

CSAM NEWS

Newsletter of the California Society of Addiction Medicine Winter 1997/8 Vol. 24, No. 3

CMA Guidelines Updated

California Medical Association has revised its **Guidelines for Physician Well-being Committees** to add new sections about recent developments and to update other sections.

The guidelines were published first in 1982 and have been regularly reviewed and revised to keep them current with new developments and with the expanding collection of experience about the functioning of well-being committees.

This edition incorporates:

- the new requirement (in Section 821.5 of the California Business & Professions Code) that a report be made to the Diversion Program if the Medical Staff begins a formal investigation of a physician who may be suffering from a disabling mental or physical condition that may pose a threat to patient care
- the impact of the 1996 California Supreme Court decision in *Arnett v. Dal Cielo* in which the Court ruled that the Medical Board can subpoena peer review records, including those from a well-being committee.

The new edition of the Guidelines includes twelve appendices on topics such as:

- communications in response to a subpoena or other demand
- the disruptive physician
- model language for bylaws suitable for physician practice entities other than hospital medical staffs

Copies may be purchased through the California Medical Association Publications Line, 415/882-5175.

Hepatitis C

BY TERESA WRIGHT, MD

Editor's note: Doctor Wright gave a brief overview of hepatitis C during CSAM's 1997 State of the Art conference. This article is a transcript of her remarks. Doctor Wright is Chief of the Gastroenterology Section, Department of Medicine at the San Francisco VA.

It is now becoming increasingly apparent to those in the hepatology community that hepatitis C is a massive public health problem which affects all spectra of society and all aspects of clinical medicine.

Injection drug use is by far the most common risk factor in the US population. Transfusions account for only 4% of all cases. Sexual and household contacts account for a small proportion. (The virus is sexually transmitted, although the sexual transmission efficiency is low. In fact, statements from the CDC say that condoms are not necessarily recommended unless there is high risk sexual activity.) Occupational exposure (e.g. health care workers after a needle stick exposure) accounts for a portion. The risk is relatively low — about 4-5% with a source-positive needle. With these factors, we can account for most cases of hepatitis C infection in this country. There probably is not an additional mode of transmission of this virus.

The role of injection drug use in the transmission of hepatitis C is well illustrated. There have been some excellent cohort studies of hepatitis C and injection drug users. In a study at Johns Hopkins, David Thomas followed over 1000 injection drug users. He noted that within 6 months from the onset of injection drug use, 60 - 80% of individuals are already infected. But, there continues to be a small number of additional infections which occur with long term follow up. He also found that about 5% of injection drug users who are epidemiologically identical to those who are infected remain HCV negative. There is interest now in identifying biological reasons why certain individuals do not become infected.

The Natural History

The natural history of hepatitis C is extremely variable. Alcohol is probably the single most important risk factor associated with progressive liver injury. Other determinants of disease progression include age of acquisition, age greater than 40 increasing the risk. Interestingly, biological features of the virus, such as the genotype of the virus, or the mode of acquisition do not appear to influence disease progression.

Very early after infection, patients become viremic. They become RNA positive within 2-3 weeks of infection and then become antibody-positive within four to six weeks. Sometimes it may take as much as 6 months to become antibody-positive, but the majority of people will be positive very early on.

Typically there are fluctuations of liver enzymes, although about 40% of individuals have normal liver enzymes at least at sometime in the course of their disease.

Most of the natural history data comes from patients exposed from transfusion where the time of exposure is known. In injection drug users, the initial infection is very often subclinical, so it is very hard to identify the time of exposure and to follow the infection from its onset.

We know that if a patient becomes infected there is an 80 - 90% persistence of virus both in serum and in liver, and in the majority of those individuals there will be disease determined either by abnormal liver enzymes or liver histology. What is much more difficult to determine is what is the progression over time and who will progress.

Complications include cirrhosis, end stage liver disease, and hepatocellular carcinoma. It takes 20 years or more for these complications to develop and they don't develop in all infected individuals.

