DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

Phone: (202)690-7850 **Fax: (202)690-5673**

To: Chris Jennings
WH

Fax: 456-5557 Phone: _____

Date: 12/16/98 Total number of pages sent: 2

Comments:

200 Independence Avenue, S.W., Bldg. HHH, Room 647-D, Washington, D.C. 20201

12/17/98

NOTE TO BRUCE REED AND CHRIS JENNINGS –

Just wanted to make you aware of several pending issues since our meeting was canceled. Please give me a call if you have any questions or comments. Thanks.

MMWR this week will have several articles on sexually transmitted diseases. The scheduled review of state tobacco legislation that Jim O'Hara mentioned to Cynthia Rice has been postponed.

The January 12 issue of Health Affairs includes a letter from several former HCFA administrators calling on the Administration and Congress to give HCFA a bigger budget. It also contains several articles on Medicare policy, and a press conference is planned. We plan to decline an invitation for Nancy-Ann to appear.

The Monitoring the Future press conference with Secretary Shalala and General McCaffrey is this Friday at 2:00 p.m. Jose Cerda is aware.

Secretary Shalala is planning to have an end of the year session with reporters, probably with the Brazda breakfast group, and probably January 30. Chris – Rich may have mentioned this to you (it's part of his legislative strategy) but please give me a call when you can.

We are working with Sarah to find a date for the VP to announce the child support PSAs I mentioned several weeks back.

Several reporters are, of course, trying to get information on the budget negotiations. One AP reporter will probably go with a story on FDA sometime soon, even without our help. OMB press office is aware.

Laurie McGinley of WSJ has written a story on the IG ambulance payment report that will run in the near future. No other press interest that I know of.

Jason DeParle's piece on welfare reform in New York City will be in the New York Times magazine this Sunday. It does not mention Medicaid.

I think that's it!

Melissa

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

FACSIMILE

DATE: 12/2/98

TO: Chris Jennings

FAX#: 456-5557

FROM: Mary Beth Donahue
Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

The following is a one-pager on the 1996 Abortion Surveillance Data and a synopsis from this week's MMWR.

The qtr is in the works. We will get it to you as soon as it's ready.

Let me know if you need anything else.

_____Pages [including this cover]

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

MMWR
MORBIDITY AND MORTALITY WEEKLY REPORT

1996 Abortion Surveillance Data

December 4, 1998
Contact: CDC, Division of Media Relations
(404) 639-3286

Many states emphasize the prevention of unintended pregnancy, particularly among teenagers. To assist efforts to prevent unintended pregnancy, each state needs an accurate assessment of abortion on an ongoing basis, including the number and characteristics of women obtaining abortions.

This report includes the preliminary analysis of national abortion surveillance data for the latest year of available data—1996. The report presents national data for 1996 on legal induced abortions compiled from the 50 states, New York City, and the District of Columbia.

- In 1996, 1,221,585 legal, induced abortions were reported to CDC, representing a slight increase (0.9%) from the number reported in 1995. As in 1995, the 1996 national abortion rate of 20 per 1,000 women of reproductive age (15–44 years of age) continues to be the lowest rate recorded since 1975. The national abortion ratio (number of legal abortions per 1000 live births) increased slightly from 311 in 1995 to 314 in 1996, and was lower than for any year since 1976.

- Since 1990 (the year in which the number of abortions was highest), the annual number of legal induced abortions in the United States declined by 15%. However, from 1995 to 1996, the number increased slightly. This change in the number of abortions reported to CDC may indicate that the numbers of legal abortions in the United States may be leveling off. In 1996, one-half (26 of 52) of reporting areas reported fewer abortions than in 1995.

- Women who obtained legal abortions in 1996, as in previous years, were predominantly white and unmarried. Since 1991, about one-fifth of women who obtained abortions were ≤19 years of age.

- Curettage (suction and sharp) remained the primary procedure, accounting for 99% of all legal abortion procedures.

- As in previous years, more than half (55%) of legal abortions were performed during the first 8 weeks of pregnancy; approximately 88% were performed during the first 12 weeks of pregnancy.

- Factors that may have contributed to the decrease in the proportion of pregnancies that ended in abortion since 1990 include: 1) a decrease in the number of unintended pregnancies; 2) changes in contraceptive practices, including an increased use of condoms among young women; 3) reduced access to abortion services; and, 4) possible changes in attitudes concerning abortion.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

MMWR articles are embargoed until 4 p.m. on Thursday.

MMWR
MORBIDITY AND MORTALITY WEEKLY REPORT

Synopsis December 4, 1998

Impact of the Sequential IPV/OPV Schedule on Vaccination Coverage Levels — United States, 1997

Implementation of the sequential polio virus vaccination schedule did not change coverage levels of the vaccines routinely recommended for infants.
Children receiving IPV as their first polio vaccination were as likely to be up-to-date at 12 months of age for routinely recommended vaccinations as children receiving OPV. Use of inactivated polio vaccine (IPV) for the initial polio vaccine doses in two large HMOs was not associated with decreases in immunization coverage levels, demonstrating that the need for additional injections associated with IPV did not impede complete vaccination at 12 months of age. Use of oral polio vaccine (OPV) is no longer recommended for the first two doses of the routine childhood polio vaccination schedule, except in special circumstances. The percentage of children who received IPV as their first polio virus vaccine increased between the fourth quarter of 1996 and the third quarter of 1997.

Fatal Car Trunk Entrapment Involving Children — United States, 1987–1998

Eleven children died this summer of fatal car trunk entrapment in three separate incidents.
From 1987–1998, nine incidents of fatal car trunk entrapment involving children occurred in the United States. All cases involved hot weather and children ≤6 years of age. Heatstroke is a medical emergency and is often fatal despite medical care. During July–August 1998, 11 children died in three separate incidents of car trunk entrapment. All cases in 1998 were related to heatstroke and no deaths occurred when temperatures were <85 °F. Cars parked in direct sunlight can reach internal temperatures of up to 131°F–172°F when outside temperatures are 80° F–100°F. No surveillance system exists that monitors or reports car trunk entrapment-related deaths.

Forecasted State-Specific Estimates of Self-Reported Asthma Prevalence — United States, 1998

The prevalence of asthma has risen dramatically; increasing by 75% from 1980–1994.
Despite the increase in the prevalence of asthma, there is limited surveillance for asthma at the state or local level. As a result, it is difficult to estimate the burden of asthma in individual states. In 1998, an estimated 17,298,000 persons in the United States have asthma. The state with the largest estimated number of persons with the disease was California, followed by Texas and New York. This report demonstrates that national data can be used to estimate the prevalence of asthma at the state level. The data also projects a continued rise in the number of people with asthma. More information is needed in order to target high risk groups within states, and to initiate and evaluate local intervention efforts.

Abortion Surveillance: Preliminary Analysis — United States, 1996

The number of legal induced abortions in 1996 remain at about the same level as in 1995.
In 1996, 1,221,585 legal, induced abortions were reported to CDC, representing a slight increase (0.9%) from the number reported in 1995. As in 1995, the 1996 national abortion rate of 20 per 1,000 women of reproductive age (15–44 years of age) continues to be the lowest rate recorded since 1975. The national abortion ratio (number of legal abortions per 1000 live births) increased slightly from 311 in 1995 to 314 in 1996, and was lower than for any year since 1976. Women who obtained legal abortions in 1996, as in previous years, were predominantly white and unmarried. As in 1995, most women obtaining abortions in 1996 were ≥20 years of age.

FACSIMILE

DATE: 12/3/98

TO: Devorah Adler

FAX #: 456-5557

FROM: Rebecca Werbel
Office of the Chief of Staff
Department of Health and Human Services

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

The following are q+a on the National Toxicology Program + declaring alcohol, etc. known carcinogens. They should answer most of your questions. If not, you can call Ripley Forbes in OPHS @ 260-2255. Let me know if you need anything else.

3 Pages [including this cover]

NIEHS
NIH OPHS/SCC

Q -- The National Toxicology Program Board of Scientific Counselors is reviewing alcoholic beverage data to see if the board should recommend to the National Toxicology Program that alcoholic beverages should be listed as a "known human carcinogen" in the Ninth Report on Carcinogens, a Congressionally mandated report planned for publication in 1999. A vote may come today (Dec. 2) or tomorrow (Dec. 3). What information have the board members been reviewing?

