NIAID Mounts Nationwide HIV–TB Treatment Study

The National Institute of Allergy and Infectious Diseases (NIAID) has launched the first large U.S. study to assess tuberculosis treatment strategies for persons infected with both tuberculosis and the human immunodeficiency virus (HIV) that causes AIDS.

Study investigators will enroll up to 650 HIV-infected persons with active tuberculosis in two nationwide clinical trials networks supported by NIAID. The networks are the AIDS Clinical Trials Group (ACTG) and the Terry Beirn Community Programs for Clinical Research on AIDS.

TB is an airborne disease, primarily of the lungs. Because of their weakened immune systems, persons with HIV are particularly vulnerable to reactivation of latent TB infections, as well as new TB infections. TB transmission occurs most frequently in crowded environments such as hospitals, prisons, and shelters—places where HIV-infected people make up a growing proportion of the population.

"This study will provide state-of-the-art treatment to HIV-infected persons with tuberculosis and answer important questions about the management of these patients," said NIAID Director Anthony S. Fauci, MD. "Although we anticipate enrolling patients nationwide, it is likely that a significant proportion of the patients will be enrolled in New York City, where TB, especially drug-resistant TB, is a persistent and growing problem."

In 1991, the Centers for Disease Control and Prevention (CDC) received reports of 26,283 active TB cases in the United States, an increase of 18 percent since 1985. Each year, 8 million people worldwide develop active TB, and 3 million die, according to the World Health Organization (WHO).

CDC estimates that 100,000 people in the United States are infected with both HIV and the TB bacterium. Worldwide, WHO estimates that 4.4 million people are coinfected with HIV and TB.

Drug-resistant cases of TB have increased dramatically in the past few years. Drug resistance occurs when patients fail to take their TB medicine for the prolonged periods necessary to destroy all vestiges of the TB organism. In New York City, one-third of all TB patients in 1991 had infections resistant to one or more antibiotic drugs.

The NIAID study will evaluate the benefits of adding a new drug for tuberculosis treatment, levofloxacin, to the usual four-drug therapy used in geographic areas, including New York, where TB organisms are commonly resistant to one or more anti-TB drugs. Levofloxacin belongs to a class of medications called fluoroquinolones that have demonstrated anti-TB activity in laboratory tests and in preliminary studies in humans.

People who live where drug-resistant TB is not common also can enroll in the trial and will receive the four-drug regimen without levofloxacin. The four-drug regimen uses isoniazid (INH), rifampin, ethambutol, and pyrazinamide.

After an 8-week induction phase of therapy using four or five drugs, patients will enter the continuation phase of their treatment, and will receive two or three drugs for an additional 18 to 70 weeks. To determine which candidate continuation therapy a patient receives, study investigators will use laboratory cultures that can identify which drugs are effective against the strain of TB bacterium that a patient carries.

In the continuation phase of therapy, participants who carry strains of the TB organism susceptible to the standard drugs will be randomly assigned to receive a two-drug regimen for either an additional 18 or 31 weeks; participants with single-drug resistant TB will receive either two- or three-drug regimens, some of which will include levofloxacin. Eligible patients with INH-resistant TB will continue treatment for 44 additional weeks, and those with rifampin-resistant TB, for 70 additional weeks.

Patients with TB strains resistant to multiple drugs will be taken off the study and switched to another, more intensive treatment regimen.

During the continuation phase of treatment, all participants will receive twice-weekly, so-called intermittent therapy rather than daily doses of the drugs. Intermittent therapy previously has been found effective in TB patients without HIV infection.

"A shorter treatment regimen or an effective intermittent regimen would facilitate directly observed therapy, with a clinic or outreach worker watching participants take their study medication," said Dr. Fauci. "Increased compliance with therapy would result in a better cure rate, less TB transmission, and fewer opportunities for the TB organisms to develop drug resistance."

The study, known as CPCRA 019/ACTG 222, has an open-label design. Both participants and the study investigators know which medications a patient is taking. Patients will be evaluated every 2 weeks in the induction phase and every 12 weeks in the continuation phase.

ACTG, established in 1987, is a nationwide clinical trials network that conducts studies to evaluate the safety and effectiveness of new drugs, drug combinations, and vaccines in adults and children at various stages of HIV disease. ACTG has 61 sites affiliated with major medical centers in 34 U.S. cities.

The Terry Beirn Community Programs for Clinical Research on AIDS involve 17 community-based research programs in 13 U.S. cities, with some 160 affiliated sites. These programs include groups of primary care physicians and nurses who work in community health centers and hospitals, private clinics or practices, and drug addiction treatment facilities.

—GREG FOLKERS, Technical Writer-Editor, National Institute of Allergy and Infectious Diseases.

Enrollment information, site location, and eligibility requirements for CPCRA 019/ACTG 222 and other AIDS clinical trials, can be obtained by telephoning 1–800–TRIALS–A, Monday through Friday, 9 am to 7 pm, EST.

16 Vanguard Centers Selected for Women's Health Research Studies

The National Institutes of Health (NIH) has selected 16 Vanguard Clinical Centers for the Women's Health Initiative, a massive national research effort to learn more about women's health.

The work of the 16 university medical programs selected will be a part of a planned 15-year, $625 million study, the largest clinical trial ever undertaken in the United States. They will link sites in 15 States to implement the study that will involve more than 160,000 women ages 50 to 79.

The study will focus on the causes and prevention of heart disease, cancer, and osteoporosis, diseases that are major causes of death and disability among women. It will examine, through clinical trials or observational studies, the effects of a low-fat diet in preventing breast and colorectal cancer and heart disease; the benefits and the risks of hormone-replacement therapy in preventing cardiovascular disease and osteoporotic fractures; and the effects of calcium and vitamin D supplements in preventing osteoporotic fractures and colorectal cancer.