Currently 1000 patients undergo liver transplantation for hepatitis C every year in the US. The prevalence of hepatitis C in people between the ages of 30 and 40 is four times higher than the prevalence in the general population, and there is concern as this cohort ages there will be four times the cases of end stage liver disease.

The interval between time of first infection (which in injection drug users is assumed to be the time of initial use of injection drugs) and the development of cirrhosis, hepatocellular carcinoma or just chronic hepatitis is between 20 years for cirrhosis and up to 25 years for development of liver cancer. However, post-transfusion hepatitis liver-related mortality is low. A study which compared liver-related mortality of non-A, non-B hepatitis (most of which is hepatitis C) compared with control groups showed that over an 18 year period the liver related mortality was only three percent.

The genome of hepatitis C is a highly variable virus that will likely develop resistance as we develop drugs to treat hepatitis C. In the US about 60 - 70% of individuals are

infected with genotype 1 infection, which unfortunately is the genotype that is most resistant to therapy.

Treatment

Currently the only FDA approved treatments are alpha interferons. There are now three on the market and they are all very similar in their efficacy and in their side effects. The current practice is to adjust the dose and duration of therapy in order to maximize the response and to reduce the relapse when treatment is stopped.

Since the overall initial response rates are only about 50%, there is also increased interest in identifying those individuals who are most likely to respond.

The NIH recently convened a consensus conference* which unequivocally recommended that those individuals who have abnormal liver enzymes, detectable virus, evidence of liver injury on liver biopsy with inflammation and fibrosis should be offered treatment in the absence of specific contraindications. The contraindications include active alcohol abuse or active drug use. At the San Francisco Veteran's Administration we currently recommend that individuals be at least 6 months abstinent before we institute treatment. Other contraindications include significant depression, because interferon can severely aggravate depression. Indeed there have been suicides reported in patients on interferon therapy. Treatment was also indicated for patients with acute hepatitis C.

What was more controversial was whether those individuals who have very early disease, that is, those with very minimal liver histology, should be offered treatment. Since the natural history includes a long period of development, one could decide to wait a few years and then offer therapy when we have better treatments available.

Also controversial was whether patients with genotype 1 infection and high levels of virus should be offered treatment because we know that both of these settings are very difficult to treat. However, the panel recommended that these individuals should not be denied therapy.

Persons with HIV co-infection are considered potential candidates for therapy, in part due to the improved survival rates of individuals infected with HIV with the availability of effective antiretrovirals, as well as the likelihood that HIV modifies or accelerates the progression of HCV disease. Thus these individuals are clearly at increased risk for progressive liver injury.

Other groups recommended for treatment are those that have extra-hepatic manifestations of hepatitis C.

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The California Society is a specialty society of physicians founded in 1973. Since 1989, it has been a State Chapter of the American Society of Addiction Medicine.

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* The National Institutes of Health consensus statement from the conference on Hepatitis C in March, 1997 is available from the NIH website <http://consensus.nih.gov> or from the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, MD 20891

Treatment Effectiveness

Now how good is our treatment? A meta-analysis of initial response rates determined by normalization of liver enzymes shows that about one half of individuals receiving standard treatment at 3 million units 3 times a week for 6 months respond. If you treat for longer, you don't change the initial response rate, but you do significantly improve the relapse rate. Sustained normalization of liver enzymes after treatment with 6 months of therapy is 23%, but you can almost double that if you increase the duration to twelve months.

Other drugs now available include consensus interferon which is a very similar interferon to alpha2B, which has been around for several years. ALT response rates are comparable. Virological response rates are comparable. And sustained off-treatment response rates are also comparable. With 6 months treatment with either drug you can achieve only about a 10-12% virological clearance. However, consensus interferon does appear to be somewhat more effective at dropping viral levels than with the interferon alpha2B. Whether this has clinical significance is under investigation.

Ribavirin is an oral agent which has FDA approved for respiratory syncytial virus in this country by inhalation. It is a quanosine analog which does not have antiviral activity directly against hepatitis C, but, in combination with interferon, does appear to improve the sustained response rates of interferon. As monotherapy it does little to viral levels.