A -- An interagency review of the data and a staff review have preceded the board's deliberations and both concluded alcoholic beverages to be a known human carcinogen based largely on epidemiological data associating drinking in a dose-related manner with cancers of the mouth, pharynx, larynx and esophagus. This relationship is most obvious among heavy drinkers -- and has been pointed out in the National Institutes of Health's and other documents and publications for about ten years. The effects are also influenced by other factors, especially smoking. (One National Institute of Alcohol Abuse and Alcoholism publication for the public, published in 1993, links drinking alcohol to an estimated 2-4 percent of all cancers – 125,000 deaths a year – is says that the risk of mouth, tracheal and esophageal cancer is 35 times greater for people who smoke and drink than for people who do neither.) However, smoking does not explain the observed increased risk of cancers associated with increased alcohol beverage consumption.

There are also less accepted associations shown in some studies of breast cancer and liver cancer, but nutrition appears to be a factor in the latter.

Increased frequencies of chromosomal aberrations, sister chromatid exchanges, and aneuploidies have been found in the peripheral lymphocytes of alcoholics. Ethanol free extracts of some alcoholic beverages induced sister chromatid exchanges in human cells in vitro and mutations in bacteria – all suggestive of potential carcinogenicity.

Acetaldehyde is the major metabolite of alcohol in man and was listed as "reasonably anticipated to be a human carcinogen" in the Eighth Report on Carcinogens.

Chronic alcoholic beverage consumption increases the rate of ethanol oxidation which results in increased levels of acetaldehyde in the liver and blood.

Q - What would listing in the Ninth Report on Carcinogens (in 1999) mean in terms of government action?

A – Nothing directly. However, the report is required by Congress as a way to alert the public and to ensure that regulatory agencies are taking reasonable steps to protect the public from known carcinogens. This can mean that agencies and Congress will review the possible

need for warning labels, masks and other protective gear in the workplace, health information campaigns and so on. Occasionally a product will be banned or be dropped by manufacturers when it is shown to be carcinogenic and safer, substitute products are available.

Alcohol already carries a number of health warnings. One possibility would be to include a new warning specifically mentioning the NTP's finding. Another would be a re-emphasis on government campaigns aimed at moderation.

Q – What is the NTP?

A – It is an organization of the HHS that reviews toxicology data. While it is headquartered at the National Institute of Environmental Health Sciences (which is one of the National Institutes of Health) and has close ties and the same director, it serves HHS regulatory agencies such as the FDA and some outside the HHS family.

Q – What is the process by which a substance or process is listed as a "known" or "reasonably anticipated" human carcinogen?

A – Anyone, including the public, can nominate a substance for review. Most substances, however, are nominated by the regulatory agencies, other parts of NIH or various scientific bodies. If the nomination is convincing in its arguments, the substance or process can be accepted for review by NTP.

The review may include both published data and, in many cases, new studies especially commissioned.

The data is reviewed by an interagency board of scientists and by an NTP scientific panel before going to the larger NTP Board of Scientific Counselors. The board's recommendations are not binding on NTP. After the review, staff prepare a draft report which is then reviewed by the director of NIEHS and NTP, and then by the Secretary of HHS before publication and presentation to Congress.

Q – What other controversies is the board dealing with?

A – The board may recommend that second-hand tobacco smoke (in addition to directly inhaled tobacco smoke which it previously recommended) be listed as a "known human carcinogen." EPA has regarded second-hand smoke as carcinogenic – and this would support that statement and possibly strengthen EPA's position in a court challenge.

The board also has before it some disputed data on diesel exhaust fumes, which could be listed as a "known" or "reasonably anticipated" carcinogen.

FACSIMILE

DATE: 12/6/98

TO: Devorah

FAX#: 456-5557

FROM: Elizabeth Summy
Deputy Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

5 **Pages [including this cover]**

DRAFT #324

EMBARGOED FOR RELEASE
Monday, December 7, 1998, 9:00 a.m.

Contact: NCHSTP Office of Communications,
(404) 639-8935

CDC Issues National Report Card on STDs Gonorrhea and Syphilis Down, but Not Beaten : Chlamydia Continues to Spread Widely

Syphilis and gonorrhea have reached all time lows in the U.S. overall, but a number of cities in the South and Northeast continue to battle high rates of both diseases, according to new data released today by the Centers for Disease Control and Prevention (CDC).

Fifteen cities share the grim distinction of leading the nation in reported rates of both STDs. The cities that made the list for highest rates of both gonorrhea and syphilis in 1997 are (in alphabetical order) Atlanta, Baltimore, Birmingham, Chicago, Detroit, Memphis, Milwaukee, Nashville, Newark, New Orleans, Norfolk, Oklahoma City, Richmond, St. Louis, and Washington, D.C.

CDC issued the "report card" on STD prevention at the 1998 National STD Prevention Conference which opened in Dallas, Texas today. CDC updated leading experts from across the nation on the status of the STD epidemic in the U.S., as the group came together to design new strategies for combating STDs in the 21st century.

According to CDC, the new data help identify areas where increased attention must be focused in the next era of STD prevention.

"For far too long, our nation has accepted the consequences of STDs as an unavoidable reality," stressed Helene Gayle, M.D., M.P.H., Director of CDC's National Center for HIV, STD, and TB Prevention (NCHSTP). "Fortunately, for the health of women and children, things are beginning to change. But we must gain momentum if we are serious about further reducing the still staggering toll."

According to Gayle, while gonorrhea and syphilis, the STDs we have been battling the longest, are now primarily isolated geographically, other diseases such as chlamydia, herpes, and human papillomavirus (HPV) remain extremely widespread.

The latest estimates indicate that 15 million Americans become newly infected

DRAFT #324

with an STD each year. One of the most common STDs in the nation is chlamydia, which remains one of the most under recognized health threats. CDC receives more reports of chlamydia each year than any other infectious disease, and an estimated three million Americans are infected annually. While the disease can be easily treated and cured if detected early, it often has no symptoms and goes undiagnosed. Untreated, chlamydia can lead to severe health consequences for women, including infertility and potentially fatal tubal pregnancies.

In her opening remarks to the conference, Judith Wasserheit, M.D., M.P.H., Director of NCHSTP's Division of STD Prevention, identified improved detection and treatment of chlamydia as one of several urgent priorities for national STD prevention efforts. The agency's first priority will be the elimination of syphilis.

In one of his first national appearances as CDC Director, Jeffrey Koplan, M.D., M.P.H., will announce at the conference that a key priority of his agency will be eliminating the threat of syphilis from the U.S. According to Koplan, syphilis is now confined to only 1% of U.S. counties and has never been more vulnerable to elimination.

"At no time in history have the prospects for eliminating syphilis been better," stressed Koplan. "We have the rare opportunity to add syphilis next to malaria and cholera on the short list of diseases we have beaten in the United States. But if we don't take the opportunity now, we will lose our chance."

Koplan's full statement on syphilis elimination will be released on Wednesday, December 9, 1998.

Syphilis elimination efforts are critical to improving infant health, slowing the spread of HIV infection, and to reducing racial disparities in health. Untreated syphilis during pregnancy results in infant death in up to 40% of cases, and over 65% of cases of congenital syphilis are among African-Americans. Moreover, syphilis is believed to be accelerating the spread of the HIV epidemic, particularly in communities of color. Given the disproportionate toll of the disease among African-Americans, syphilis and its preventable consequences constitute one of the most glaring racial gaps in health status in the United States. "CDC is committed to eliminating this gap," added Koplan.

DRAFT #324

According to CDC, the goals of eliminating syphilis and reducing the toll of chlamydia can be achieved with existing knowledge, technology, and treatments.

"The good news is we have the power to make a tremendous difference in STD prevention and treatment," stressed Wasserheit, "With many diseases today, we are still searching frantically for the solutions. With STDs, we need only to make better use of the sustained solutions we already have."

Wasserheit released new figures on chlamydia for the nation, which demonstrate a significant reduction in the percentage of young women with chlamydia in areas with widespread screening and treatment programs. She stressed the importance of expanding these efforts throughout the United States. While the programs can make a dramatic difference in preserving women's reproductive health, they currently reach only 50 percent of women at risk in 20 states, and less than 15 percent in 30 states.

