

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: Treating patients who have chronic hepatitis C and advanced liver disease with long-term pegylated interferon significantly decreased their liver enzymes, viral levels and liver inflammation, but the treatment did not slow or prevent the progression of serious liver disease, a study finds. These findings come from the clinical trial, Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) and are reported in the Dec. 4 issue of the *New England Journal of Medicine*. HALT-C was funded by the National Institutes of Health (NIH) with additional support from Hoffmann-La Roche Inc. -- additional details are provided in this *Washington Report*.

The *CSTE Washington Report* is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S.

SEN. HARKIN HOLDS HEARING ON PREVENTION, PUBLIC HEALTH AND HEALTH CARE REFORM – The Health, Education, Labor and Pensions Committee held a hearing on December 10th on, “Prevention and Public Health: The Key to Transforming Our Sick Care System.” The hearing was chaired by Sen. Tom Harkin (D-IA). Witnesses included the HHS Office of the Secretary; Jeff Levi, Executive Director, Trust for America’s Health (TFAH), a representative of Pitney Bowes and an executive with the YMCA of the USA. Sen. Harkin noted that the Office of Public Health Science, and public health in general, need a higher profile within HHS and that public health should be a part of health care reform. He expressed interest in TFAH’s recommendation that a “National Prevention Strategy” be employed for all government agencies with a health prevention agenda similar to the pandemic flu effort. Sen. Christopher Dodd (D-CT) expressed concern about the public health workforce and how Congress could assist with its development. Sen. Coburn stressed the importance of communicating preventive health guidelines to the public, such as the recently released physical activity guidelines, and the need to use advertisements and other media to engage the public. At the end of the hearing, Sen. Harkin noted that the public health and prevention measures discussed during the hearing need to be incorporated into the developing stimulus package that is expected to be passed early in January.

ANNUAL REPORT TO THE NATION FINDS DECLINES IN CANCER INCIDENCE AND DEATH RATES; SPECIAL FEATURE REVEALS WIDE VARIATIONS IN LUNG CANCER TRENDS ACROSS STATES --A new report from the nation’s leading cancer organizations shows that, for the first time since the report was first issued in 1998, both incidence and death rates for all cancers combined are decreasing for both men and women, driven largely by declines in some of the most common types of cancer. The report notes that, although the decreases in overall cancer incidence and death rates are encouraging, large state and regional differences in lung cancer trends among women underscore the need to strengthen many state tobacco control programs. The findings come from the “Annual Report to the Nation on the Status of Cancer, 1975-2005, Featuring Trends in Lung Cancer, Tobacco Use and Tobacco Control”, online Nov. 25, 2008, and appearing in the Dec. 2, 2008, *Journal of the National Cancer Institute*.

Although cancer death rates have been dropping since the publication of the first Annual Report to the Nation 10 years ago, the latest edition marks the first time the report has documented a simultaneous decline in cancer incidence, the rate at which new cancers are diagnosed, for both men and women. Based on the long-term incidence trend, rates for all cancers combined decreased 0.8 percent per year from 1999 through 2005 for both

sexes combined; rates decreased 1.8 percent per year from 2001 through 2005 for men and 0.6 percent per year from 1998 through 2005 for women. The decline in both incidence and death rates for all cancers combined is due in large part to declines in the three most common cancers among men (lung, colon/rectum, and prostate) and the two most common cancers among women (breast and colon/rectum), combined with a leveling off of lung cancer death rates among women.

“The drop in incidence seen in this year’s Annual Report is something we’ve been waiting to see for a long time,” said Otis W. Brawley, M.D., chief medical officer of the American Cancer Society (ACS). “However, we have to be somewhat cautious about how we interpret it, because changes in incidence can be caused not only by reductions in risk factors for cancer, but also by changes in screening practices. Regardless, the continuing drop in mortality is evidence once again of real progress made against cancer, reflecting real gains in prevention, early detection, and treatment.”

The new report shows that, from 1996 through 2005, death rates for all cancers combined decreased for all racial and ethnic populations and for both men and women, except for American Indian/Alaska Native men and women, for whom rates were stable. The drop in death rates has been steeper for men, who have higher rates, than for women. Death rates declined for 10 of the top 15 causes of cancer death among both men and women. However, death rates for certain individual cancers are increasing, including esophageal cancer for men, pancreatic cancer for women, and liver cancer for both men and women. Overall cancer death rates were highest for African-Americans and lowest for Asian American/Pacific Islanders.