On the Horizon

We have modified interferon to increase the half life of the drug by linking it to polyethylene glycol. This process is known as pegylation.

Early information shows that the highest dose of pegylated interferon, 180 micrograms, vs. standard interferon, resulted in an initial loss of virus in 75% of all individuals treated. We assume that the initial high induction rate will be reflected in the sustained response rates.

There is preclinical development of hepatitis C-specific protease inhibitors. None is yet in clinical trials. There are at least 5 different pharmaceutical companies attempting to develop these drugs. It is likely that these drugs will not be effective as monotherapy and that we will need to combine them with other agents.

Questions and Answers

Q: Why do we have 6 months of sobriety as a standard for treating hepatitis C?

A: The major issue is making sure the patient has a safe social situation. If there is any question of depression, it needs to be controlled first because interferon clearly puts patients at risk for aggravation of depression.

The consensus statement from the National Institutes of Health says: "Because severity of disease or progression to cirrhosis has not been conclusively related to the mode of transmission of hepatitis C or to particular risk groups, therapy should not be denied on the basis of these factors. However, treatment of patients who are drinking significant amounts of alcohol, or who are actively using illicit drugs should be delayed until these habits are discontinued for at least 6 months. Such patients are at risk for the potential toxic effects of alcohol and other drugs and also present problems with compliance. Treatment for addiction should be provided prior to treatment for hepatitis C."

Q: I see a lot of patients who need to go on Antabuse who have hepatitis C and have mildly elevated liver functions tests. In the community where I practice a lot of people say there is no correlation between Antabuse-induced problems and hepatitis C, and they don't check liver functions. I do check them and I find that a lot of patients seem to have an increasing rise in their AST/ALT and I have to take them off Antabuse. Can you comment on that?

A: To my knowledge there are no data. With good hepatic function, patients have good clearance of drugs so they're not inherently at increased risk of dose-related hepatotoxicity, but I know of no data that has really addressed that question. Of note however, enzymes do fluctuate during the normal course of hepatitis C so that careful prospective assessment will be needed to address this issue.

Comment from the moderator, Peter Banys: We review this from time to time and I agree we can't find any guidance about that question from the data. In our program we tend to put people with mild elevations of liver function tests on Antabuse and monitor the liver functions. If they begin to go in the wrong direction then we may take them off Antabuse. By far the greatest liver toxin I've ever seen is alcohol, and most of the time when alcohol use stops the liver functions either stay the same or slowly improve. Liver function may not improve in the people with hepatitis C, but we'll continue Antabuse in attempts to get the benefit of stopping the alcohol use.

Comment from audience: An NIAAA report of a study at the Naval Hospital at Bethesda about 4 years ago shows that SGPT is the most sensitive to Antabuse effects. The recommendation was if SGPT goes to over 3 times the normal upper limit, the Antabuse should be stopped.

Q: Is tattooing a risk for hepatitis C?

A: There was a large epidemiological study from blood donors who tested positive at the NIH which came out last year in the *New England Journal of Medicine*. Tattooing was found to be a risk factor in univariate analysis, but, it was not a risk factor in multivariate analysis.

Q: In the people who deny drug use or other kinds of behavior, where does the virus come from?

A: I don't think we need to look for other modes of transmission. I think that there are clearly individuals who don't see themselves as injection drug users because they probably think that what they did 20 years ago has absolutely nothing to do with what is going on today. So that likely accounts for a fair proportion of the "unknowns." The other issue relates to occult parenteral transmission. For example, we have heard from veterans who say, "We were all lined up in Vietnam and they just went down the line with a straight razor and shaved us all".

Q: The San Francisco Epidemiological Bulletin does not list hepatitis C. Furthermore, no cases of non-A, non-B hepatitis are shown in this year or last year. Why is that? I work in San Francisco and I report all the cases of hepatitis C.

A: There is massive, massive under-reporting at this time.