The latest data from screening in family planning clinics nationwide demonstrate a 67% reduction in the proportion of women, ages 15-24, infected with chlamydia in the Northwest (Washington, Oregon, Idaho, and Alaska) since they initiated large scale screening efforts in 1988. Similar declining trends are now beginning in other regions which have recently initiated screening and treatment programs–with the largest burden of disease remaining in the South.

The ten states with the most severe level of chlamydia among young women 15-24 tested in family planning clinics, include Arkansas (11.2 % of young women infected), South Carolina (11.1%), Mississippi (11.0%), North Carolina (10.7%), Alabama (10.6%), Louisiana (10.2%), Texas (8.2%), Georgia (7.6%), Illinois (7.4%), and Florida (7.2%).

Improved treatment of chlamydia, syphilis, and gonorrhea are vital, not only to reduce the severe reproductive consequences of these diseases, but also to stem the sexual spread of HIV infection. Because infection with these STDs greatly increases a person's risk of both acquiring and spreading HIV infection, improved STD treatment is critical to slowing the HIV epidemic.

DRAFT #324

"It is unconscionable that diseases that can be cured with one dose of antibiotics continue to exact such a tremendous toll on the nation," stressed Wasserheit, "We simply must reach people with the prevention, screening, and treatment needed to reduce this toll."

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FACSIMILE

DATE: 12/15/98

TO: Devorah A

FAX#: 456-5557

FROM: Elizabeth Summy
Deputy Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

Please share w/ Chris J.

_____**Pages [including this cover]**

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Thursday, Dec. 17, 1998

Contact: CDC, National Center for Health Statistics
(301) 436-7551
CDC, Division of Media Relations
(404) 639-3286

Teens Less Likely to Have Second Baby
New Study Points to Decline in Rate of Second Births

Teenage birth rates have declined substantially during the 1990s, but a new study shows that the most dramatic decline is in the birth rate for young women who have already had one child, HHS Secretary Donna E. Shalala announced today.

While there was a 6-percent decline in first births to teenagers, the rate of second births for teens was down by 21 percent between 1991 and 1996. This detailed analysis of teen childbearing shows that the decline in second births began early in the decade and was joined later by the drop in first births to teens.

"This is a very positive change in the pattern of teen childbearing in America," Secretary Shalala said. "While a first baby poses difficulties for a young woman, her baby and her family, a teenager with two or more children is at greater risk for a host of difficulties," she said. "From an ability to recover physically and financially from a earlier pregnancy to the capacity to raise her child in a secure and healthy environment, a second baby can dim not only the hopes for that teenager but the future of her child as well," the Secretary said.

"Declines in Teenage Birth Rates: National and State Patterns, 1991-97," issued by the National Center for Health Statistics, a part of HHS' Centers for Disease Control and Prevention tracks teenage childbearing in the United States, looking at the long term trends for the nation and the patterns by state in recent years.

"These new data clearly show that efforts to help the teenage mother avoid a second pregnancy are working," said CDC Director, Dr. Jeffrey Koplan. Many programs--nationwide and at the community level--have sought to provide these young women with the information and resources they need to postpone their childbearing in favor of education and personal growth and maturity," he said.

Despite the reduction in repeat childbearing, about 90,000 teens gave birth to their second child in 1997, out of a total of just over 500,000 births to teenagers. The overall teen birth rate dropped 15 percent from 1991 through 1997.

- More -

The report shows that after increasing sharply in the late 1980s, birth rates have been on the decline for American teenagers since 1991. Rates are down more for younger teens (15-17) than older teens (18 and 19). Teenage childbearing is down in all race and ethnic groups, but the largest declines documented are for black teenagers, especially younger black teens. Despite this decline, however, the birth rate for black teens is still high, exceeded only by the rate for Hispanic teens.

Most teenagers who had a baby in 1997 were unmarried. Among teenage mothers 15-17 years of age, the proportion who were unmarried more than doubled from 43 percent in 1970 to 87 percent in 1997. Similarly, among teenage mothers ages 18-19, the proportion more than tripled from 22 percent in 1970 to 72 percent in 1997.

While the majority of teen mothers are unmarried, teenagers do not account for the majority of all births to unmarried women. The study shows that as recently as 1975, more than half of all births to unmarried women were to teenagers; by 1997, that proportion had dropped to less than a third.

Based on information from birth certificates filed in State vital statistics offices and reported to NCHS, the report documents a wide variation--a three-fold difference--in teen birth rates by state, yet all states reported a decline. The report presents data for the nation for 1997; state estimates and detailed rates by birth order are available through 1996.

Copies of the report can be viewed or downloaded without charge from the CDC website, NCHS Home Page at http://www.cdc.gov/nchswww.

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Note: HHS press releases are available on the World Wide Web at: *http://www.hhs.gov.*

FACSIMILE

DATE: 12/18

TO: David Beaubaire / Devorah Adler

FAX#: 456-6704 / 456-5557

FROM: Elizabeth Summy
Deputy Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

Listeria press info

2 **Pages [including this cover]**

Talking Points prepared for HHS/OS and the White House

Multi-state Listeriosis Investigation

The Centers for Disease Control and Prevention (CDC) is working closely with the U.S. Department of Agriculture and state health departments to investigate an outbreak of Listeriosis in the United States.

To date more than 35 cases of Listeriosis caused by the same strain of *Listeria monocytogenes* have been reported to CDC from New York, Ohio, Tennessee, Massachusetts, Michigan, West Virginia, Connecticut, Oregon, and Vermont. Four patients have died. The investigation is ongoing.

Listeriosis is a serious infection caused by eating food contaminated with a bacteria. Illness is most serious for pregnant women, newborns and adults with weakened immune systems and can be fatal. Symptoms of listeriosis include fever, muscle aches, and sometimes nausea or diarrhea. In serious cases, the nervous system is involved and symptoms include headache, stiff neck, confusion, loss of balance, or convulsions.

To avoid listeriosis illness: **cook** raw food from animal sources thoroughly; **wash** raw vegetables thoroughly; **avoid** unpasteurized milk; and **wash** hands, knives and cutting boards after handling uncooked foods.

In addition, pregnant women and persons with weakened immune systems should consider: avoiding soft cheeses such as feta, Brie, Camebert, blue-veined and Mexican-style cheese; cooking until steaming hot left-over foods or ready-to-eat food, such as hot dogs, before eating.

For additional information about listeriosis, visit CDC's website at:
www.cdc.gov/ncid/diseases/foodborn/lister.htm

Note to spokespersons, if pressed - based on current news accounts, you could say —

Q. What is source of this outbreak?

A. While there are some preliminary indications that hot dogs may be involved, the investigation continues. And, as of now, we have not with certainty traced the illness to any specific product or source.

FACSIMILE

DATE: 1/28/99
Sarah Bianchi

TO: Deborah Adler

FAX #: 456-5557

FROM: Rebecca Werbel
Office of the Chief of Staff
Department of Health and Human Services

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

The following is paper on the Hanford study that we talked about last night.

- press release
- background paper
- what's next?
- q+a

_____Pages [including this cover]

assessed the thyroid health for 3,441 people. Each study participant was interviewed and given physical, ultrasound, and laboratory examinations to investigate possible problems with the thyroid gland. In addition, medical records were reviewed to identify thyroid diseases diagnosed before the study began.

Although the study found no evidence that thyroid disease risk was increased by I-131, it did show that participants with higher I-131 doses were somewhat more likely to have small abnormalities that were too small to be felt by a physician, but were detected by ultrasound scans. These abnormalities are quite common among people not exposed to I-131, and physicians agree they do not likely represent a disease. Also, participants with higher doses showed very slightly lower levels of serum calcium in their blood tests. This decrease, though unexpected, was well within normal ranges for a healthy person.

While conducting the study, researchers found that death rates in the study population, particularly for congenital anomalies and conditions which occurred late in pregnancy or in the first seven days after birth, were slightly higher than death rates in the state of Washington for the same period. However, none of this increase was related to thyroid disease.

This is a preliminary analysis, and the reasons for this statistically significant elevation in mortality are not known. The highest rate of overall excess in mortality occurred prior to the beginning of Hanford Operations. Another study of infant and fetal deaths in eight Washington counties during the years 1940 to 1952 is currently being conducted by the Agency for Toxic Substances and Disease Registry with the results expected by late spring. Though the counties in this study are different from those included in the thyroid disease study, the study will provide additional information on rates of infant mortality, fetal death, and pre-term birth by geographic area.

