special acknowledgement goes to **Sheree Martin** who owns and maintains the only Hepatitis B Research List online and co-owns the Hepatitis B Information & Support Listserv.

To subscribe to this free electronic service that posts research abstracts and news reports on a daily basis, send an email to HBV_Research-on@mail-list.com. View the archived articles at http://archive.mail-list.com/hbv_research.

New HBF Web-Tutorial Goes Live! Navigating the National Library of Medicine

The HBF has created an easy to navigate web-based tutorial to help people benefit from the tremendous resources of the National Library of Medicine (NLM), which is a division of the National Institutes of Health.

Our new tutorial consists of 10 short slides with simple instructions and interactive graphics that make learning a snap! To make things even easier, there are several features to accommodate both novice and advanced users: the tutorial is available in text, html, flash and print versions.

The NLM is the world's largest biomedical library and has many web-based resources that can help people become better educated about their health and make informed health decisions. It has information that can be especially helpful to those affected by hepatitis B.

The NLM's three primary databases - MEDLINE, MEDLINEplus, and ClinicalTrials.gov - are a goldmine for those searching for accurate and timely information.

The Hepatitis B Foundation received a three-year grant from the NIH/National Library of Medicine to develop and expand its website, which included the re-design of www.hepb.org that was launched last April, and the creation of our innovative tutorial to help individuals navigate through the NLM's searchable databases. Visit www.hepb.org

A special thanks goes to **Chari Cohen, MPH**, HBF program coordinator, who wrote the NIH/NLM grant and serves as principal investigator of this important initiative.

SAVE THIS DATE !

*The Hepatitis B Foundation is proud to honor
Former Pennsylvania Governor Mark Schweiker*

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April 3, 2004*

*Doylestown Country Club
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Thank you to all of the individuals and organizations that have generously supported the Hepatitis B Foundation through donations, grants, matching gifts, memorials, and attendance at our annual gala celebration and golf tournament.

Thank you also to those who have made in-kind gifts of time and talent this past year. We truly appreciate your generosity in contributing to our *Cause for a Cure!*

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 Mrs. Yuk Tong Lee
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We apologize for any errors or omissions in the donor list despite our best efforts to be as accurate as possible. Please contact us with any corrections. Thank you!

A SPECIAL ACKNOWLEDGEMENT

The Hepatitis B Foundation would like to publicly acknowledge the **Nagy Family** and son-in-law **Kevin Drake** who have so generously donated their time, talent and funds to organizing The Joseph Nagy Golf Tournament for our benefit. Over the past four years, this charitable outing has become a big success and has raised \$12,000!

We are so grateful to this wonderful family for their strong commitment to honoring their father and grandfather, Joseph Nagy, who passed away from complications of hepatitis B. We greatly appreciate being chosen as their charity and for their incredible volunteer efforts each year.

Thank you!



Speaking Personally

Steve Bingham

Co-Owner of the Internet Hepatitis B Information and Support List (HB-L)

The B Secret ... Telling Others

Many of those with hepatitis B worry about revealing their infection to others. "Others" may include family members, friends, bosses, fellow workers, and possible sexual partners.

Parents of children with HBV have their own unique "disclosure" problems as they negotiate the tricky minefields of day-care centers and schools. Ordinary play dates and sleepovers can become problematic. One parent confided, "I became my child's stalker for those first years of her life, trying to control as many situations as possible."

Even though hepatitis B is classified as a "sexually transmitted disease", or STD, most people didn't get it that way. Yet, that seems to be a common assumption. As a result, some feel that the STD label creates an unwanted stigma, and they are embarrassed when doctors, dentists, and sometimes complete strangers demand to know how they got the disease.

Myself, I've been lucky and haven't had many problems relating to disclosure. I sometimes tell my friends that maybe I'm too naive to know when I'm being shunned. The only problem that I can recall is when my sister panicked in a restaurant, thinking she had been infected with hepatitis B after sampling a few bites of food off my plate.

But for all of us living with chronic hepatitis B, below are some guidelines that members on our HB-List have found useful to consider before telling others.

1. Think twice before you tell. In the beginning, you may feel a great need to talk about it with everyone around you, but during this early period, give yourself time to get comfortable with this new diagnosis. Remember, you can't "un-tell" people. Consider joining our on-line support listserv, The Hepatitis B Information and Support List, at www.hblist.org. This is a safe place where others are ready to listen to you and share their experiences.

2. Educate yourself about hepatitis B. Learn the facts so you can answer people's questions in a simple and calm manner.

3. Pick the right time to tell. For example, wait for a calm day at work or at home. When telling someone you're dating, wait until there's a possibility of physical intimacy.