Q: If in fact there is 10% sexual transmission why aren't people encouraged to use protection.

A: First of all there are no good data. From the kind of cross sectional data we do have, the assumption is that the risk is small and low. The reason the CDC recommendations are in place is because there is no evidence that we can reduce that risk any further by using condoms. The bottom line is that if you are engaging in high risk sexual activity, you should use condoms for other reasons. I understand it is somewhat paradoxical, but, that's the thought behind it.

REFERENCES

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Web Surfer's Alert

DONALD R. WESSON, MD

National Clearinghouse

Many publications of interest to addiction medicine specialists can be ordered or downloaded from a web site. Center for Substance Abuse Treatment (CSAT) Treatment Improvement Protocols are on the National Library of Medicine's web site at <http://text.nlm.nih.gov/ftsr/dbaccess/tip>. Links at the bottom of the page can take you to additional information about CSAT, a complete listing of TIPs (including those not on line), or to the National Clearinghouse of Drug and Alcohol Information website.

Up to five free hard copies of TIPs can be ordered from the National Clearinghouse of Drug and Alcohol Information (NCADI) by accessing its electronic catalog at <http://www.health.org/pubs/catalog/ordering.htm> or by calling 1-800-729-6686. You can download an order form to be faxed or mailed to The National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20847-2345. Their fax number is 301-468-6433.

National Institutes of Health (NIH) Consensus Statements

About 6 times a year, the National Institutes of Health Consensus Development program organizes consensus conferences on controversial issues in clinical practice in an effort to synthesize new information from recently completed or ongoing medical research that has implications for re-evaluation of routine medical practices. The statement from the conference on Effective Medical Treatment of Heroin Addiction, November 17-19, 1997, noted that the FDA's regulations of methadone treatment seemed to have "little if any effect on quality of methadone maintenance treatment care." "However well-intended the FDA's treatment regulations when written in 1972, they are no longer necessary." The complete text, minus references, can be downloaded at the NIH Consensus web site at <http://consensus.nih.gov> or by writing to the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, MD 20891, or by calling 1 888 644-2667.

Dear readers: Please send information about other websites of interest to addiction medicine specialists to wesson@ccnet.com or mail to the CSAM office, 3803 Broadway, Oakland, CA 94611.



THE CALIFORNIA SOCIETY OF ADDICTION MEDICINE

presents

THE VERNELLE FOX AWARD

to

John Nelson Chappel, MD

*in recognition of the pivotal contributions he has made
to our understanding of addiction treatment;*

*in acknowledgement of all the benefits our field has reaped
from his passion for good teaching;*

*in appreciation for his generativity, integrity,
generosity and good humor.*

He teaches us all.

*Presented on this 7th day of November 1997
San Francisco*

1997 CSAM AWARDS



News About Members

Steve Eickelberg has completed his residency in psychiatry at the University of Arizona and is now with Charter Hospital in Phoenix.

Max Schneider is now chairing the Orange County Medical Association's Committee on the Well-being of Physicians.

New Members

As ASAM notifies us of new members, we ask each one for information to put in the newsletter.

Gregory E. Gray, from Los Angeles, is Chairman of the Department of Psychiatry and Human Behavior at Charles R. Drew University of Medicine and Science and is Director of the Agustus Hawkins Community Mental Health Center.

M. A. Shamie, from Beverly Hills, is Medical Director, Psychiatric Division, Los Angeles Metropolitan Medical Center.

Sheela Surapaneni, from Anaheim, is a psychiatrist with Orange County. She completed a psychiatric residency at King Drew Medical Center in 1995.



THE CALIFORNIA SOCIETY
OF ADDICTION MEDICINE

presents its

1997
COMMUNITY SERVICE AWARD

to

Marty Jessup, RN, MS

*in recognition of
her landmark contributions
to the treatment of women and children.*

*As an educator and clinician,
an advocate and a policy guru,
she is a model for all who work
in addiction medicine.*

*Presented 7th November 1997
SAN FRANCISCO*

You Can Write For

NIDA NOTES, a newsletter from the National Institute on Drug Abuse, is available free from NIDA. It reports advances in the field, describes research, gives references, and provides information about NIDA grants and how to apply for them. Write to NIDA NOTES Subscription Department, ROW Sciences, Inc., Suite 400, 1700 Research Blvd, Rockville, MD 20850-3142.