The nine-year, $18 million HTDS study was mandated by Congress in 1988 after the Department of Energy (DOE) made public thousands of documents which showed large quantities of radioactive materials were released from the Hanford Nuclear Reservation during its early years of operation in the 1940's and 1950's. The materials that accounted for most of the radiation dose to exposed individuals was I-131. The release of these documents raised public concerns about possible health effects of exposure to I-131, and prompted the study.

In response to the high level of public interest in the study, the results were released earlier than originally planned. The results are in draft form — and open to public comment — from CDC and the FHCRC. Public comments will be accepted through April 1, 1999.

The draft report will also be reviewed by the National Academy of Sciences' Committee on Assessment of CDC Radiation studies.

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Members of the public who want to be sent more detailed information, or have specific questions regarding this study, should call:

HANFORD THYROID DISEASE STUDY

TOLL-FREE PHONE: 1-800-638-4837
(Available Weekdays; also offers voice mail system)

CDC
CENTERS FOR DISEASE CONTROL
AND PREVENTION

Embargoed until
3:00 p.m. PST January 28, 1999
6:00 p.m. EST

Contact: CDC Division of Media Relations
(404) 639-3286

Draft Report: Results from the Hanford Thyroid Disease Study

Results announced today from the Hanford Thyroid Disease Study show no relationship between thyroid disease and exposures to radioactive iodine-131 (I-131) released from the Hanford Nuclear Site.

"This is a very impressive study given the large number of people who participated and the high level of community involvement in the study throughout its' course," said Jeffrey P. Koplan, M.D., M.P.H., Director, Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances & Disease Registry.

The draft report was released by CDC and the Fred Hutchinson Cancer Research Center (FHCRC) at a community meeting held on Jan. 28th in Richland, Washington.

"We looked at all types of thyroid disease and found no evidence that the number of cases was significantly elevated among those with higher I-131 doses," said Scott Davis, Ph.D., principal investigator for the study at FHCRC. "This was a very powerful study because it included a large number of people estimated to have a wide range of exposures to I-131. Each person also had very thorough clinical evaluations. If the exposure to I-131 from Hanford had affected the thyroid health of as many people as you would predict from past studies in other populations exposed to radiation, this study would almost certainly have detected those effects," he said.

The study focused on a group of people exposed as children to I-131 released from Hanford during the years 1944 to 1957. The purpose of it was to determine if there was a relationship in the study population between the risk of thyroid disease and different levels of thyroid radiation doses from I-131. This relationship was evaluated by determining if individuals with higher doses also had a higher risk of thyroid disease. Because iodine concentrates in the thyroid gland, the most likely health effect resulting from such exposures would be the development of thyroid disease. The thyroid diseases assessed in this study included thyroid cancer, benign thyroid nodules, hypothyroidism, hyperthyroidism and autoimmune thyroiditis.

"Studies like the HTDS cannot tell us if a specific person's thyroid disease is or is not caused by Hanford radiation. It can only tell us that in this specific group of people, we did not find a link between the risk of thyroid disease and their estimated thyroid radiation dose from Hanford," said the CDC scientific advisor for the study, Paul Garbe, D.V.M.

Study participants were selected from those born between 1940 and 1946 to mothers who lived in Benton, Franklin, Adams, Walla Walla, Okanogan, Ferry and Stevens counties. Researchers

Or visit the following web sites:

http://www.cdc.gov/nceh

http://www.fhcrc.org/science/phs/htds/

Editor's Note: FHCRC media point of contact is Kristin Woodward, she can be reached at (206) 667-5095.

BACKGROUND

HANFORD THYROID DISEASE STUDY

THE HANFORD NUCLEAR RESERVATION

The Hanford Nuclear Reservation is located on 570 square miles of land in southeastern Washington, near the cities of Richland, Pasco, and Kennewick. The federal government chose this area as one of the sites for the Manhattan Project – the secret program to build an atomic bomb. The Hanford area was chosen for its remote location, arid climate, abundant electricity, and access to river water to cool nuclear reactors. Construction began in 1943 and the first reactor became operational in 1944. During the early years of operation, large amounts of radioactive materials, primarily iodine-131, were released to the atmosphere. Radioactive releases to the Columbia River also occurred.

Public concern about past Hanford operations led the U. S. Department of Energy (DOE) in 1986 to release thousands of pages of previously classified or unavailable documents. These documents detailed Hanford's operating history and demonstrated off-site releases of radioactive material. Following the release of this information, Washington, Oregon, regional Native American Tribes and CDC convened a panel of experts to evaluate this information. The panel, named the Hanford Health Effects Review Panel, found that people in the area were exposed to radioactive materials and recommended dose reconstruction and thyroid health effects feasibility studies.

THE HANFORD DOSE RECONSTRUCTION PROJECT (HEDR)

Consequently, a dose reconstruction project (HEDR) began at Hanford in the late 1980s. A DOE contractor conducted the work. Public distrust of this relationship paved the way to the development of a Memorandum of Understanding (MOU) between DOE and the Department of Health and Human Services (HHS). This MOU, signed in 1990, transferred responsibility for analytic epidemiologic research at DOE sites to the Centers for Disease Control and Prevention (CDC). The National Center for Environmental Health (NCEH) assumed responsibility for community research (including HEDR) and the National Institute of Occupational Safety and Health (NIOSH) assumed responsibility for occupational health studies. The purpose of the HEDR Project was to determine how much radioactive material was released from Hanford, how that material may have reached and exposed people, and what radiation dose people may have received. The HEDR Project developed mathematical computer models to estimate radiation doses to people. HEDR was completed in 1995. Additional scientific work for the HEDR Project is in progress. This work focuses on: (1) exposures to radioactive particles and short-lived radionuclides on the Hanford site, and (2) the doses people may have received from Hanford's radioactive releases to the Columbia River.

THE HANFORD THYROID DISEASE STUDY

In 1988, the Hanford Thyroid Disease Study (HTDS) was mandated by an act of Congress. The CDC was directed by Public Law 100-607 to conduct a study of thyroid morbidity among persons who lived near the Hanford Nuclear Site between 1944 and 1957. The Fred Hutchinson Cancer Research Center (FHCRC) of Seattle, Washington was selected by CDC to conduct the study and a contract was awarded to the FHCRC in 1989. The primary purpose of the study was to determine whether thyroid disease has increased among persons exposed to air releases from Hanford between 1944 and 1957, the years when the greatest releases of iodine-131 occurred. Since the dose models developed by the HEDR project would be used by HTDS, close coordination of these two studies occurred throughout the life of both projects.

The HTDS was conducted as a retrospective cohort study. Because health effects resulting from exposure to radioactive iodine would most likely have affected those who were children at the time of exposure, the study focused on people who were children during the time of highest releases. A group of individuals, or cohort, was selected to participate in the study from among persons born in 1940-46 to mothers whose usual residence was in one of seven counties in eastern Washington State: Benton, Franklin, Walla Walla, Adams, Ferry, Stevens, and Okanogan. An extensive tracing effort located these individuals throughout the United States. Study participants had a dose estimate calculated from answers to a dosimetry questionnaire, and were examined for the presence or history of thyroid disease. The work was conducted in two stages. The first phase was a Pilot Study, the primary purpose of which was to evaluate the feasibility of the methods proposed, and to develop the specific operational procedures and data collection instruments needed for a full study. The second stage was to implement the remaining fieldwork to complete such a study. The Pilot Study was completed in December 1994, with a report issued publicly in January 1995. Reviews of the Pilot Study by the National Research Council's Board of Radiation Effects Research of the Commission on Life Sciences and the federal Advisory Committee for the HTDS concluded that a full-scale epidemiologic study should be undertaken. The fieldwork for the Full Study was completed in December 1997. Since then, analysis of the data and writing of the final report have been underway.

WHAT'S NEXT?
At Hanford

CDC has released important information in a draft report on the results of the Hanford Thyroid Disease Study (HTDS). Findings from this draft report can be useful to individuals, communities, health care providers, and government public health planners and policy makers in deciding what steps to take next.