Researchers expect that results derived from the Women's Health Initiative will provide scientifically valid information for women and their physicians in hopes of improving overall health and promoting longer life.

The initial 16 Vanguard Clinical Centers will test, refine, and implement the final study design and operating procedures to enroll women nationwide in the first stage of clinical trials by September 1993. By mid-1994, an additional 29 clinical centers will be added, constituting an unprecedented alliance of 45 medical schools, hospitals, and nonprofit institutions committed to uncovering vital information to improve the quality of life for women. The average contract award per Vanguard Clinical Center amounts to nearly $10.5 million over a 15-year period.

Each of the 45 Vanguard Clinical Centers will recruit 3,490 women over 3 years for the clinical trial and observational study. The broad geographic distribution of the Vanguard Clinical Centers allows for recruitment efforts in medically underserved areas and targets minority populations across the country to obtain a representative cross-section of the United States population.

Four of the 16 centers chosen will primarily recruit minority participants. They are Emory University School of Medicine, Atlanta, GA, University of Alabama at Birmingham, University of Arizona, Tucson, and University of California, San Diego.

The other 12 Vanguard Centers:

The Bowman Gray School of Medicine, Winston-Salem, NC; Brigham and Women's Hospital Department of Medicine, Boston, MA; Fred Hutchinson Cancer Research Center, Seattle, WA; Memorial Hospital of Rhode Island Division of Health Education, Pawtucket; Northwestern University Medical School Department of Preventive Medicine, Chicago, IL; State University of New York at Buffalo Department of Social and Preventive Medicine; University of California, Davis, School of Medicine Department of Internal Medicine; University of Iowa College of Medicine Department of Preventive Medicine and Environmental Health, Iowa City; University of Medicine and Dentistry of New Jersey Medical School, Newark; University of Minnesota Medical School, Minneapolis; University of Pittsburgh Graduate School of Public Health; and University of Tennessee, Memphis, Prevention Center.

The Hutchinson Center in Seattle is also the clinical coordinating center for the Women's Health Initiative.

—JOHANNA SCHNEIDER, Senior Adviser, Media Relations, and ANITA GREENE, Media Relations Specialist, NIH.

HHS, HUD Fund Projects for Homeless Mentally Ill

The Departments of Health and Human Services (HHS) and Housing and Urban Development (HUD) will provide approximately $17 million this year to fund the first year of demonstration projects to care for homeless people with severe mental illnesses, including those who also have substance use disorders.

The money will be used for a 5-year national demonstration program called Access to Community Care and Effective Services and Supports (ACCESS) that seeks to integrate fragmented services and thereby contribute to ending homelessness.

About one-third of the homeless population are single adults suffering from severe mental illnesses such as schizophrenia or manic-depressive disorder. A sizable proportion of the homeless severely mentally ill population—estimated at one-half or more—also abuse alcohol or other drugs or both. On any given night, up to 600,000 people in the United States are homeless.

ACCESS creates incentives to improve the integration of existing Federal, State, local, and voluntary services to homeless people. The grants will test alternative approaches to the development of an integrated system to improve the availability, quality, and comprehensiveness of services, as well as to evaluate the effectiveness of these approaches.

HHS Secretary Donna E. Shalala said, "The last things that homeless people need to encounter are cumbersome, uncoordinated bureaucracies. ACCESS is an attempt to cut through the complexities and deliver services to people who badly need it."

"This program has enormous potential to serve as a model for the nation," said HUD Secretary Henry Cisneros. "I am particularly pleased that so many different components of our government collaborated to create it."

HHS and HUD worked with the Departments of Labor, Education, Agriculture, and Veterans Affairs to establish the ACCESS Program.

The resulting interdepartmental effort will provide funds to States and communities to develop and test integrated systems of treatment, supportive services, and housing for the target population. The Program will be administered by the Center for Mental Health Services, a component of the Substance Abuse and Mental Health Services Administration of the Public Health Service.

All State mental health authorities are eligible to apply for funding. Awards for this year will be made in September 1993.

Funds will be awarded through cooperative agreements that allow the Federal Government to play an active role in program implementation and evaluation.

Medicaid Spending, Recipients Rose in 1992

Medicaid spending by the Federal Government and the States increased 25 percent in fiscal year 1992, with total outlays reaching $118.2 billion, compared with $94.5 billion in FY 1991, according to the Health Care Financing Administration (HCFA).

The rate of increase declined slightly, however, from the 31-percent rise recorded for FY 1991 over FY 1990.

HCFA estimates the number of people covered by Medicaid in FY 1992

Medicaid payments (in millions of dollars) and number of recipients, by State, fiscal years 1991 and 1992