KEEPING SCORE 1997 is a publication of Drug Strategies, a private research and policy institute in Washington. The 36-page, four-color booklet makes good use of graphics to illustrate data such as the figures from the Rand Drug Policy Research Center comparing the cost of reducing cocaine consumption by 1% by treatment (\$34 million), by domestic enforcement (\$246 million), by interdiction (\$366 million), by source-control (\$783 million).

Keeping Score has been an annual review of the impact and effectiveness of Federal drug control spending since 1995. It is supported by a grant from the Carnegie Corporation of New York.

For information on this and other publications, contact Drug Strategies, 202/663-6090. Write to 2445 M Street, NW, Suite 480, Washington, DC 20037.

ADDICTION MEDICINE

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UCSF FACULTY POSITION Attending Psychiatrist Outpatient Substance Abuse Services

The Department of Psychiatry at the University of California, San Francisco (UCSF) is searching for an Attending Psychiatrist for the Outpatient Substance Abuse Service (OSAS), at San Francisco General Hospital (SFGH), a major teaching hospital of UCSF. This clinician-teacher position is in the clinical series at the Clinical Instructor, or Assistant Clinical Professor level, and will be available on July 1, 1998. The ideal candidate will be a Board-certified/Board-eligible psychiatrist with a commitment to an academic career as a clinician-teacher and a demonstrated interest, commitment, and cultural competence in working with underserved, culturally diverse populations.

California licensure is essential. Required: an interest in substance abuse, dual diagnosis of psychiatric disorders and substance abuse, and medical/psychiatric issues including HIV/AIDS; the ability to work effectively with cocaine- and heroin-dependent patients in outpatient substance abuse treatment; strong organizational and writing abilities and interpersonal skills. Research interest is highly desirable.

Applications must be received by January 20, 1998. Please send letter of interest, curriculum vitae, and names, addresses, and telephone numbers of three references to Mark Leary, MD, Search Committee Chair, c/o Susan Brekhus, Department of Psychiatry-7M36, San Francisco General Hospital, 1001 Portrero Ave., San Francisco, CA 94110. UCSF is an Equal Opportunity/Affirmative Action Employer. Woman and minorities are strongly encouraged to apply.

ADDICTION PSYCHIATRIST, RENO

Assistant/Associate Professor, Department of Psychiatry, University of Nevada School of Medicine. Full-time faculty position to teach addiction psychiatry/medicine to residents and medical students. Must have completed accredited residency training program in general psychiatry with training or experience in addiction medicine/psychiatry. Accredited fellowship training in addiction medicine/psychiatry preferred. Must qualify for malpractice insurance and licensure in Nevada.

Attractive geographical area with varied recreational and entertainment resources.

Send letter of application, CV, and three references to: Henry Watanabe, MD, Department of Psychiatry/354, University of Nevada School of Medicine, Reno, NV 89557-0046. (702) 784-4917.

Applications received by February 1, 1998 are assured of full review. AA/EOE.

CONTINUING MEDICAL EDUCATION

10th Annual Physicians' Well-being Committee Conference

Wednesday, May 20, 1998 / Founders Center, Parkside Community Hospital, Riverside, CA

Sponsored by Riverside County Medical Association and CSAM

Fees: \$300 per hospital team

For information: Riverside County Medical Association, 909/686-3342.

60th Annual Scientific Meeting

College on Problems of Drug Dependence

June 13-18, 1998 / Scottsdale Princess Resort, Scottsdale, AZ

Fees: Before April 14, \$345 for CPDD members and \$395 for nonmembers

For information: write to Martin Adler, PhD, CPDD, Temple University, 3420 North Broad Street, Philadelphia, PA 19140. 215/707-3242.