EDUCATION & COMMUNICATION

CDC will work with other state and federal government agencies, area public health providers and Hanford community organizations to develop appropriate education and communication programs regarding:

- Results of this study and what they mean to Hanford area residents;
- The signs and symptoms of thyroid disease;
- Special concerns and needs of Hanford area residents regarding thyroid diseases or other health outcomes that could be related to Hanford;
- Communication/Education with health care providers to share the results of this project, when and how to examine for thyroid disease, and how to discuss HTDS results with patients; and
- Availability of other federal and state programs.

PUBLIC HEALTH ACTIVITIES

CDC will work closely with the Agency for Toxic Substances and Disease Registry (ATSDR), the state health agencies of Washington, Oregon and Idaho and the Hanford Health Effects Subcommittee to determine the most appropriate public health follow-up activities at Hanford related to the HTDS findings. Several public health activities are currently in place or being considered. They are:

Follow-up of HTDS Cohort

CDC plans to follow-up the HTDS cohort (study population) in order to examine the natural history of thyroid nodules and ultrasound detected abnormalities. This will allow scientists to determine if these small nodules and abnormalities progress to thyroid cancer.

Follow-up of Mortality Analysis

While conducting the HTDS, researchers found that the death rates in the study population were slightly higher than predicted, based on death rates in the state of Washington for the same period, particularly for causes related to congenital anomalies and conditions occurring late in pregnancy or within the first seven days after birth. The reasons for this apparent elevated rate in overall mortality are not known. However, a study of infant and fetal deaths in eight Washington counties during the years 1940-52 is currently being conducted by the ATSDR with the results expected by late spring. Though the counties in this ATSDR study are different from those included in the HTDS, the study will provide additional information on rates of infant mortality, fetal death and pre-term birth by geographic area.

ATSDR's Proposed Medical Monitoring Program (HMMP)

The Hanford Medical Monitoring Program was created as a reasonable response to alleviate concern of those people living around Hanford who have an estimated increased exposure to I-131. After taking into consideration the results of the Institute of Medicine Report on I-131 as well as the HTDS, and upon discussions with community and tribal representatives, the medical monitoring program for Hanford will be modified. The modifications will provide for information and education for eligible people and clinicians to ensure that informed decision making occurs. If after individuals are informed of the HTDS results and the risk of screening, they decide they still wish to be medically evaluated, the HMMP will assure high quality testing and minimize the risk associated with thyroid screening. For more information, call the ATSDR at 1-888-42ATSDR and ask for "Hanford Medical Monitoring."

QUESTIONS & ANSWERS

Hanford Thyroid Disease Study (HTDS)

HANFORD HISTORY

Q: WHAT TYPES OF RADIATION WERE RELEASED FROM HANFORD, AND HOW MUCH WAS RELEASED?

A: *A large number of radioactive materials were released into the air from Hanford. However, I-131 is of greatest concern because it was responsible for most of the radiation dose that people received from Hanford.*

Q: WHY ARE YOU ONLY STUDYING RADIOACTIVE IODINE AND THYROID DISEASE?

A: *Most of the radiation dose people may have received from Hanford was the result of radioactive iodine, primarily I-131. Because iodine concentrates in the thyroid, the most likely health effect resulting from such exposures would be the development of thyroid disease. While it is possible that exposures from other radionuclides may have occurred, this study focused on the most likely health effect (thyroid disease) from the most likely source of exposure (I-131).*

ABOUT THE HANFORD THYROID DISEASE STUDY

Q: WHAT ARE THE HEALTH EFFECTS OF EXPOSURE TO I-131?

A: *Because I-131 is concentrated in the thyroid glands of those who consume it, as is regular iodine, the most likely health effects from these exposures would be various forms of thyroid disease. Based on what we know from other studies, the thyroid diseases most likely to be caused by radiation exposure include thyroid cancer, hypothyroidism, thyroid nodules and perhaps autoimmune thyroid disease.*

Requests for more detailed information, or specific questions regarding this study, should be directed to:

HANFORD THYROID DISEASE STUDY
Fred Hutchinson Cancer Research Center

TOLL-FREE PHONE: 1-800-638-4837
(Available Weekdays; also offers voice mail system)

Or visit the following web sites:

http://www.fhcrc.org/science/phs/htds/

http://www.cdc.gov/nceh

Persons who would like to provide written comments on the Hanford Thyroid Disease Study Draft Final Report are encouraged to do so by writing:

Centers for Disease Control and Prevention
Radiation Studies Branch (Attn: HTDS)
MS F-35
4770 Buford Highway NE
Atlanta, GA 30341

In order to begin work on the final Hanford Thyroid Disease Study report, we request that comments by sent by April 1, 1999. All comments will be given consideration in preparation of the final report.

Q: WHO WAS INCLUDED IN THE STUDY?

A: *Potential study participants were selected from among persons born between 1940 and 1946 to mother who lived in seven counties in eastern and north central Washington state. These counties were chosen in a effort to ensure that the participants included people with the highest doses, as well as those who received littl or no dose.*

Q: HOW MANY PEOPLE WERE INCLUDED IN THE STUDY?

A: *A group of 5,199 people were identified from the birth records between 1940 and 1946. Of these, 344 participated in the study and had sufficiently complete data for evaluation of thyroid disease.*

Q: WHY DID YOU ONLY STUDY CHILDREN BORN BETWEEN 1940 AND 1946?

A: *The HTDS was designed to focus on persons who might have received the highest doses from Hanfor and be most at risk of developing thyroid disease as a result of their exposure. Previous studies have show that the risk of thyroid disease after exposure to radiation is greater in persons exposed at earlier ages. Th birth years 1940 through 1946 were chosen to ensure that participants in the study were very young childre during the times of the largest releases of radioactive iodine, and therefore subject to the highest doses an highest potential risk.*

Q: IS IT POSSIBLE THAT PEOPLE WHO CHOSE NOT TO PARTICIPATE COULD HAVE CHANGED THE OUTCOM OF THE STUDY?

A: *There were some people who were located for the study who declined to participate in the study or wer not able to be evaluated for a variety of reasons, such as incomplete residential histories. With the exception o one person, none of these people cited current thyroid disease as a reason for not participating. Also researchers believe that people with thyroid disease and those who felt they had been highly exposed woul have been more likely to participate. Therefore, it is highly unlikely that the study results would chang substantially by including those people who chose not to participate.*

Q: HOW WERE THYROID RADIATION DOSES ESTIMATED FOR THIS STUDY?

A: *The Hanford Environmental Dose Reconstruction (HEDR) Project, which was a separate study t estimate radiation doses that persons may have received from Hanford, provided the mathematical model needed to allow the HTDS to calculate estimates of radiation doses to the thyroid received by individual stud participants. These calculations were based upon information collected from personal interviews with th participants and their close relatives.*

A second analysis was conducted by estimating radiation dose based upon where a participant lived when th releases of I-131 were highest as well as whether or not they drank milk.

Q: HOW DO I KNOW THIS STUDY IS RIGHT?

A: *The level of public involvement in and scientific review of the HTDS is unprecedented. Generally, epidemiological studies undergo scientific review at their institution prior to the study being submitted for funding, and by the funding agency (in this case, CDC). Opportunities for the public to review and comment on study plans before they are implemented are extremely rare. There is often no further review until the analyses of the data are completed. Scientific review of the study results is then sought prior to publication. The HTDS was designed and conducted as a public, open process. Extensive review by independent scientific experts and the public has been conducted at every stage of the study, from design, through implementation, to analysis of*

data. A federally-chartered Advisory Committee composed of scientists and representatives of the public and Native American communities has monitored the study throughout and provided advice to the CDC and Study Management Team. A committee of the National Academy of Sciences has reviewed the study protocol and analysis plan, and judged both to be scientifically sound.

HANFORD THYROID DISEASE STUDY FINDINGS

Q: WHAT DID THE STUDY FIND?

A: *The study found no evidence that thyroid or parathyroid disease is increased in this population. Study participants who received higher doses were no more likely to have any form of thyroid disease or hyperparathyroidism than those who received low doses.*

Q: WHAT DO THE RESULTS MEAN?

A: *If the I-131 releases from Hanford were the cause of the thyroid diseases in question, we would expect to see more thyroid disease in people with a higher dose. All dose categories used, whether high or low, showed statistically similar amounts of thyroid disease in those individuals participating in the HTDS. These conclusions remained the same when alternative methods of assessing radiation exposure were used. Therefore, there is no evidence that thyroid disease increased in the population surrounding Hanford as a result of Iodine-131 exposure.*

Q: DOES THIS STUDY TELL ME IF MY HEALTH PROBLEMS ARE RELATED TO HANFORD RADIATION?