4. Consider using the telephone. This will give the other person time to digest the information without being watched by you. Share your feelings about having to tell this person, and emphasize that you're trusting this person to keep this information private.

5. Know your legal rights. Know what OSHA rules apply to you at work and become familiar with the Americans with Disabilities Act. Unfortunately, discrimination can be subtle and difficult to document.

6. Advocate immunization and "standard precautions". It's especially important to encourage family members, sexual partners and close friends to get vaccinated and to use caution when handling *anyone's* blood or bodily fluids.

Finally, try not to feel like an outcast. Hold your head high, develop good self-esteem, and realize that having hepatitis is nothing to be ashamed of. Your positive attitude will rub off on those around you.

To be honest, some of us even consider hepatitis B to be a good screening tool, separating the people of substance in our lives from those not worthy of our friendship.

Best wishes, STEVE

Internet Support Groups



Hep B Information and Support List www.hblist.org

To subscribe, send a blank email to:
hepatitis-b-on@mail-list.com

Well-supervised list with useful information and lively exchanges between supportive members. For those with HBV, their caregivers, and anyone interested in or affected by HBV are invited to participate.

HBV Adoption Support List

<http://www.onelist.com/community/hbv-adoption>

For adoptive or biological parents of children with HBV. This is a restricted list to protect the privacy of parents and children, and requires pre-approval by the list owner to join.

PKIDS Support List

<http://www.pkids.org/>

For adoptive and biological parents of children with chronic viral infectious diseases, including HBV, HCV, and HIV.

Fast Fact

An estimated 48% of chronic hepatitis B infections are acquired in early childhood (age 5 years or less).

Hepatitis B Clinical Trials

Hepatitis B Foundation HBV Clinical Trials

www.hepb.org/clinicaltrials

National Institutes of Health Clinical Trials

www.clinicaltrials.gov

Centerwatch Clinical Trials

www.centerwatch.com/studies/cat79.html

NEW

Lamivudine and Adefovir to Treat Chronic Hepatitis B

This NIH study will evaluate the safety and effectiveness of lamivudine plus adefovir versus adefovir alone to treat chronic hepatitis B infection. Candidates may not have received lamivudine treatment in the past 6 months or prior treatment with adefovir and must not be taking other antiviral treatments for their hepatitis. *Contact: NIH Patient Recruitment at 1-800-411-1222 or email prpl@mail.cc.nih.gov*

NEW

Telbivudine versus Lamivudine in Adults with Decompensated Chronic Hepatitis B and Evidence of Cirrhosis

Idenix Pharmaceuticals is conducting this research study to see if the investigational medication, LdT (Telbivudine), is safe and effective in the treatment of decompensated hepatitis B infection over two years. The results for patients taking LdT will be compared to results for patients taking lamivudine (EpiVir-HBV). *Contact: Gloria Dubuc at 617-995-9814 or email dubuc.gloria@idenix.com*

NEW

Evaluate Efficacy, Safety and PK of Adefovir Dipivoxil Liquid Suspension in Patients with Chronic Hepatitis B

Gilead Sciences is sponsoring a multi-center phase 3, open-label, parallel-group study designed to evaluate the efficacy, safety and pharmacokinetics of adefovir dipivoxil liquid suspension in patients with chronic hepatitis B and varying degrees of renal impairment. *Contact: Anant Jain at 650-522-5523 or email ajain@gilead.com*

Open Enrollment for Phase III Trial of LdT (telbivudine)

Idenix Pharmaceuticals Inc. is sponsoring a phase III clinical trial of LdT for treatment of chronic hepatitis B, conducted at over 100 sites in North America, Asia, Europe, Australia, and New Zealand. Adults with chronic hepatitis B who have never been treated with lamivudine or other nucleoside or nucleotide analogues are eligible and will be randomized to receive either LdT or lamivudine for 2 years. *Contact: Barbara Fielman, RN, at 617-250-3100, ext. 145 or email fielman.barbara@idenix.com*

Open Enrollment for Phase III Trials of Entecavir

Bristol-Myers Squibb (BMS) is conducting three different studies are being conducted based on the results of patients' serological status (hepatitis B e-antigen positive or negative), and whether the patient is currently on lamivudine therapy and has evidence of resistance to lamivudine. *Contact: BMS toll-free at 1-866-892-1BMS.*

Columbia-Presbyterian Medical Center Entecavir Study

The safety of Entecavir (BMS 200,475) will be evaluated in adults with chronic HBV. Those co-infected with HIV are not eligible to participate. *Contact: Ms. Cabilia Gomez at 212-305-3839 (New York, NY).*