State	1991				1992			
	Federal	State	Total	Recipients	Federal	State	Total	Recipents
Alabama	$ 796	$ 307	$ 1,103	403,255	$ 1,119	$ 421	$ 1,540	466,918
Alaska	105	85	190	51,288	115	97	212	57,540
Arizona	526	326	852	313,142	780	453	1,233	402,212
Arkansas	560	193	753	284,674	720	239	959	320,875
California	4,520	4,479	8,999	4,019,084	6,187	6,116	12,303	4,485,743
Colorado	423	355	778	223,444	567	457	1,024	258,690
Connecticut	758	748	1,506	271,903	1,152	1,139	2,291	316,278
Delaware	99	95	194	50,680	119	114	233	60,696
District of Columbia	254	252	506	100,065	307	303	610	108,514
Florida	1,841	1,540	3,381	1,248,883	2,312	1,909	4,221	1,537,926
Georgia	1,254	780	2,034	746,241	1,575	971	2,546	863,671
Hawaii	148	125	273	91,162	190	170	360	99,666
Idaho	162	61	223	70,060	206	78	284	86,924
Illinois	1,308	1,284	2,592	1,144,272	2,224	2,187	4,411	1,313,140
Indiana	1,132	662	1,794	415,167	1,440	819	2,259	506,829
Iowa	512	298	810	261,419	595	322	917	278,828
Kansas	390	315	705	209,329	554	385	939	226,991
Kentucky	1,113	374	1,487	525,497	1,351	509	1,860	583,089
Louisiana	1,507	528	2,035	640,562	2,534	851	3,385	702,264
Maine	380	219	599	150,623	468	283	751	162,441
Maryland	747	784	1,531	362,520	1,025	1,007	2,032	377,075
Massachusetts	2,216	2,329	4,545	651,056	2,123	2,102	4,225	675,872
Michigan	1,906	1,564	3,470	1,112,533	2,226	1,775	4,001	1,129,023
Minnesota	943	825	1,768	421,738	1,105	923	2,028	406,491
Mississippi	660	176	836	469,684	876	228	1,104	486,861
Missouri	1,012	687	1,699	503,310	1,440	924	2,364	554,477
Montana	179	69	248	63,615	199	81	280	60,186
Nebraska	264	157	421	133,751	320	175	495	150,791
Nevada	100	99	199	59,296	191	186	377	77,525
New Hampshire	202	198	400	59,684	561	557	1,118	71,179
New Jersey	1,587	1,715	3,302	614,073	2,357	2,331	4,688	697,193
New Mexico	285	106	391	161,995	402	138	540	211,805
New York	8,036	9,922	17,958	2,461,537	9,781	9,641	19,422	2,557,701
North Carolina	1,405	704	2,109	667,203	1,672	856	2,528	785,043
North Dakota	162	70	232	52,539	185	70	255	57,068
Ohio	2,318	1,560	3,878	1,299,285	2,962	1,928	4,890	1,442,289
Oklahoma	631	287	918	304,659	781	337	1,118	360,039
Oregon	471	277	748	263,303	557	326	883	295,320
Pennsylvania	2,473	1,929	4,402	1,277,428	3,611	2,742	6,353	[1] 1,426,887
Puerto Rico	79	79	158	1,201,199	79	79	158	[1] 1,341,739
Rhode Island	344	301	645	163,704	421	370	791	[1] 182,857
South Carolina	928	359	1,287	375,233	1,125	431	1,556	431,083
South Dakota	147	57	204	57,145	178	66	244	64,230
Tennessee	1,300	601	1,901	697,411	1,641	764	2,405	785,231
Texas	2,678	1,551	4,229	1,728,629	4,043	2,263	6,306	2,024,554
Utah	275	98	373	129,274	331	114	445	137,264
Vermont	131	81	212	70,699	163	103	266	77,502
Virgin Islands	2.5	2.5	5.0	11,722	2.6	2.6	5.2	13,221
Virginia	671	654	1,325	442,073	838	820	1,658	515,064
Washington	873	731	1,604	506,279	1,168	951	2,119	568,673
West Virginia	438	157	595	283,708	742	224	966	308,034
Wisconsin	1,068	723	1,791	415,942	1,241	811	2,052	440,134
Wyoming	68	31	99	36,804	87	39	126	42,401
Totals	52,533	41,915	[2] 94,525	28,279,781	67,827	50,339	[2] 118,166	[3] 31,594,047

[1] Latest estimate, final total not reported to HCFA.
[2] Includes adjustments after fiscal years 1991 and 1992.
[3] Includes the estimates from Pennsylvania, Rhode Island, and Puerto Rico.

rose approximately 12 percent to about 31.6 million, up from 28.3 million in FY 1991.

Under the Medicaid Program, the States, with Federal matching funds, pay for health care for certain groups of low-income Americans, mainly women, children, the elderly poor, and the disabled. States get from 50 percent to 83 percent of their Medicaid spending from the Federal Government, depending on the per capita income of their residents. Thus, the Federal Government pays a greater share of a poorer State's Medicaid expenses.

The Federal share amounted to $67.8 billion in FY 1992, up from $52.5 billion in FY 1991.

Increases in Medicaid expenditures and the number of people served are attributed to the economic recession, expanded eligibility mandated by congressional legislation, and State use of provider tax and donation programs.

According to the current estimates, total Medicaid spending will reach about $140.3 billion in FY 1993 and $161.9 billion in FY 1994.

In addition, a recent HCFA study projected that Medicaid's portion of national health expenditures could increase from 11.3 percent in 1990 to nearly 21 percent by the year 2000, given recent rates of growth.

PHS Funds Five Minority Health Research Centers

Health and Human Services Secretary Donna E. Shalala has announced establishment of five research centers designed to increase research efforts to prevent, diagnose, and treat illnesses among minority populations.

Funding for the centers, which was provided by the Agency for Health Care Policy and Research (AHCPR) of the Public Health Service (PHS), includes $2.7 million for the first year, with an overall commitment of more than $15 million over the next 5 years. The centers are located in Baltimore, Detroit, Nashville, San Francisco, and Chicago.

Secretary Shalala said a principal focus of the centers' efforts will be variations in practice styles and treatment for specific diseases and conditions to determine what treatments are most effective and are most likely to lead to favorable patient outcomes.

"The centers will support outcomes research in health problems that are especially prevalent among minorities," she said. "In addition, they will provide training opportunities for researchers specializing in minority health issues, offer technical assistance to policymakers and State and local health officials, and disseminate health information pertinent to minority communities."

AHCPR Administrator J. Jarrett Clinton, MD, said that minority populations, when viewed as a whole, have higher rates of hypertension, heart disease, and many other diseases.