A: *No. The HTDS is an epidemiological study designed to assess the risk of thyroid disease in groups of individuals exposed. It is not scientifically possible to determine whether an individual case of disease is due to radiation. The results of this study answer the question: "Did the releases of radioactive iodine from Hanford result in an increased risk of thyroid disease in the population exposed and, if so, by how much?" Although no increased risk of thyroid disease was identified by the study, this does not rule out the possibility that an individual's thyroid disease was or was not related to the I-131 released from Hanford. It is also important to understand that the results do not provide information regarding any health problems other than thyroid disease.*

NEXT STEPS

Q: WHAT SHOULD I DO?

A: *Although this study found no evidence that the risk of thyroid disease increased at higher doses when compared to the risk at lower doses, any person who is concerned about the radiation dose they may have received, or who is experiencing signs or symptoms of thyroid disease, should talk to their health care provider.*

Q: HOW DO I FIND OUT WHAT MY RADIATION DOSE IS FROM HANFORD?

A: *If you were a participant in the HTDS, your dose estimate will be sent to you along with the results of the study when the draft report is released to the public. In addition, individuals who lived in the Hanford area during the 1940s or 1950s may call the Washington State Individual Dose Assessment Project at 1-800-432-6242.*

Q: WILL THE PUBLIC HAVE AN OPPORTUNITY TO COMMENT ON THIS REPORT?

A: *Comments from the public are welcomed and will be considered when decisions are made about any additional analyses of HTDS data, future research, and other programs at Hanford. Written comments should be mailed to the following address:*

Centers for Disease Control and Prevention
Radiation Studies Branch, Attn: HTDS
Mailstop F-35
4770 Buford Highway
Atlanta, Georgia 30341

Q: WILL OTHER SCIENTISTS HAVE AN OPPORTUNITY TO ANALYZE HTDS DATA?

A: *A public use tape, excluding all personal identifying information, will be made available by CDC following the secondary analyses of the data so that others can examine and/or analyze the data for themselves.*

Q: WILL YOU RELEASE INFORMATION ON SPECIFIC INDIVIDUALS TO OTHER GOVERNMENT AGENCIES?

A: *No. The HTDS data are protected by a federal Assurance of Confidentiality. This means that unless an HTDS participant gives written consent to CDC or the Fred Hutchinson Cancer Research Center for release of their records, no information on specific individuals will be released to anyone except that person.*

Q: HOW CAN I GET A COPY OF THE COMPLETE RESULTS FOR MY DOCTOR?

A: *The draft report and other informational materials will be made available on the Internet on the afternoon of January 28, 1999. You and your doctor can find the final version of the report when it is completed later this year at the University of Washington Health Science Library, Seattle Public Library System, King County Public Library System, Gonzaga University Library, Richland Library, and the Department of Energy Reading Room.*

Researchers plan to brief state and local health officials on the study findings.

Your physician can contact a state or local health official for more information, can access the study report and additional materials on the Internet, or can request the HTDS Summary of Results booklet or other materials directly from the HTDS office.

COMPARISONS AND STUDY QUALITY

Q: DON'T WE ALREADY KNOW THAT RADIATION CAUSES THYROID CANCER AND OTHER DISEASES?

A: *It is indeed well known that certain types of radiation exposures increase the risks of certain types of cancers and other diseases. However, this does not mean that any kind of radiation causes every kind of disease. For example, among survivors of the atomic bombings of Hiroshima and Nagasaki, the risk of thyroid cancer has clearly increased in relation to the dose of radiation they received. This involved very short exposures to gamma radiation and neutrons, not exposure to I-131 over months or years, as occurred around Hanford. There have been no studies like the HTDS that are directly comparable to the Hanford exposure situation (e.g., a general population exposed to I-131 over a prolonged period of months or years).*

Q: WHY WAS THE RELEASE OF THE STUDY RESULTS DELAYED FOR FOUR MONTHS AFTER CDC RECEIVED THE DRAFT FINAL REPORT?

A: *The scheduled release was actually moved up by six weeks in response to public requests. Although the Draft Final Report was completed on September 30,1998, scientific review of any study is an important step to ensure the science is thorough and that the results are accurate. The draft report is very long and detailed. Although CDC shortened the review time, it still takes time for each reviewer to read, evaluate and respond to the report. In addition, because of the length and complexity of the draft report, CDC and the FHCRC believed it was necessary to develop a booklet that summarizes the findings of the study in an easy to read format. This booklet could not be completed until after the initial stages of peer review were finished.*

Q: WHAT ABOUT ALL THE PEOPLE WHO DIED AND COULDN'T PARTICIPATE IN THE STUDY? WHAT IF THEY ALL HAD THYROID CANCER?

A: *Of the 5199 people originally identified for inclusion in the study, it was determined that 541 were deceased. In an effort to see whether exclusion of these individuals from the study might in some way bias or influence the results, an investigation was undertaken to determine whether these deaths might be related in some way to thyroid cancer or other thyroid diseases. We were able to obtain information from death certificates for 502 of the 541 deceased individuals. An analysis of the underlying causes of death revealed no indication that thyroid disease or thyroid cancer was responsible for any of these deaths. We do not have any reason to believe that individuals with high thyroid radiation doses and thyroid disease would be any more likely to die than people with low doses and thyroid disease. Consequently, while cases of thyroid disease may have been missed among those who died, it is unlikely that these cases would have changed the results of the dose response analyses.*

Q: WHAT IF THE HEDR MODEL TO ESTIMATE RADIATION DOSES IS WRONG?

A: *As part of the study analyses, calculations of risk were performed without using the HEDR model. For these analyses, participants were divided into a high exposure group and a low exposure group, based on where they lived at the time of the highest exposures and whether they drank milk. Comparisons of the high and low dose groups did not show significantly different results than those using the HEDR model, although the occurrence of Graves' disease, hyperthyroidism and some ultrasound detected abnormalities was somewhat greater in the high dose group than the low dose group. It is difficult to know whether these slight increases are meaningful in terms of health risk for two reasons: 1) this method of analysis is based on a much less accurate way of estimating radiation dose; and 2) when many outcomes are evaluated using multiple analyses, some may appear statistically significant based on chance alone.*

Q: THE NATIONAL ACADEMY OF SCIENCE'S COMMITTEE ON AN ASSESSMENT OF CDC RADIATION STUDIES RECENTLY RELEASED A LETTER REPORT ADDRESSING A NUMBER OF SPECIFIC ISSUES RELATED TO THE VALIDATION OF THE HANFORD ENVIRONMENTAL DOSE RECONSTRUCTION (HEDR) ATMOSPHERIC I-131 PATHWAY MODELS. HOW DOES THIS REPORT IMPACT THE HTDS RESULTS?

A: *The committee recommends some specific actions that need to be taken to improve the quality of the HEDR model validation reports. However, the committee concludes that "...the HEDR model can be considered satisfactory for the purpose of setting bounds on the potential health impact of Hanford releases on the surrounding populations." At the same time, the committee believes that the dose estimates for selected individuals are more imprecise than the representative doses that were published at the conclusion of the HEDR study. HTDS staff are conducting analyses that will account for uncertainty in the dose estimates in the HTDS results for the final report. As this draft report is reviewed over the next several months, the analysis procedures used will be carefully evaluated to make sure that the uncertainties in the dose estimates have been correctly accounted for in these procedures.*

Q: BATTELLE RECENTLY REPORTED FINDING AN ERROR IN THEIR REPORTED ESTIMATE OF THE AMOUNT OF I-131 RELEASED FROM HANFORD? HOW WILL THIS IMPACT THE HTDS RESULTS?

A: *Battelle recently reported to CDC that the total I-131 released from Hanford for the period August 1950 through December 1957 was underestimated due to an error in their calculations. Because most of the total release of I-131 from Hanford took place prior to 1950, the total release for the period December 1944 through December 1957 will increase approximately 2.9%. This error will impact some individual dose estimates, but HTDS staff do not expect it to greatly impact HTDS results. CDC is currently evaluating the impact of this error, and all HTDS doses will be recalculated before the final report is prepared.*

Q: WE KNOW PEOPLE WERE AFFECTED BY HANFORD RADIATION. WHY DIDN'T THE STUDY SHOW ANYTHING?