Among men, incidence rates dropped for cancers of the lung, colon/rectum, oral cavity, and stomach. Prostate cancer incidence rates decreased by 4.4 percent per year from 2001 through 2005 after increasing by 2.1 percent per year from 1995 to 2001. In contrast, incidence rates increased for cancers of the liver, kidney, and esophagus, as well as for melanoma (2003-2005), non-Hodgkin lymphoma, and myeloma. Incidence rates were stable for cancers of the bladder, pancreas, and brain/nervous system, and for leukemia.

For women, incidence rates dropped for cancers of the breast, colon/rectum, uterus, ovary, cervix, and oral cavity but increased for cancers of the lung, thyroid, pancreas, brain/nervous system, bladder, and kidney, as well as for leukemia, non-Hodgkin lymphoma, and melanoma.

“While we have made progress in reducing the burden of cancer in this country, we must accelerate our efforts, including making a special effort to reach underserved cancer patients in the communities where they live,” said National Cancer Institute (NCI) Director John Niederhuber, M.D. “This report gives us a better understanding of where we may need to redouble our efforts and try to find new ways of preventing or reducing the occurrence of kidney, liver, and other cancers that continue to show increases in both mortality and/or incidence.”

The Special Feature section of the Report highlights wide variations in tobacco smoking patterns across the United States, which, coupled with differences in smoking behaviors in younger versus older populations, helps explain the delay in an expected decrease in lung cancer deaths among women and a slowing of the decrease in lung cancer deaths among men.

The report finds substantial differences in lung cancer death rate trends by state and geographic region. For example, lung cancer death rates dropped an average of 2.8 percent per year among men in California from 1996 through 2005, more than twice the drop seen in many states in the Midwest and the South. The geographic variation is even more extreme among women, for whom lung cancer death rates increased from 1996 through 2005 in 13 states and decreased only in three. The report also notes that, in five states (Pennsylvania, Illinois, Minnesota, Nebraska, and Idaho), lung cancer incidence among women showed an increasing trend, whereas the mortality trend was level.

“It’s very promising to see the progress we are making in our fight against cancer,” said Centers for Disease Control and Prevention (CDC) Director Julie Gerberding, M.D. “Unfortunately, tobacco use continues to plague our country, and it’s the primary reason why lung cancer continues to rob too many people of a long, productive, and healthy life. We must recommit ourselves to implementing tobacco control programs that we know work if we are truly going to impact the staggering toll of tobacco on our society.”

Variation in smoking prevalence among the states is influenced by several factors, including public awareness of the harms of tobacco use, social acceptance of tobacco use, local tobacco control activities, and tobacco industry promotional activities targeted in a geographic area. The 13 states where lung cancer death rates for women are on the rise have higher percentages of adult female smokers, low excise taxes, and local economies that are traditionally dependent on tobacco farming and production. In contrast, California, which was the first state to implement a comprehensive, statewide tobacco control program, was the only state in the country to show declines in both lung cancer incidence and deaths in women.

According to a U.S. Surgeon General’s report, cigarette smoking accounts for approximately 30 percent of all cancer deaths, with lung cancer accounting for 80 percent of the smoking-attributable cancer deaths. Other cancers caused by smoking include cancers of the oral cavity, pharynx, larynx, esophagus, stomach, bladder, pancreas, liver, kidney, and uterine cervix and myeloid leukemia.

“We can see that, in areas of the country where smoking and tobacco use are entrenched in daily life, men and women continue to pay a price with higher incidence and death rates from many types of cancer. This type of geographic variation in smoking-related cancers is due to smoking behaviors, not regional environmental factors,” said Betsy A. Kohler, M.P.H., executive director of the North American Association of Central Cancer Registries (NAACCR).

“The observed decrease in the incidence and death rates from all cancers combined in

men and women overall and in nearly all racial and ethnic groups is highly encouraging,” conclude the authors. “However, this must be seen as a starting point rather than a destination.” They say a dual effort, combining better application of existing knowledge with ongoing research to improve prevention, early detection, and treatment will be needed to sustain and extend this progress into the future.