"Type II diabetes is 33 percent more common among African-Americans than among whites. Untreated, diabetes can lead to heart disease, stroke, kidney failure, and blindness. AIDS affects proportionately more African Americans and Hispanics—and rates are increasing disproportionately," Dr. Clinton said. "In some Asian-American communities the incidence of tuberculosis is 40 times higher than in the general population."

The Research Centers on Minority Populations are part of AHCPR's Medical Effectiveness Treatment Program (MEDTEP), which includes outcomes research, development of clinical practice guidelines, and widespread dissemination of research findings and practice guidelines to health care practitioners and consumers.

The funded centers include

- University of California at San Francisco, Institute for Health Policy Studies ($748,166 for fiscal year 1993). Principal investigator, A. Eugene Washington, MD, will investigate cardiovascular disease, breast and cervical cancer screening, type II diabetes, and prenatal care issues among African Americans and Latinos (target populations will be extended to Native Americans in FY 1994).
- University of Maryland, Department of Pediatrics, Baltimore, ($677,663 for FY '93). Principal investigator, Bonita F. Stanton, MD, will study child and adolescent health among African Americans, focusing on AIDS, emergency room outcomes, violence, and substance abuse.
- Meharry Medical College, Nashville, TN. ($400,000 for FY '93). Principal investigator, Robert Levine, MD, will study hypertension, substance abuse, infant mortality, and chronic diseases among African Americans.
- Henry Ford Hospital, Detroit, MI. ($400,000 for FY '93). Principal investigator, Mark J. Young, MD, will study hip fracture and total hip replacement, type I diabetes, asthma, and geriatric outcomes among African Americans.
- University of Illinois, Chicago, ($400,000 for FY '93). Principal investigator, Aida Giachello, PhD, will study type II diabetes, substance abuse, and infant mortality outcomes among midwest Latinos.

In addition to the five research centers, AHCPR has also funded six other MEDTEP Research Centers on Minority Populations. These are located in New York, Texas, California, Georgia, New Mexico, and Hawaii.

Worksite Health Promotion Increases by 25 Percent

More employers are sponsoring activities to help employees lose weight, stop smoking, and stay fit, according to a national survey by the Public Health Service.

Investigators found that at 81 percent of the worksites, at least one health promoting activity was offered to their employees—a 25-percent increase since the first survey in 1985.

Programs on the rise include physical fitness, nutrition, weight control, stress management, back care, and blood pressure and cholesterol reduction. In addition, the percentage of worksites with formal policies that prohibit or severely restrict smoking more than doubled, increasing from 27 to 59 percent.

Improved employee health and morale and reduced health insurance costs are the benefits cited most frequently by respondents at worksites with health promotion activities.

The survey showed that employers encourage participation in worksite health promotion activities in several ways.

- 72 percent allow employees to use company time to participate in health promotion activities,
- 12 percent adjust health insurance premiums based on smoking status,
- 8 percent provide annual fixed reimbursements for health promotion expenses, and
- several offer subsidized discounts or reduced fees for participation in community-based programs such as smoking cessation and exercise classes.

Worksites with 750 or more employees and companies that are self-insured are more likely to offer health promotion activities. There was little or no variation reported in different parts of the country.

The results are based on responses from 1,507 private worksites that employed 50 or more people and spanned 6 categories of industry. The data were collected by telephone in the winter of 1992.

Copies of a summary report of the results of the survey may be obtained through the U.S. Government Printing Office at (202) 783-3238).

Decline in State Mental Hospital Population Accelerated in 1990

The number of State and county mental hospital residents at the end of the year and the number added during the year declined sharply in 1990, according to data collected by the National Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, in an annual survey of patient characteristics in State and county mental hospital inpatient services.

The decline followed a period beginning in the early 1980s when these numbers were leveling off. The 1990 statistics suggest an acceleration of the deinstitutionalization process, first observed in these hospitals in 1955.

The number of State and county mental hospital residents at the end of the year decreased each year between 1956 and 1989. Therefore, it was not surprising that the number of residents also decreased in 1990. However, the magnitude of the decrease from 101,402 in 1989 to 92,059 in 1990 (9 percent) was unexpected. The decrease between 1984 and 1989, the previous 5 years, was only about 13 percent, or an average of 2.5 percent per year.

The number of patients added to these hospitals, which includes first admissions, readmissions, and returns from long-term leave, also decreased sharply between 1989 and 1990. The 277,813 added in 1990 were 8 percent fewer than the 302,358 recorded for 1989, a decline that greatly exceeded the average annual decrease of 2 percent for the previous 5 years.

The accelerated decrease in number of residents and additions is due in part to a reduction in the number of hospitals from 290 to 281 between 1989 and 1990. However, it should be noted that the number of State and county mental hospitals has remained relatively stable since 1978, when the number of additions and residents was considerably higher.

A second factor in the decline is that State mental health agencies are using community-based ambulatory care services and private inpatient facilities as alternatives to State mental hospitals. Finally, the State agencies are reducing the size of State mental hospitals in reaction to decreases in State mental health budgets. Data for 1991 and beyond will show whether the accelerated decline will be sustained.

Single copies of the report on a survey of patient characteristsics in State and county mental inpatient services can be obtained from the National Center for Mental Health Services, tel. (301) 443-3343.

Mental Health Staffs, Organizations Up, 1986–88

The Center for Mental Health Services (formerly the National Institute of Mental Health) of the Public Health Service has produced the latest in its series of Statistical Notes, No. 206, entitled, "Staffing of Mental Health Organizations, United States 1988."

