

# Summary of the Preliminary Results

## THE HANFORD THYROID DISEASE STUDY DRAFT FINAL REPORT

May 1999

### Preliminary Results

On January 28, 1999, the Centers for Disease Control and Prevention (CDC) released the Draft Final Report from the Hanford Thyroid Disease Study (HTDS) which was conducted by the Fred Hutchinson Cancer Research Center in Seattle, WA, and funded by the CDC. This nine-year study evaluated whether or not the occurrence of thyroid disease was related to different levels of estimated radiation dose in a group of 3,441 people who were exposed as children to radioactive iodine (I-131) from the Hanford Nuclear Site during the 1940s and 1950s. This study was designed to investigate possible health effects of exposures to I-131 though other radionuclides were also released from the Hanford Facility. I-131 was the main radionuclide released from the facility and concentrates in the thyroid gland when inhaled or ingested. Therefore thyroid disease was the most likely health effect to occur in the population.

While thyroid diseases were observed among the HTDS participants, the initial study results did not show a link between the estimated dose to the thyroid from I-131 and the amount of thyroid disease in the study population.

Based on initial study results provided in the Draft Final Report, those who had higher estimated radiation doses appear to be no more likely to have thyroid diseases than those who had very low doses. (If study participants with higher estimated doses showed higher risk of thyroid disease, then that would provide evidence of a link between exposure and thyroid disease.)

These preliminary results do not mean that people living in the Hanford area during the 1940s and 1950s were not exposed to I-131 and other radionuclides, or that these exposures had no effect on the health of people living in the Hanford area. Although no link between estimated I-131 radiation dose and the amount of thyroid disease was identified by the HTDS in the study population, the study results do not prove that a link between I-131 and thyroid disease does not exist. There may be individuals in the overall population who were exposed to Hanford radiation and did develop thyroid disease because of their exposure.

Epidemiological studies are designed to examine large populations, and through analysis of levels of exposure and rates of disease, establish an association between exposure and the risk of disease in a general population. It is not possible in any epidemiological study to determine whether an *individual* person's thyroid disease is or is not caused by Hanford radiation exposure. ❖

**THE COMPLETE TEXT OF THE HTDS DRAFT  
FINAL REPORT AND SUMMARY PUBLIC  
INFORMATION MATERIALS ARE AVAILABLE ON  
THE WEB AT:**

**[WWW.FHCRC.ORG/SCIENCE/PHS/HTDS](http://WWW.FHCRC.ORG/SCIENCE/PHS/HTDS)**

**AND AT**

**[WWW.CDC.GOV/NCEH/PROGRAMS/RADIATION](http://WWW.CDC.GOV/NCEH/PROGRAMS/RADIATION)**

# Background

The HTDS was mandated by Congress in 1988, after the U.S. Department of Energy released documents showing that large amounts of I-131 were released into the air from Hanford, primarily during the late 1940s and early 1950s. Many area residents were concerned that their health might have been affected by the radiation from Hanford. Diseases of the thyroid (a small gland at the base of the neck that helps regulate growth and metabolism) were of particular concern because radioactive iodine inhaled or ingested by an individual concentrates in the thyroid.

## How the Study Was Conducted

The Hanford Thyroid Disease Study was based on a group or cohort of 5,199 people born during 1940-46 to women who lived in any of seven counties of Washington State: Benton, Franklin, Adams, Walla Walla, Okanogan, Ferry, and Stevens. Starting with the birth certificates for this group, the research team tried to locate as many people as possible. A total of 4,875 (94%) were located. Those who could be contacted were invited to participate in the study. Because of these efforts, 3,441 people attended special HTDS clinics between 1992 and 1997, and provided information that could be used to determine their estimated thyroid radiation dose. At the study clinics, participants received thorough thyroid examinations by physicians experienced in the diagnosis of thyroid disease. They were also asked if they had any past history of thyroid disease. Pertinent medical records were obtained whenever possible to document and clarify past diagnoses.

Radiation dose to the thyroid was estimated for study participants based on information about residential history and factors such as milk consumption. Using this information, the study estimated thyroid doses using mathematical models that

## PUBLIC INVOLVEMENT AND EXPERT REVIEW

Since the beginning of the study, scientists at the FHCRC and the CDC have actively included other scientists and the public at every step in the study. This began with a series of public meetings in 1990 to inform the public and interested scientists on the study design. Copies of the study protocol, which outlined the plans for conducting the study were distributed to a number of experts and were made available to the public in area libraries. Many of the recommendations made during that process became part of the final study protocol. The first meeting of the federally chartered Hanford Thyroid Disease Study Advisory Committee was held in March 1991. This committee consisted of eight members representing areas of scientific expertise, environmental groups, the public, and Native American tribes. A consultant from the Hanford Downwinders Coalition was added a short time later. The study did not begin until this HTDS Advisory Committee, another committee at the FHCRC in charge of protecting the rights of research study participants, and the federal Office of Management and Budget approved the study protocol.