A: *This study only addressed thyroid disease and exposure to I-131. Other diseases and exposures were not evaluated. The HTDS was designed to determine whether exposure to atmospheric releases of I-131 from Hanford resulted in increased thyroid disease. When a study of this type is done, great care is taken to design the study so that only a real cause and effect relationship will give a positive result. It is important to be sure that there is nothing in the way the study is done that would cause an incorrect finding. The presence of a disease that could be caused by that exposure is not enough to show that the exposure caused that disease. For example, thyroid cancer must occur significantly more often in those with higher exposures than in those with little or no exposure in order to say that there is an association between the thyroid radiation dose and thyroid cancer risk. In the case of the HTDS, the thyroid diseases under study either did not occur more often in those highly exposed, or occurred no more often than could be explained by chance. The HTDS was designed to have enough statistical power to detect an increase in thyroid disease risk with dose that has been reported in other studies, and in fact had sufficient power to detect even smaller increases than have been previously reported. This does not rule out the possibility that there may be individuals in the population exposed to Hanford radiation that have developed thyroid disease as a result of their exposure, but an epidemiologic study like the HTDS is not capable of determining whether an individual case of thyroid disease is or is not caused by Hanford radiation.*

Q: WHAT ABOUT ALL THE OTHER HEALTH EFFECTS STUDY PARTICIPANTS REPORTED IN THE INTERVIEWS? CAN'T YOU ANALYZE THOSE DATA TO FIND OUT IF OTHER DISEASES ARE RELATED TO HANFORD?

A: *The HTDS was designed specifically to study the presence of thyroid disease. The interviews were therefore designed only to provide pertinent history regarding thyroid disease. To study any additional diseases, a completely different set of interview questions (as well as examinations and lab tests) would have been required.*

FACSIMILE

DATE: 12/23

TO: Chris F; Deborah Adler

FAX#: 456-5557

FROM: Elizabeth Summy
Deputy Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

MMWR

1 **Pages [including this cover]**

HIV Testing Among Populations at Risk for HIV Infection — Nine States, November 1995–December 1996

Extending acquired immunodeficiency syndrome (AIDS) case surveillance systems to include confidential (name-based) reporting of human immunodeficiency virus (HIV) infections provides data representing recent HIV transmission patterns (*1*). These data may improve the ability of public health agencies to plan and evaluate HIV prevention and treatment services. Thirty-two states conduct name-based HIV infection case surveillance as an extension of AIDS case surveillance (*2*), and such surveillance is being considered in other states. Some community representatives and public health officials, however, are concerned that HIV infection surveillance may deter some at-risk persons from seeking HIV testing. This report describes the results of a survey conducted to assess deterrents to HIV testing in populations at risk for HIV infection during 1995 and 1996. The findings indicate that in these populations knowledge of state HIV reporting policies was low, and fear of a positive HIV test result and a lack of perceived risk for HIV infection were the most common deterrents to testing in all risk groups. However, untested men who have sex with men (MSM) who resided in states with name-based reporting cited concerns about reporting as a reason they had not tested more often than untested MSM in states without name-based reporting.

HIV Testing — Continued

The HIV Testing Survey (HITS) was a cross-sectional study conducted among persons at risk for HIV infection in nine states with different HIV reporting policies.* MSM were recruited from gay bars; injecting-drug users (IDUs), through street outreach; and sexually active heterosexuals, through sexually transmitted disease clinics. The study was designed to recruit approximately equal numbers of persons from each of these populations in all states. Using an anonymous structured questionnaire, trained interviewers from health departments and community-based organizations assessed participants' knowledge of state HIV reporting laws, self-reported HIV testing history, and reasons for delaying testing or not being tested.

During December 1995–November 1996, 2570 eligible participants were interviewed. Of these, 200 (7.8%) reported being HIV infected and were excluded from this analysis. Of the remaining 2370 HIV-negative or untested persons, 1810 (76%) had been tested for HIV at least once. The proportion of persons who had been tested for HIV differed by risk group: 582 (68%) of 851 heterosexuals, 596 (79%) of 750 MSM, and 632 (82%) of 769 IDUs had been tested. Testing rates were the same for men and women (76% of 1774 men and 592 women); similar for non-Hispanic blacks (76% of 934), non-Hispanic whites (76% of 873), and Hispanics (75% of 444); and differed significantly by age group (persons aged 18–24 years were less likely to have been tested [68%] than persons in older age groups [range: 76%–81%]).

Most of the respondents stated that they did not know whether persons with HIV infection were reported to the health department by name: 60% in name-based reporting states, 60% in unique identifier (UI)-based reporting states, and 66% in nonreporting states. Only a small proportion of respondents knew their state's HIV reporting policy: 19% in states with name-based reporting, 12% in states with UI-based reporting, and 11% in states with neither name-based or UI-based reporting.

Respondents were asked about the likelihood of being tested for HIV infection during the next 12 months according to several scenarios. Overall, 84% of respondents stated that they were likely to get tested during the next year if they could be tested anonymously and no results were reported to the health department. Respondents were then asked their likelihood of seeking testing during the next 12 months if no anonymous testing was available and various HIV case reporting scenarios existed: no HIV reporting, 72%; UI-based HIV reporting, 73%; and name-based HIV reporting, 61%.

Respondents were asked to indicate whether each of 17 factors had contributed to not being tested (556 respondents) or to delaying testing (1810 respondents) and which of these was the main factor (Table 1). The main factors for not being tested or delaying testing were fear of learning they were HIV-positive (25% and 23%, respectively); thinking they were unlikely to have been exposed to HIV (18% and 10%); thinking that they were HIV-negative (13% and 11%); not wanting to think about the possibility of being HIV-positive (8% and 9%); and thinking there was little they could do about being HIV-positive (6% and 4%). Among persons who had not been tested, a concern about having one's name reported to the government was cited as one of the factors for not testing for 19% and was the main factor for 2% (Table 1). Concern about

*Name-based HIV case surveillance was conducted in Arizona, Colorado, Mississippi, Missouri, and North Carolina (patient names are not reported to CDC); unique identifier (UI)-based HIV case surveillance was conducted in Maryland and Texas; neither name-based nor UI-based HIV case surveillance was conducted in New Mexico and Oregon during the study period. All states except Mississippi offered publicly funded anonymous HIV testing and counseling.

TABLE 1. Percentage of untested respondents reporting factors* for not testing for HIV, and percentage of tested respondents reporting factors* for delaying testing, by HIV risk factor — HIV Testing Survey,† December 1995–November 1996

Testing status/Factor	Men who have sex with men		Heterosexual		Injecting-drug user		Total§	
	A factor	Main factor	A factor	Main factor	A factor	Main factor	A factor	Main factor
Not testing¶	(n=151)		(n=269)		(n=136)		(n=556)	
Afraid to find out	59	27	41	21	51	30	**48**	**25**
Unlikely to have been exposed	52	17	48	25	25	7	**44**	**18**
Thought they were HIV negative	57	19	49	15	33	6	**47**	**13**
Didn't want to think about being positive	55	7	42	8	54	10	**48**	**8**
Could do little if HIV positive	45	9	19	3	40	7	**31**	**6**
Didn't have time	14	3	20	4	20	5	**19**	**4**
Unsure where to go	15	2	21	4	32	6	**22**	**4**
Worried name would be reported	28	4	13	1	18	1	**19**	**2**
Test costs too much	5	2	5	<1	17	3	**8**	**2**
People might think you have AIDS	27	1	10	<1	18	4	**17**	**1**
Delaying testing**	(n=596)		(n=582)		(n=632)		(n=1810)	
Afraid to find out	53	26	38	18	47	24	**46**	**23**
Thought they were HIV negative	41	10	45	13	36	9	**41**	**11**
Unlikely to have been exposed	29	9	34	14	25	6	**29**	**10**
Didn't want to think about being positive	49	8	42	8	49	10	**47**	**9**
Didn't have time	16	5	16	6	18	5	**17**	**5**
Could do little if HIV positive	22	2	18	3	31	6	**24**	**4**
Waiting for results would be hard	38	7	22	3	28	3	**30**	**4**
Afraid of needle used to draw blood	15	4	16	4	7	<1	**12**	**3**
Worried name would be reported	22	4	11	<1	18	3	**17**	**2**
Worried about who would learn results	25	3	15	1	19	1	**20**	**2**

*Data presented for the 10 most frequently cited factors of 17 listed in the survey.
†Survey was conducted in Arizona, Colorado, Maryland, Mississippi, Missouri, New Mexico, North Carolina, Oregon, and Texas.
§The totals are based on unweighted data from all participants included in this analysis; data do not represent the general population or a weighted average of populations at increased risk for HIV infection.
¶Main factors do not sum to 100% because 10 of 17 factors are presented and 62 (11%) of 556 untested respondents cited no factors for not testing.
**Main factors do not sum to 100% because 10 of 17 factors are presented and 374 (21%) of 1810 tested respondents cited no factors for delaying testing.