Written by Richard W. Redick, PhD, Michael J. Witkin, MA, CPA, Joanne E. Atay, MA, and Ronald W. Manderscheid, PhD, the note discloses that between 1986 and 1988, the number of full-time equivalent (FTE) staff people employed in specialty mental health organizations in the United States increased 7 percent, from 494,515 to 531,067.

Much of this increase could probably be attributed to the 4-percent increase in the number of mental health organizations during this period, from 4,747 to 4,930, according to the authors.

With the exception of State mental hospitals and Veterans Administration (VA) psychiatric organizations, all of the other types of mental health organizations showed varying amounts of increase in FTE staff with the most notable gains being reported by private psychiatric hospitals, residential treatment centers for emotionally disturbed children, and multiservice mental health organizations.

Of the 531,067 FTE staff employed in mental health organizations in 1988, 72 percent were classified as patient care staff and 28 percent as administrative and support staff. State mental hospitals had 35 percent and VA psychiatric organizations had 32 percent administrative and support staff.

Seventy percent or more of the staff employed in the various types of specialty mental health organizations in 1988 worked on a full-time basis, the two exceptions being staffs of free-standing psychiatric outpatient clinics with 52 percent and non-Federal general hospital psychiatric services with 69 percent of all staff members.

For the most part, the majority (50 percent or more) of each of the staff disciplines employed in mental health organizations worked full time. The major exceptions were psychiatrists and other physicians, most of whom worked either on a part-time or trainee basis.

Further information can be obtained from Berdie Firestone, Center for Mental Health Services, Survey & Analysis Branch, Rockwall II, Suite 501, CMHS, SAMHSA, 5600 Fishers Lane, Rockville, MD 20857; tel. 301–443–3343.

Panel Recommends Primary Care Detection, Treatment of Major Depression

A panel of health care experts urges family physicians and other primary care providers to be more aggressive in detecting and treating major depression that can disable the patient and sometimes lead to suicide.

The clinical guidelines for major depression were developed for the Agency for Health Care Policy and Research (AHCPR) of the Public Health Service by a private sector panel composed of psychiatrists, primary care physicians, a clinical psychologist, a psychiatric nurse, a social worker, and a consumer advocate.

The panel stressed that early detection and treatment appear to be more effective in shortening the depression, lessening disability, and cutting costs. Primary care providers, the panel said, should go beyond a patient's initial complaint, such as chronic headache, to ask about emotional, mental, behavioral, and other physical symptoms of major depression.

More than 11 million people in the United States suffer depression and 1 in 8 Americans will be affected some-

time in life. Up to two-thirds of all sufferers either seek no treatment or are inadequately diagnosed or treated.

Major depression, which affects people of all ages but strikes women twice as often as men, cost the nation at least $27 billion in 1989 in medical care, worker absenteeism, and related costs.

Major depression is a form of clinical depression characterized by symptoms such as sad mood, low energy, loss of interest in usual activities, difficulty concentrating, changes in eating or sleeping, and suicidal thoughts. Risk factors include family history and genetics, other illnesses, certain medicines, and drug or alcohol abuse.

The panel, which was formed in 1990, reviewed more than 3,500 studies and sought information from a wide range of organizations.

AHCPR will distribute the guidelines to physicians, nurse practitioners, mental health nurse specialists, physician assistants, social workers, and others through national and State professional societies and journals.

Copies of the two-volume "Depression in Primary Care" which covers detection and diagnosis of most forms of depression, and the treatment of major depressive disorder—an accompanying quick reference guide for providers, and an easy-to-understand guide for patients (a Spanish-language guide will be available later), are available free from DEPRESSION, P.O. Box 8547, Silver Spring, MD 20907; tel. 1-800-358-9295.

WHO Acts to Prevent Vaccine Crises in Former USSR

Urgent measures to provide millions of doses of vaccine against major childhood diseases in the Newly Independent States (the countries of the former Soviet Union) have been undertaken by the World Health Organization (WHO) with the participation of international donors and health and finance ministries.

A WHO-led coordinating committee of outside agencies, among them governmental aid agencies of Canada, Japan, and the United States, UNICEF, and Rotary International, has been set up to assist with vaccine supplies.

The 1993 shortfall to meet the WHO schedule of immunization of infants is in the order of 4-7 million doses of DPT (diphtheria, pertussis, tetanus), 4-10 million doses of OPV (oral polio vaccine), 3-5 million doses of measles vaccine, and 2 million doses of BCC (tuberculosis). In addition, some 20 to 30 million doses of diphtheria-containing toxoids may be needed to control current outbreaks of diphtheria.

The disintegration of the former Soviet Union played havoc with the domestic pharmaceutical industry. Many production plants were shut down indefinitely for technological and ecological reasons. Production links between various plants were severed. Overall output plummeted to dangerously low levels.

According to Dr. Artur Calazka of WHO's Expanded Program on Immunization, "The international community will probably be able to raise a one-time vaccine donation as a short-term relief measure, but for a long-term solution, ways and means need to be found for restoring and upgrading domestic production facilities in the Newly Independent States.".

It is feared that outbreaks of other major childhood diseases could occur soon, unless urgent preventive measures are taken.

"Already diphtheria is back in epidemic proportions", stressed Dr Ralph H. Henderson, WHO Assistant Director-Ceneral, "If international experience is anything to go by, it will be followed by pertussis (whooping cough). Shortages of measles vaccine may possibly aggravate the current situation even further. This is a danger we cannot ignore."

Recent outbreaks of diphtheria in Russia and Ukraine put the spotlight on a childhood disease that was successfully controlled in Europe for the last 30 years. In some European countries, not a single case of diphtheria was reported for the last 15 years. In the former Soviet Union, the disease was virtually eliminated in the 1970s but staged a powerful comeback some ten years later.