ASAM MRO Course

The Basics of Being a Medical Review Officer — Friday morning

The Latest on the Science, Rules and Art of Drug Testing and Assessment — Friday 1pm to Sunday noon

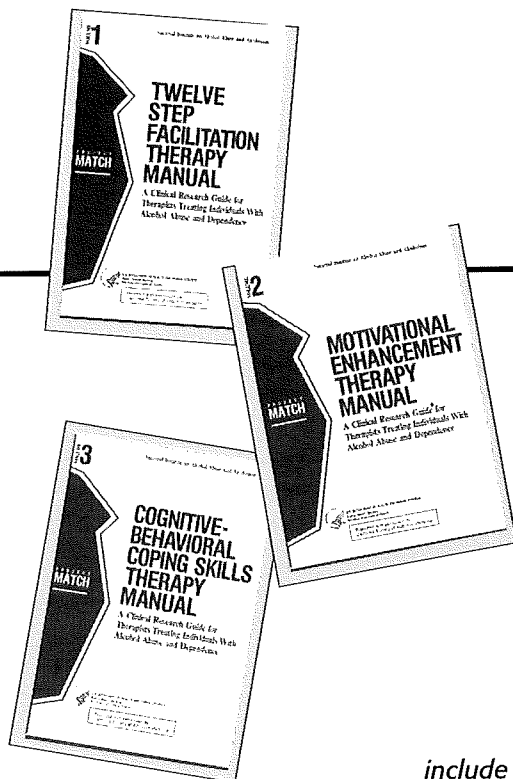
February 20-22 in Atlanta; July 17-19 in San Diego; November 13-15 in Toronto, Canada

Credit: Up to 19 hours of Category 1 credit

Fees: For *The Basics*, \$75 for ASAM members, \$100 for nonmembers; for *The Latest*, \$500 for ASAM members, \$550 for nonmembers. Full Course, \$575 for members, \$650 for nonmembers

For information: ASAM, 4601 North Park Drive, Suite 101, Chevy Chase, MD 20815. Phone: 301/656-3920.

MRO Certification: The Medical Review Officer Certification Council (MROCC) will be offering the Medical Review Officer Certification Exam immediately following each ASAM course. A separate application/eligibility form must be requested from the MROCC. 9950 West Lawrence Ave., Suite 106A, Schiller Park, IL 60176. 847/671-1829.



The Manuals from Project Match

Twelve Step Facilitation Therapy
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\$15.00 each, plus \$3.00 per manual for shipping.

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To pay by credit card (VISA and Mastercard only)
include your card number and expiration date along with your order.

CSAM Events



Workshop on the new Section 821.5

Proceed With Caution

In cooperation with the Healthcare Practice Group of the law firm Latham & Watkins, CSAM is sponsoring half-day workshops to review the new requirement for medical staffs to report formal investigations to the MBC Diversion Program.

Saturday, January 31 8:30 to 12:30
at the Ritz-Carlton Hotel, 600 Stockton Street,
San Francisco

Saturday, February 7 8:30 to 12:30
at the Sheraton Gateway Hotel, 6101 West
Century Blvd, Los Angeles

Registration fee: \$75 for individuals; \$100 for hospital team, plus \$20 for each team member after the first registrant.

For information, contact CSAM 510/428-9091,
or contact Ashley Osterkamp at Latham and
Watkins, 213/891-8580



Fundraising Gala

**bringing CSAM members together with
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February 28, 1998

Center Club, 650 Town Center Drive,
Costa Mesa

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and the Orange County
Performing Arts Center)*

*A fun-filled event to celebrate
CSAM's 25 years and to pay
tribute to CSAM's Guest of Honor
(& Roastee) Max A. Schneider, MD*



*The purpose of the evening is to
bring CSAM members together for an evening of
fun and fellowship and to raise money for CSAM
and for the Scholarship Program.*

\$100 per person.

*Attendance limited to CSAM members and their
guests.*

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