A Randomized, Double Blind Trial of LdT (Telbivudine) versus Lamivudine in Hepatic Compensation

This is a trial for adults with compensated chronic hepatitis B who have never been treated. *Contact: Debora Goldman, RN, clinical trials coordinator for Dr. Douglas Dieterich at 212 241-7270 (Mt. Sinai School of Medicine, NY, NY).*

Phase II Comparison of Adefovir and Tenofovir for the Treatment of Lamivudine-Resistant HBV

This NIAID study will compare the combination of adefovir and lamivudine with the combination of tenofovir and lamivudine to determine which drug combination is most effective in people who are infected with both HBV and HIV. *Contact: NIH Patient Recruitment at 1-800-411-1222 or email prpl@mail.cc.nih.gov. Visit the HBF website at www.hepb.org for the locations and contact information in 12 states.*

Pilot Study of Telbivudine Treatment for HBV Prior to Starting Anti-HIV Drugs in Co-infected Patients

This NIAID study will evaluate telbivudine (LdT) for the treatment of hepatitis B in HIV infected patients. The primary aim of this study is to assess the safety of telbivudine alone and in combination with a lamivudine-based highly active antiretroviral therapy (HAART) regimen in patients coinfected with HBV and HIV.

Contact: Karen Savage, RN, CCRC, at 205-975-7925 (kgsavage@uab.edu) at the Univ. of Alabama.

Prevention of Recurrent HBV After Liver Transplantation

Eligible patients for this study MUST be on a liver transplant waiting list or have already received a liver transplant for hepatitis B. HBIG, EpiVir-HBV and Hepsera will be evaluated. *Contact: Doug Armstrong at darms@umich.edu or call 734-936-1712 at the Univ. of Michigan Medical Center.*

Treatment of Hepatitis in Patients Who are Triple-Infected With HIV, HBV and HCV

This NIAID phase II study will investigate the safety and effectiveness of using adefovir, pegylated interferon, and ribavirin in patients with HBV, HIV, and HCV. All patients in this study must be taking lamivudine. *Contact: Karen Savage, RN, CCRC, at 205-975-7925 (kgsavage@uab.edu) at the Univ. of Alabama or M. Ray at 303-372-5535 (graham.ray@uchsc.edu) at the Univ. of Colorado Health Sciences Center.*

Comparison of Entecavir to Adefovir in Chronic HBV Patients with Hepatic Decompensation

A Phase IIIb comparative study of entecavir vs. adefovir in patients who have chronic hepatitis B and hepatic decompensation for up to 96 weeks. *Contact: Bristol-Myers Squibb toll-free at 1-866-892-1BMS.*

A Phase II Study of the Safety and Efficacy of Adding Entecavir to Current Lamivudine Therapy in HBV and HIV Co-Infected Patients

The purpose of this clinical research study is to assess the safety and effectiveness of adding entecavir in the treatment of adults with chronic hepatitis B infection who are co-infected with HIV and are already taking lamivudine. *Contact: Bristol-Myers Squibb toll-free at 1-866-892-1BMS.*

New Resources

Hepatitis B Help

A new website with educational materials for health care professionals and patients about hepatitis B and the FDA approved drug Eпивir-HBV (lamivudine) from GlaxoSmithKline. Information is available in English and several Asian languages. Links to other hepatitis B education sites are included. Visit www.hepatitisbhelp.com.

HepLink

The Hepatitis Foundation International created HepLink as a search portal to gather comprehensive information from a wide variety of sources such as government, consumer and patient resources, medical journals, and current news sources. Visit www.heplink.org.

Latino Organization for Liver Awareness (LOLA)

Founded in 1994, LOLA is the first national bilingual, bicultural organization dedicated to viral hepatitis and liver diseases. Information is available in both English and Spanish. Visit www.lola-national.org.

MEDscape DrugInfo

A comprehensive drug information website that provides clinical information about thousands of drugs, potential side effects, interactions with other drugs, and additional patient precautions. Search by disease or drug name. Visit www.medscape.com/druginfo.

The National AIDS Treatment Advocacy Project

NATAP is a New York State non-profit corporation whose mission is to provide information and advocacy to those living with HIV and viral hepatitis. They offer a free newsletter, e-newsletter, and community-based programs to serve women and those at risk. Call 1-888-26-NATAP or visit www.natap.org.

Visit the Hepatitis B Foundation Bookstore Online at www.hepb.org

For every book that you order through our website (click "Our Resources" on the homepage) at Amazon.com, we will receive 15% of the total sale.