In 1990, the overall number of cases in Russia reached more than 1,000; the next year it came close to 2,000. Last year saw a dramatic surge that resulted in a doubling of the number of cases from the previous year—3,899 cases and 125 deaths.

According to the information received by WHO from Russia and Ukraine, the epidemic goes on unabated. For a variety of reasons, the diphtheria immunization rates among infants and children especially in big cities, remain very low, hovering just above the 50-percent mark. In Russia, an emergency immunization program aimed at children, adolescents, and high-risk groups among the adult population was launched earlier this year and is designed to cover all adults at risk within the next 3 years. If the program is to succeed, Russia needs considerable amounts of vaccine that is not readily available.

Several factors for the low immunization coverage were at work. Among them

- excessive and unnecessary objections to immunization put forward by some pediatricians have denied many children the opportunity to benefit from vaccination;
- public concern over the safety of vaccines, especially DPT (diphtheria, pertussis, tetanus), with inadequate reassurance from the health authorities; and
- ineffective education of parents on the benefits of currently available and recommended vaccines.

NCI Offers Fellowships in Cancer Prevention

The National Cancer Institute (NCI) is offering an opportunity for persons with doctoral degrees in medicine, dentistry, public health, or philosophy to train in the emerging discipline of cancer prevention and control with its Cancer Prevention Fellowship Program.

The 3-year program provides independent research opportunities within the Division of Cancer Prevention and Control (DCPC) at NCI. Many training opportunities are available, including an academic course covering the current principles, methods, and practice of cancer prevention and control.

A feature of the program is master of public health (MPH) training at accredited schools of public health during the first year for Fellows accepted into the program.

Applications are due September 1, 1993. Fellows begin July 1, 1994.

The program provides for

- master of public health training at accredited university programs,
- participation in the DCPC Cancer Prevention and Control Academic Course,

• working at NCI directly with individual preceptors on cancer prevention and control projects, and
• field assignments in cancer prevention and control programs at other institutions.

Funding permitting, as many as 10 Fellows will be accepted for up to 3 years of training. Benefits include selected relocation and travel expenses, paid Federal holidays, and participatory health insurance.

Details on the program and an application catalogue may be obtained from Douglas L. Weed, MD, MPH, PhD, Director, Cancer Prevention Fellowship Program, Division of Cancer Prevention and Control, National Cancer Institute, Executive Plaza South, T-41, Bethesda, MD 20892, telephone (301) 496-8640 or 8641.

Journal Seeks Manuscripts for Special Issue on Health Education

The journal, Health Education Research Theory and Practice, is soliciting manuscripts for a theme issue dealing with measurement in health education and health promotion to be published in 1994. It will focus on quantitative and qualitative measurement in health education and health promotion research or practice.

Examples of topics suitable for this issue include, but are not limited to

1. conceptual discussions of measurement-related issues as they apply to health education or health promotion, theory, research, and practice;
2. the challenges of operationalizing variables stemming from theories that inform health behavior and health education research and practice;
3. examples of innovative solutions to measurement problems;
4. presentations of new instruments or methods for measuring variables of broad interest in health education and health promotion;
5. critical examinations of measurement procedures or instruments widely used in health education;
6. comparisons of qualitative and quantitative measurement approaches;
7. innovations in measurement theory with particular bearing on health education theory, research, and practice or on health promotion; and
8. integrative reviews of measurement issues or approaches in health behavior or health education.

To process manuscripts for this theme issue, the editorial staff must receive them no later than Dec. 1, 1993. Manuscripts or inquiries may be submitted to one of the following:

Robert F. DeVellis, PhD, Department of Health Behavior and Health Education, Bolin Creek Research Office, Suite 103, CB 7330, University of North Carolina, Chapel Hill, NC 27599-7330; tel. (919)966-7534.

John B. Davies, PhD, Centre for Occupational and Health Psychology, University of Strathclyde, Graham Hills Building, 50 George Street, Glasgow G1 1QE, U.K. Tel. 041-552-4400 Ext. 2577.

Thomas Baranowski, PhD, Emory University School of Public Health, Division of Behavioral Sciences and Health Education, 1599 Clifton Road, NE, Atlanta, GA 30329; tel. (404) 727-8742.

NIAID to Test New AIDS Vaccines on Pregnant Women with HIV

The National Institute of Allergy and Infectious Diseases (NIAID) has begun the first clinical trials of therapeutic AIDS vaccine for pregnant women who are HIV-infected but otherwise healthy.

In these separate Phase I trials, two experimental vaccines are being evaluated primarily for safety but also for their potential to stimulate anti-HIV immune responses in expectant mothers and to prevent their passing HIV infection to their babies.

No one knows exactly when HIV passes to the fetus, or why some babies get infected and others do not. Evidence suggests that HIV frequently is transmitted either late in pregnancy or during birth.

"By vaccinating HIV-infected pregnant women, we hope to induce immune responses that will reduce the amount of virus present, thus helping the women, while simultaneously stimulating antibody responses that can cross the placenta and protect their babies from HIV infection," said NIAID Director Anthony S. Fauci, MD

One precedent for using maternal immunization to prevent the transmission of infectious diseases from a mother to her newborn is tetanus immunization. Vaccinating pregnant women in nonindustrialized countries has proved to be the most cost-effective way to prevent neonatal tetanus, a significant cause of newborn deaths in these countries.

The two new trials in pregnant women and a similar one expected to begin in mid-1993 will test genetically engineered candidate HIV vaccines. Completed and ongoing trials of these experimental vaccines in healthy people with and without HIV infection have shown them to be well-tolerated. Because each candidate contains no live HIV and only a piece of the virus, these so-called subunit vaccines cannot transmit HIV infection.