HIV Testing — Continued

reporting was the main factor for not testing for 4% of untested MSM, 1% of untested IDUs, 1% of untested heterosexuals, 3% of untested non-Hispanic whites, <1% of untested non-Hispanic blacks, and 3% of untested Hispanics. Among persons who had been tested, the proportions of these subgroups citing concern about reporting as the main factor for delaying testing were similar (≤4%).

Among the 556 untested persons, concern about name-based reporting was stratified by state HIV reporting policy (Table 2). A higher proportion of MSM in states with name-based reporting than in states without name-based reporting cited concern about having their name reported to the government as a factor for not testing (35% compared with 11%; p<0.01), but there was no difference in the frequency of concern about reporting as the main factor for not testing (3% compared with 7%, p=0.4).

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Editorial Note: The findings in this report indicate that, although the proportion of respondents that had been tested was high (76%), most reported at least some delay before getting tested. Fear of learning that one is infected with HIV and the belief that one is unlikely to have been exposed to HIV were cited most frequently as factors for delaying testing or not testing. Reducing fear and increasing knowledge about HIV risk present ongoing challenges to designing effective prevention programs.

TABLE 2. Frequency of concern about having one's name reported to the government as a factor for not testing for HIV infection, by state HIV reporting policy — HIV Testing Survey,* December 1995–November 1996

Characteristics	Named		Non-named†		p value§
	No.	(%)	No.	(%)	
Men who have sex with men	107		44		
A factor	38	(35)	5	(11)	<0.01
Main factor	3	(3)	3	(7)	0.4
Heterosexual	177		92		
A factor	22	(13)	14	(15)	0.5
Main factor	3	(2)	1	(1)	1
Injecting-drug user	66		70		
A factor	14	(21)	10	(14)	0.3
Main factor	2	(3)	0	(0)	0.2
Total¶	**350**		**206**		
A factor	**74**	**(21)**	**29**	**(14)**	**0.05**
Main factor	**8**	**(2)**	**4**	**(2)**	**1**

*Name-based HIV case surveillance was conducted in Arizona, Colorado, Mississippi, Missouri, and North Carolina (patient names are not reported to CDC); unique identifier (UI)-based HIV case surveillance was conducted in Maryland and Texas; neither name-based nor UI-based HIV case surveillance was conducted in New Mexico and Oregon during the study period.

†UI-based reporting was implemented during the year preceding the study in Maryland and Texas; 67% of tested respondents in these states had been tested at least once before this policy change. Because of the state reporting policy changes and to avoid small cell sizes in the analysis restricted to the minority of respondents who had never been tested, UI-based reporting and nonreporting states were combined in the non-named reporting category.

§Fisher's exact test.

¶The totals are based on unweighted data from all participants included in this analysis; data do not represent the general population or a weighted average of populations at increased risk for HIV infection.

HIV Testing — Continued

Although concern about having one's name reported to the government was a less commonly cited factor for not testing or delaying testing for HIV infection, the findings suggest that state HIV reporting policies may deter or delay some persons, particularly MSM, from being tested. The effect of HIV-infection reporting policies on actual testing may be limited because in this study most respondents did not know their state's HIV reporting policy and because the implementation of name-based HIV reporting policies also does not appear to have a significant effect on use of publicly funded counseling and testing programs (*3*). However, any potential deterrent effect on HIV testing among MSM or other at-risk populations (e.g., racial/ethnic minorities) is important. The findings in this report support the importance of addressing privacy concerns both in states that are considering implementing name-based HIV reporting and in states that already have adopted such policies. CDC and the Council of State and Territorial Epidemiologists are promoting development of model privacy statutes, which will strengthen current state confidentiality protections. In addition, CDC requires standardized security measures for all recipients of CDC HIV/AIDS surveillance funds and continues to provide technical assistance to all states to monitor the effect of changes in HIV testing and reporting policies on testing behaviors.

In this study, respondents reported they would be more likely to seek future testing if an anonymous HIV test option were available. Persons who recognize their risk, seek early HIV testing, and receive counseling can modify their behavior to reduce HIV transmission and seek medical care and other services that promote health and improve survival. Maintaining access to anonymous HIV testing is an important option for some persons at high risk for HIV infection (*4*), and CDC strongly recommends that all states provide publicly funded anonymous HIV testing and counseling.

The findings in this report are subject to at least four limitations. First, the study was not population-based; it was designed to enroll equal proportions of each of three groups recruited from specific venues and it may not represent all at-risk populations or their distribution in the general population. Second, findings from the nine states included in the survey may not be generalizable to all other states. Third, stated intentions by respondents in this survey may not reflect actual behaviors in obtaining testing for HIV infection. Finally, the beneficial effects of recently available therapies (*5,6*) or increased knowledge about state HIV reporting policies (*7*) may alter current test-seeking behavior.

HITS and related studies and analyses (*3,4,8–10*) were conducted to enhance the scientific basis for public health policy on HIV case surveillance. To monitor the effect of changes in HIV reporting policies on HIV testing behaviors, studies similar to HITS will be conducted in additional states. CDC will continue to provide technical assistance to state and local health departments so that they, in collaboration with public health organizations, health-care providers, and representatives of affected communities, can adopt effective HIV/AIDS surveillance practices that continue to protect confidentiality and permit an effective public health response to the epidemic.

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HIV Testing — Continued

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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TOTAL NUMBER OF PAGES SENT: 3
(including cover page)

COMMENTS:

Here's guidance of IOM Report released to press this evening.

FINAL Questions and Answers: *Lesbian Health: Current Assessment and Directions for the Future*
IOM Report on Lesbian Health
Thursday, January 14, 1999
(For Internal Use Only)

Q1. What is the Department of Health and Human Services' response to the report?

A1: We will review the report and its recommendations carefully. But upon initial review, the strength of this report appears to lie mainly in the methodological framework it provides for the study of special population groups and the comprehensive review of related literature and data.

Q2: Why did you fund the report?

A2: There has been little research done on health issues of lesbians as a group. And, there was a need to review and develop effective methodologies to determine if there are health conditions for which lesbians tend to be at greater/lesser risk than women in general.

Q3: Does HHS believe lesbians have special health needs?

A3: We commissioned the report to help us determine that. Upon initial review, the report states that there is not enough existing literature to determine if lesbians as a group have special health issues, but it does state: "Given the limited availability of data that would allow a comparison of lesbian with heterosexual women, the committee did not find that lesbians are at greater risk for any particular health problems simply because they have a lesbian sexual orientation." (Executive Summary, page 5)

We will review the report and its conclusions carefully.

Q4: Will this report be used in future policy-making decisions and will there be any specific funding for lesbian health?

A4: We have just received the report. We will carefully review the report and its conclusions.

Q5: What is HHS currently doing regarding lesbian health?

A5: The Department has a variety of educational programs and research activities that benefit women in general. We commissioned the report to determine if there are health conditions for which lesbians tend to be at greater/lesser risk than women in general. We plan to review the report carefully.

BACKGROUND ON THE IOM REPORT - *Lesbian Health: Current Assessment and Directions for the Future*

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) funded the report, 80% and 20% respectively, for a total cost of $125,000. The Institute of Medicine (IOM) Committee on Lesbian Health Research Priorities was established in 1997 to assess the strength of the science base regarding the health problems of lesbians. In October 1997, the Committee organized and convened a scientific workshop on Lesbian Health.

At the workshop, the Committee examined the need for future research on the health issues of lesbians and evaluated research methodologies. The Committee reviewed existing data in the scientific literature on lesbian health. Because there is no standard definition of "lesbian," the Committee focused on women who have sex with or primary relationships with women.

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