New! Frontiers in Viral Hepatitis

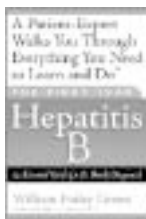
Edited by Raymond Schinazi, Jean Pierre Sommadossi, and Charles Rice
JAI Press (December 2003)

The breadth of information published in this scholarly volume provides insight into current prevention and treatment options. Research has been compiled from over 40 key opinion leaders in the field of hepatitis. The book focuses on the latest advances in the search for new, more effective treatments for viral hepatitis and hepatocellular carcinoma.



Hepatitis B: The Hunt for a Killer Virus

Baruch S. Blumberg, MD, PhD
Princeton University Press (2002)
The discovery of the deadly hepatitis B virus and the vaccine against it was one of the great triumphs of twentieth-century medicine. Dr. Blumberg, who won the Nobel Prize for this discovery and is a co-founder of the Hepatitis B Foundation, shares this story in his new scientific memoir.



First Year: Hepatitis B

William F. Green
Marlowe & Company (2002)
Drawing upon his own personal experience of living with hepatitis B, Will Green provides insight for both the newly diagnosed and the experienced veteran. This is a book that pulls you in and keeps your interest, almost like a good novel.



Living with Hepatitis B: A Survivor's Guide

Gregory T. Everson, MD, and Hedy Weinberg
Hatherleigh Press (2002)
This patient guide walks readers through the process of diagnosis, ongoing care, and treatment options. Hedy Weinberg addresses the unique challenges of living with a chronic illness and successfully translates medical jargon into everyday language.



Get Out Your Soft Spikes Tee-Up For A Good Cause!

5th Annual Joseph Nagy Golf Tournament

To Benefit The Hepatitis B Foundation July 16, 2004

Wedgewood Golf Course
Coopersburg, PA

Shotgun start at 8:00am with team and door prizes, refreshments, and good company – join the fun!

Sponsors are needed, so please contact
Kevin Drake at (610) 864-4446
or email skdrakes@att.net

For more information or to register online
visit www.hepb.org

Resource Roundup



Hepatitis B Foundation

215-489-4900

www.hepb.org

info@hepb.org

Comprehensive website dedicated to hepatitis B. Facts, useful advice, Drug Watch, liver specialist directory, and a responsive email service. Includes *Chinese, Vietnamese, Korean, and Spanish Language Chapters*.

American Liver Foundation

1-800-GO-LIVER

www.liverfoundation.org

webmail@liverfoundation.org

Information about all liver diseases, including viral hepatitis. Fact sheets, legislative advocacy, research funding.

Asian Liver Center at Stanford University

650-725-4837

<http://livercancer.stanford.edu>

This website informs, updates, and educates people about hepatitis B and liver cancer among Asians and Asian-Americans. Information is available in English, Chinese and Korean.

Centers for Disease Control, Hepatitis Division

1-888-443-7232

www.cdc.gov/ncidod/diseases/hepatitis

The national authority for viral hepatitis information: epidemiology, disease facts, prevention, scientific studies, national recommendations, and more.

CDC Hepatitis Immunization Hotline

1-800-232-2522 (English)

1-800-232-0233 (Spanish)

www.cdc.gov/nip

nipinfo@nip1.em.cdc.gov

Hepatitis B Research List

To subscribe, send a blank email to:

HBV_Research-on@mail-list.com

A free electronic research list maintained by Sheree Martin that provides abstracts, reports and notices.

Hepatitis B Research Archive Website

http://archive.mail-list.com/hbv_research.

Archived research bulletins posted on the Hepatitis B Research List, from 1998 until current year.

Hepatitis B Virus Page

<http://www.globalseve.net/~harlequin/HBV/index.html>

Maintained by Robert Garces, Ph.D. Candidate in Virology, at the University of Toronto.

HCV Advocate

sfhepcat@pacbell.net

<http://www.hcvadvocate.org>

Excellent research, education and support information for the HCV community. One of the few HCV websites that also includes information about hepatitis B.

Hep C Connection

1-800-522-4372

www.hepc-connection.org

info@hepc-connection.org

Comprehensive information to assist Hep C-challenged individuals and their families.

Hepatitis Foundation International

1-800-891-0707

www.hepfi.org

mail@hepfi.org

Information about viral hepatitis, support groups, research articles, and education programs.

HepLink

www.heplink.org

This is a search engine that gathers comprehensive information from government, consumer and patient resources, medical journals, and current news sources.

Hepatitis Magazine

1-800-310-7047

www.hepatitismag.com

editor@hepatitismag.com

The only print magazine published bi-monthly for those affected by viral hepatitis.