Although testing different candidate HIV vaccines, the trials are designed similarly. Both enroll women between ages 16 and 40 who are free of AIDS-defining symptoms and have 400 or more CD4+ T cells, a primary cell of the immune system. Volunteers must not have any other medical conditions, such as insulin-dependent diabetes or moderate to severe hypertension, that would make their pregnancy high risk. Therapy with zidovudine (AZT) can be continued during the trial.

The multicenter trial will enroll 24 women. Of these, 16 will receive the experimental vaccine, the rest a non-active dummy vaccine, or placebo. The smaller trial will enroll 12 women, 9 assigned to receive vaccine and the others a placebo. Assignments will be made randomly, and throughout the trial, neither the investigators nor the participants will know if the women are receiving the active vaccine or the placebo.

Each trial volunteer will receive at least four or five immunizations: the first between the 16th and 24th week of pregnancy and thereafter monthly booster doses until the end of her pregnancy. The health of the women will be monitored with regular blood and urine tests, and the health of their fetuses with ultrasound.

The mothers may opt for a second series of booster immunizations at 3, 6, 9, and 12 months after delivery. Both trials will last about 2 years, including an 18-month followup period after delivery.

Newborns will be examined at birth and 6 weeks later, and then every 3 months during followup. The investigators will periodically sample the babies' blood to monitor their health and determine any vaccine effects.

"By intentionally altering the HIV

immune status of pregnant women through active immunization, eventually we hope to discover the critical factors that prevent mothers from passing the infection to their babies," says Patricia Fast, MD, PhD, who leads the Phase I-II HIV vaccine trials program for NIAID's Division of AIDS.

The trials are being conducted through two of NIAID's national clinical trials networks, the AIDS Vaccine Evaluation Group (AVEG) and the AIDS Clinical Trials Group (ACTG). Study co-chairs and AVEG investigators Peter Wright, MD, of Vanderbilt University, and John Lambert, MD, of the University of Rochester in New York, will coordinate the trials. Dr. Fast, along with James McNamara, MD, and Evelyn Rodriguez, MD, both medical officers in NIAID's Division of AIDS who specialize in perinatal and pediatric clinical trials, will help facilitate the studies.

One trial will be conducted at Johns Hopkins University, Baltimore, MD; St. Louis University School of Medicine, St. Louis, MO; Washington University, St. Louis; University of Rochester Medical Center, Rochester, NY; University of California at San Francisco, San Francisco; University of Washington, Seattle; and Vanderbilt University, Nashville, TN.

Women in this trial will receive an experimental vaccine that contains a genetically engineered surface protein of HIV and a substance formulated with a vaccine to boost specific immune responses.

The second trial will be carried out at Yale University School of Medicine, New Haven, CT. This trial uses a vaccine that contains the parent protein of the substance used in the first trial and the same immune response booster. The response booster will be used in both trials as the placebo vaccine.

—LAURIE K. DOEPEL, Writer-Editor, Office of Communications, NIAID.

More information about the trial sites or eligibility criteria can be obtained from the AIDS Clinical Trials Information Service, 1-800-TRIALS-A, 9 am to 7 pm ET weekdays. Spanish-speaking information specialists are available.

AIDS History Conference Set for Oct. 28–29 at NIH

The AIDS History Group of the American Association for the History of Medicine has scheduled a conference on the theme "AIDS and the Public Debate: Epidemics and Their Unforeseen Consequences" for October 28–29, 1993 at the National Institutes of Health in Bethesda, MD.

C. Everett Koop, MD, former Surgeon General of the Public Health Service, will deliver the keynote address on "The Early Days of AIDS as I Remember Them." Anthony S. Fauci, MD, Director, Office of AIDS Research, and Director, National Institute of Allergy and Infectious Diseases, will close the conference with "AIDS: Reflections on the Past and Considerations for the Future."

Other speakers and their subjects during the conference include

Virginia Berridge, London School of Hygiene and Tropical Medicine, "AIDS and Voluntarism in Britain;" Allan M. Brandt, Harvard Medical School, "AIDS: From Public History to Public Policy;" Daniel Bross, AIDS Action Council, "Community Health Activists and AIDS: Forces for Change?"; James W. Curran, Centers for Disease Control and Prevention, "The CDC and the Investigation of the Epidemiology of AIDS;" R. Gordon Douglas, Jr., Merck & Co., Inc., "The Implications of AIDS for the Development of Therapies and Vaccines: The Pharmaceutical Perspective;" Paul Farmer, Harvard Medical School, "AIDS, Haiti, and the Assignment of Blame;" Victoria A. Harden, National Institutes of Health, "The Impact of AIDS on the NIH Intramural Program;"

Ruth Kulstad, Clinical Chemistry, "Publishing AIDS Papers in the Early 1980s;" Maryinez Lyons, University of London, "AIDS and the Political Economy of Health in Uganda;" Anne Marie Moulin, INSERM, Paris, "Blood Transfusion and the Spread of AIDS in France;" Mark Smith, Henry J. Kaiser Foundation, "AIDS and Minority Health;" Nancy Tomes, SUNY at Stony Brook, "AIDS and the Resurgence of Tuberculosis;" and James Harvey Young, Emory University, "AIDS, Drugs, and the FDA."

Further information about registration and accommodation can be obtained from AIDS and the Public Debate Conference, c/o NIH Historical Office, Building 31, Room 2B09, National Institutes of Health, Bethesda, MD 20892. If you use e-mail, address vh2Qnihcu.BITNET.

FDA Clears the Way for Ending Shortage of TB Treatment Drug

The Food and Drug Administration (FDA) has approved resumption of the manufacture of streptomycin sulfate injections to treat patients with tuberculosis. The action is designed to end a shortage that started in mid-1991 after the last U.S. manufacturer ceased production.