The study was conducted by scientists at the ACS, CDC, NCI, which is part of the National Institutes of Health, and the NAACCR.

HEPATITIS C TREATMENT REDUCES THE VIRUS BUT LIVER DAMAGE CONTINUES -- Treating patients who have chronic hepatitis C and advanced liver disease with long-term pegylated interferon significantly decreased their liver enzymes, viral levels and liver inflammation, but the treatment did not slow or prevent the progression of serious liver disease, a study finds.

These findings come from the clinical trial, Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) and are reported in the Dec. 4 issue of the New England Journal of Medicine. HALT-C was funded by the National Institutes of Health (NIH) with additional support from Hoffmann-La Roche Inc.

"The results from HALT- C show without question that maintenance therapy with peginterferon does not prevent progression of liver disease among patients who have failed prior treatments," said James Everhart, M.D., project scientist for HALT-C in the Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the principal sponsor of HALT-C at NIH. "These findings heighten the incentive to develop more effective drugs for patients with severe liver disease due to hepatitis C."

Peginterferon therapy for up to 48 weeks is standard for chronic hepatitis C. But patients who do not have a sustained response to initial therapy have been given the drug over a longer time based on studies showing that this approach suppresses viral and enzyme levels, even if the virus is not completely eliminated. However, it was not known if long-term therapy would improve important clinical outcomes such as liver damage and death.

HALT-C, a randomized multicenter trial of 1,050 patients with chronic hepatitis C who had failed prior treatment to eradicate the infection, tested whether long-term treatment with peginterferon alfa-2a would reduce the development of cirrhosis, liver cancer, or liver failure. The 517 patients randomized to the treatment arm received 90 micrograms of peginterferon in weekly injections for 3.5 years. The 533 patients in the control arm underwent the same follow-up and care as the treated patients including liver biopsies, quarterly clinic visits and blood tests. All patients had advanced liver fibrosis, a gradual scarring of the liver that puts patients at risk for progressive liver disease and liver failure.

The outcomes studied in HALT-C were death, liver cancer, or liver failure, and for those

who did not have cirrhosis initially, the development of cirrhosis. At the end of the study, 34.1 percent of the treated group and 33.8 percent of the control group had experienced at least one outcome. Patients in the treated group had significantly lower blood levels of the hepatitis C virus and improvement in liver inflammation. However, there was no major difference in rates of any of the primary outcomes between the groups.

Among treated patients, 17 percent stopped peginterferon after 18 months and 30 percent stopped the drug after two years. Infections, musculoskeletal or digestive problems were the most common reasons for stopping the drug.

According to HALT-C study chair and principal investigator Adrian M. Di Bisceglie, M.D., professor of internal medicine at Saint Louis University School of Medicine in Missouri, looking into how maintenance therapy works in non-responders is an important step. "Patients should not receive interferon as maintenance therapy for chronic hepatitis C. However, we can build on what was learned in HALT-C to identify better treatments that may delay or prevent liver damage in patients with advanced disease," he said.

The hepatitis C virus infects more than 100 million persons worldwide and as many as 4 million in the United States. Hepatitis C ranks with alcohol abuse as the most common cause of chronic liver disease and leads to about 1,000 liver transplants in the United States each year. The best current antiviral therapy of pegylated interferon given by injection in combination with oral ribavirin for about 6 months to a year eliminates the virus in about 50 percent of infected patients.

STUDY OF ANCIENT AND MODERN PLAGUES FINDS COMMON FEATURES

-- In 430 B.C., a new and deadly disease — its cause remains a mystery — swept into Athens. The walled Greek city-state was teeming with citizens, soldiers and refugees of the war then raging between Athens and Sparta. As streets filled with corpses, social order broke down. Over the next three years, the illness returned twice and Athens lost a third of its population. It lost the war too. The Plague of Athens marked the beginning of the end of the Golden Age of Greece.

The Plague of Athens is one of 10 historically notable outbreaks described in an article in *The Lancet Infectious Diseases* by authors from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The phenomenon of widespread, socially disruptive disease outbreaks has a long history prior to HIV/AIDS, severe acute respiratory syndrome (SARS), H5N1 avian influenza and other emerging diseases of the modern era, note the authors.