Hepatitis Neighborhood

www.hepatitisneighborhood.com

info@HepatitisNeighborhood.com

Features a Town Hall with a Live Speakers Forum. Sponsored by Priority Healthcare Corporation.

HepTrec

1-866-HEPTREC

www.heptrec.org

The Delaware Valley Hepatitis Treatment, Research and Education Center (HepTREC) provides support group information, training and prevention programs in the greater Philadelphia area.

HIV and Hepatitis Treatment Advocates

www.hivandhepatitis.com

Professional online publication with updates, conference reviews, free teleconferences, and an e-mail service.

Immunization Action Coalition

651-647-9009

www.immunize.org

www.vaccineinformation.org

Comprehensive resource of immunization information. "IAC Express" is a free email announcement service. "Vaccine Information" is a new complementary website launched by IAC and is specifically written for the general public.

MEDLINEplus Health Information

www.medlineplus.gov

A goldmine of reliable health information from the world's biggest medical library of medicine, the National Library of Medicine. This database is maintained in collaboration with the NIH.

Memorial Sloan Kettering "About Herbs"

aboutherbs@mskcc.org

www.mskcc.org/aboutherbs

Objective information about herbs, their side effects, drug interactions, and links to scientific research. This site is maintained by experts at Memorial Sloan Kettering.

National Center for Complementary and Alternative Medicine

1-888-644-6226

www.nccam.nih.gov

Sponsored by the National Institutes of Health (NIH), this site contains databases galore and research articles.

Parents of Kids with Infectious Diseases

1-877-55-PKIDS (toll-free)

www.pkids.org

pkids@pkids.org

An excellent resource for parents and professionals. Pediatric clinical trials, research list and support listserv.

Calendar of Events



- April 1-3 Hepatocellular Carcinoma National Institutes of Health**
Natcher Conference Center, Bethesda, MD
www.niddk.nih.gov/fund/other/conferences.htm
- April 3 Crystal Ball Awards Gala Hepatitis B Foundation**
Honoree: Former PA Governor Mark Schweiker
Doylestown Country Club, Doylestown, PA
Contact: (215) 489-4900 or info@hepb.org
- April 10 Hawaii's 1st Hepatitis B & C Conference**
Hepatitis Network of Hawai'i
Harris United Methodist Church, Honolulu, HI
Contact: (808) 221-6204 or email KenAkinaka@aol.com
<http://hometown.aol.com/kenakinaka/myhomepage/faith.html>
- April 14-18 39th Annual European Association for the Study of the Liver (EASL)**
The Internationales Congress Centrum, Berlin, Germany
www.easl.ch/easl2004
- May 2-6 17th International Conference on Antiviral Research**
International Society for Antiviral Research (ISAR)
Hilton El Conquistador, Tucson, AZ
www.georgetown.edu/research/arc/ISAR
- May 11-14 38th National Immunization Conference**
Gaylord Opryland Hotel, Nashville, TN
www.cdc.gov/nip/nc
- May 16-19 Digestive Diseases Week (DDW)**
Morial Convention Center, New Orleans, LA
www.ddw.org
- June 24-27 Clinical Care Options for Hepatitis**
iMedOptions
Ritz-Carlton Laguna Nuevael, Dana Point, CA
<http://clinicaloptions.com/go/ccohep2004>
- June 25-27 4th Annual B-Informed Patient Conference**
Hepatitis B Foundation
Asian Liver Center, Stanford, CA
Contact: (215) 489-4900 or info@hepb.org
www.hepb.org

- July 16 5th Annual Joseph Nagy Golf Tournament**
To benefit the Hepatitis B Foundation
Wedgewood Golf Course, Coopersburg, PA
Contact: *Kevin Drake* at (610) 865-4446 or sdrake@att.net
www.hepb.org
- Oct 24-28 International Meeting of the Molecular Biology of HBV**
Woods Hole, MA
Contact: *Dr. Jianming Hu* at jmhu@bu.edu
- Oct 29-Nov 2 AASLD Annual Meeting American Association for the Study of Liver Disease**
Boston, MA
www.aasld.org
- Oct 30-Nov 2 44th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)**
American Society for Microbiologists
Washington, DC
www.icaac.org
- Oct 29-Nov 3 69th Annual Meeting of the American College of Gastroenterology**
Orlando, FL
www.acg.gi.org



HB FOUNDATION
700 East Butler Avenue
Doylestown, PA 18901-2697

We are a national non-profit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide.

Tele 215-489-4900 • Fax 215-489-4920
email: info@hepb.org • website: www.hepb.org

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