FDA Commissioner David A. Kessler, MD, said, "Tuberculosis is again on the rise, and Pfizer, Inc. is to be commended for answering our call for an assured supply of therapies to curb this resurgence."

FDA set out to counter the threat of streptomycin shortages as soon as they became apparent 2 years ago. A special task force headed by Mary Pendergast, Dr. Kessler's deputy commissioner and senior adviser, canvassed pharmaceutical manufacturers in the United States, Europe, and Asia to identify a firm that would seek approval of this product for the U.S. market.

Reported TB cases in the United States continued to rise in 1992. After reaching an all-time low of 22,201 cases in 1985, cases reported to the Centers for Disease Control and Prevention (CDC) climbed to 26,673—an increase of 20 percent over the 7-year period and a 1.5-percent increase over 1991.

Evidence from previous years suggests that cases among HIV infected persons and the foreign born are responsible for much of the rise. Increases in recent years in TB cases in U.S.-born children younger than age 5 indicate that, since such cases result from recent infection, increased transmission may also be playing a role.

CDC guidelines recommend the addition of streptomycin to a core regimen of isoniazid, rifampin and pryazinamide, to prevent the emergence of drug resistant TB. Also, the four-drug regimen can be more easily administered through directly observed therapy, since this regimen can be given three times per week from the beginning of therapy or two times per week after a 2-week daily induction phase.

Car Baby Seats, Air Bags Don't Mix, CDC Points Out

Rear-facing child safety restraints, recommended for infants up to about 20

pounds, should not be used in the front seat of vehicles with passenger-side airbags, according to the Centers for Disease Control and Prevention (CDC).

This type of child restraint, with its back close to the instrument panel, could be struck by the airbag when it rapidly inflates in a crash, and a child in the restraint could be seriously injured.

The CDC advisory is based on information from the American Academy of Pediatrics, Society of Automotive Engineers' Task Force on Child Restraint Airbag Interaction, and CDC's National Center for Injury Prevention and Control.

CDC said that children should ride in the rear seat of vehicles whenever possible. To be properly protected, infants must ride in a rear-facing child restraint until they weigh about 20 pounds and are a year old. Under no circumstances should an infant younger than age 1 and weighing less than 20 pounds be placed in a child safety restraint facing forward.

Forward-facing child restraints may be used in the front seat of a vehicle equipped with a passenger-side airbag, according to CDC, if the child's age and weight meet the restraint manufacturer's requirements. In this case, the vehicle seat should be moved as far back as possible, placing the child in a similar position relative to the airbag as a restrained adult.

Airbags are very effective and have saved many lives but are not compatible with rear-facing child restraints. Fortunately, there have been no reports of children being injured in this way. However, with at least 8 million vehicles in the United States equipped with passenger-side airbags and 3.8 million babies born each year, the likelihood of this type of injury occurring is increasing.

Injury is the leading cause of death among American children and for all Americans through age 44.

FDA Survey Finds Food Stores Providing Produce and Seafood Information

Results of a a nationwide survey by the Food and Drug Administration (FDA) show that more than 70 percent of food stores are voluntarily providing nutrition information about raw produce and seafood.

"The survey shows that food labeling reform has really caught on," said FDA Commissioner David A. Kessler, MD. "These products were not labeled in the past. Now, consumers are demanding more information about the food they buy, and retailers know it's good business to give consumers what they want."

The voluntary participation in the site-of-sale labeling program satisfies the standard that FDA established under the Nutrition Labeling and Education Act of 1990 requiring that at least 60 percent of the stores take part, or the program becomes mandatory.

The foods covered by the voluntary labeling program are 20 each of the top-selling raw fruits, vegetables, and seafood.

The survey, conducted in November and December 1992, in approximately 2,000 stores from coast to coast, found that 75.7 percent of the sampled stores selling raw fruit and vegetables and 73.2 percent of the stores selling raw seafood were taking part in the program.

To comply, retailers must provide consumers with nutrition information for at least 90 percent of the 60 specified raw products. The information displayed must include per-serving values for calories, protein, fat, carbohydrates, sodium, vitamin A, vitamin C, calcium and iron. Information on dietary fiber may also be provided for fruits and vegetables, and information on cholesterol and saturated fat for seafood.

FDA will monitor national produce and seafood consumption data and update the list of the top 20 varieties of fruits, vegetables, and seafood every 2 years. Another survey will be conducted in 1994 to determine whether most food retailers continue to comply with the voluntary program. The following are the raw products in FDA's program:

Vegetables—asparagus, bell pepper, broccoli, cabbage, carrot, cauliflower, celery, corn, cucumber, green bean, green onion, iceberg lettuce, leaf lettuce, mushroom, onion, potato, radish, summer squash, sweet potato, tomato.

Fruits—apple, avocado, banana, cantaloupe, cherry, grape, grapefruit, honeydew, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plum, strawberry, tangerine, and watermelon.

Seafood—blue crab, catfish, clam, cod, flounder, haddock, halibut, lobster, mackerel (Atlantic/Pacific and jack), ocean perch, orange roughy, oyster, pollock, rainbow trout, rockfish, salmon (Atlantic/coho), scallops, shrimp, sole, and whiting.

Erratum

In *Public Health Reports*, Vol. 108, No. 3, May-June 1993, "Risk Factors for Drowning and Near-Drowning Among Children in Hillsborough County, Florida," Karen D. Liller, PhD, and coauthors, on page 348, table 1 contains a misprint. Under the characteristic "Sex," in the column headed "County," the number of women should read 427,837. The percent of men should read 48.7 and the percent of women should read 51.3.

*U.S. G.P.O.:1993-342-341:80003