"There appear to be common determinants of disease emergence that transcend time, place and human progress," says NIAID Director Anthony S. Fauci, M.D., one of the study authors. For example, international trade and troop movement during wartime played a role in both the emergence of the Plague of Athens as well as in the spread of influenza during the pandemic of 1918-19. Other factors underlying many instances of emergent diseases are poverty, lack of political will, and changes in climate, ecosystems

and land use, the authors contend. "A better understanding of these determinants is essential for our preparedness for the next emerging or re-emerging disease that will inevitably confront us," says Dr. Fauci.

"The art of predicting disease emergence is not well developed," says David Morens, M.D., another NIAID author. "We know, however, that the mixture of determinants is becoming ever more complex, and out of this increased complexity comes increased opportunity for diseases to reach epidemic proportions quickly."

For example, more people travel more often over greater distances and in less time now than at any time in the past. One consequence of the increased mobility in the modern age can be seen in the 2003 outbreak of the novel illness SARS, which rapidly spread from Hong Kong to Toronto and elsewhere as infected passengers traveled by air.

To better understand and predict disease emergence, Dr. Morens and his coauthors stress the need for research aimed at broadly understanding infectious diseases as well as specifically understanding how disease-causing microorganisms make the jump from animals to humans.

In a narrow sense, epidemics are caused by particular microorganisms, and the study of infectious disease has historically been microbe-focused. For example, the Black Death (bubonic plague), which killed some 34 million Europeans in the middle of the 14th century, was caused by the bacterium *Yersinia pestis*. In a broader sense, however, epidemics are caused by complex and not fully predictable interactions between the disease-causing microbe, the human host and multiple environmental factors, the authors note. The Black Death, for instance, was borne westward along newly established land and sea trade routes from its probable origin, China, into multiple European countries. Similarly, patterns of human movement along trade routes, specifically truck routes throughout Africa, played a role in the spread of HIV throughout that continent. Greater consideration must be given, say the NIAID authors, to broader, interlinked factors such as climate, urbanization, increased international travel and the rise of drug-resistant microbes, and the ways in which these factors combine to spark new epidemics.

Aside from commerce and travel, the NIAID authors point to several other factors that underlie many notable emerging diseases: poverty, the breakdown of public hygiene practices, and susceptibility of human populations to microbes against which they have no pre-existing immunity. This last factor played a key role in the smallpox epidemic that afflicted the Aztecs of 16th century Mexico. Smallpox had ravaged European communities for centuries, but until the Spanish arrived on the Yucatan coast in 1519, the disease was unknown in the New World. Historians believe that some 3.5 million people in central Mexico died in the first year of the epidemic.

Epidemics also can spur advances in public health, note the authors. They point to the yellow fever epidemics of 1793-98, which began in the then-U.S. capital, Philadelphia. Though the entire federal government and most Philadelphians fled, those who remained

formed an emergency government and mobilized such marginalized groups as African-Americans and immigrants to fight the outbreak. In 1798, Congress established the Marine Hospital System — forerunner of the modern U.S. Public Health Service — to provide, at public expense, medical care for sick and injured merchant seamen. Historians generally agree that a prime impetus for creating the Marine Hospital System was the yellow fever epidemics.

Modern epidemiology began in reaction to another epidemic, says Dr. Morens. In the early 1830s, as cholera made its way along waterways from Asia towards Europe, French officials attempted to prepare their country in advance of an outbreak. Teams of scientists were sent to Poland and Russia to observe the outbreaks there. Throughout France, coastal health agencies and new quarantine stations were established; in Paris, a network of health inspection offices was created to coordinate inspection of wells, cesspools and latrines of both public and private buildings. Despite these efforts, cholera arrived in Paris on March 29, 1832, with explosive effect — within two weeks, there were 1,000 cases, 85 percent of them fatal. Daily newspapers published lists of cases allowing armchair epidemiologists to see trends in illness and deaths. "For the first time in history," write the NIAID authors, "a large-scale emerging epidemic was scientifically investigated in 'real time' using census data in a prospective population-based approach that featured analyses of morbidity and mortality stratified by age-group, sex, occupation, socioeconomic status and location."