The HTDS Advisory Committee met on a regular basis throughout the study, making recommendations to the CDC regarding the research plan and conduct of the study. In 1997, the HTDS Advisory Committee reviewed and approved the written HTDS Analysis Plan, a detailed document describing how the study would be analyzed. In February 1998, the HTDS Advisory Committee reviewed and approved a written HTDS Communications Plan, which described how the first available results from the study would be made public. Due to the high level of public interest in the results, the CDC and the FHCRC decided jointly to make the Draft Final Report available to the public while the peer review process was still underway, and before CDC or others made any revisions.

The National Academy of Sciences' Committee on Assessment of CDC Radiation Studies also reviewed the HTDS Pilot Study Report and the HTDS Analysis Plan. Currently, the NAS is conducting a scientific peer review of the HTDS Draft Final Report. The results of their review are expected by late summer 1999. Suggested revisions and clarifications from all reviews will be incorporated into the HTDS Final Report. ❖

### *How the Study Was Conducted, Cont'd*

were developed by the Hanford Environmental Dose Reconstruction (HEDR) Project. This was a separate research project that investigated the releases of radioactive materials from Hanford, and estimated the radiation doses that people may have received as a result of exposure. Doses were estimated for the time period between December 1944 through the end of 1957 for individuals residing inside a region called the HEDR Study Area during any part of that time period. The HEDR study area consists of an approximately 75,000 square mile area surrounding Hanford. Results of the HEDR project indicated that people living in Benton, Franklin, and Adams Counties during 1944 (the year that the largest amounts of radioactive iodine were released from Hanford) most likely received the highest thyroid doses.

Of the 3,441 HTDS participants, 3,193 or (93%) had dose estimates calculated. Their estimated thyroid doses ranged from essentially zero to a maximum of more than 2,800 mGy (280 rad). (A *mGy* and a *rad* are units of radiation dose.) The average (mean) estimated dose among HTDS participants was 186 mGy (18.6 rad). About half of these 3,193 participants had doses over 100 mGy (10 rad), and only about 1% had doses over 1000 mGy (100 rad). The remaining 248 HTDS participants whose doses were not estimated never lived inside the HEDR Study Area between December 1944 and the end of 1957. Therefore, researchers could not estimate a thyroid dose for them. While this does not mean that they were completely unexposed to Hanford's radioactive iodine, their doses are believed to be very low.

Nine categories of thyroid disease were studied in the HTDS. Some individuals were diagnosed with more than one disease (for example, goiter and thyroid nodules)

## **FREQUENTLY ASKED QUESTIONS ABOUT THE HTDS RESULTS**

### **Q: Why was the study done?**

A: The HTDS was conducted to find out whether there has been an increase in thyroid or parathyroid disease related to exposures from releases of radioactive iodine-131 into the air from the Hanford Nuclear Site in the 1940s and 1950s.

### **Q: What did the study find?**

A: The initial study results provided in the Draft Final Report do not show a link between the estimated dose to the thyroid from I-131 and the amount of thyroid disease in the HTDS study population. While thyroid diseases were observed among the HTDS participants, those who had higher estimated radiation doses appeared to be no more likely to have thyroid diseases than those who had lower doses. Although no link between estimated I-131 radiation dose and the amount of thyroid disease was identified within the HTDS study population, the study results do not prove that a link does not exist. In addition, these results do not mean that people living in the Hanford area during the 1940s and 1950s were not exposed to I-131. Nor do these results prove that these exposures had no effect on the health of people living in the Hanford area. There may be individuals in the overall population who were exposed to Hanford radiation and did develop thyroid disease because of their exposure. However, it is not possible in an epidemiological study like HTDS to determine whether an individual person's thyroid disease is or is not caused by Hanford radiation exposure. 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 due to birth defects, complications of pregnancy and delivery, and premature birth. Preliminary results from the HTDS indicate that the excess in mortality was evident before releases from Hanford began and continued after the Hanford facility started operation. The reasons for this apparent elevated rate in overall mortality are currently 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.

and are included in multiple disease categories. Nineteen confirmed cases of thyroid cancer (0.6%) were found among the 3,441 study participants. Five of the nineteen participants with thyroid cancer were among the 248 who never lived inside the HEDR Study Area between December 1944 and the end of 1957. Two hundred forty-nine participants (7.2%) had confirmed diagnoses of benign (noncancerous) thyroid nodules. Confirmed diagnoses of hypothyroidism (underactive thyroid) and autoimmune thyroiditis (an inappropriate reaction of the immune system) were recorded for 267 (7.8%) and 648 (18.8%) participants, respectively. Thirty-four (1.0%) had confirmed diagnoses of Graves' disease (an autoimmune thyroid disease that causes an overactive thyroid). However, none of these diseases appeared to be significantly more common among study participants with higher estimated radiation doses than among those with lower doses. If there were a link between radiation dose and thyroid disease, we would expect thyroid diseases to occur more frequently in study participants with higher radiation doses.

In addition to thyroid diseases, the study evaluated whether three other outcome measures were related to radiation dose from Hanford's I-131: hyperparathyroidism (a disease of the parathyroid glands, which are located adjacent to the thyroid); results of an ultrasound examination of the thyroid; and results of the blood tests related to thyroid and parathyroid function.

There was some indication that the proportion of individuals with small focal (individual) thyroid abnormalities detectable only by ultrasound increased slightly at higher doses. However, this increase was not statistically significant, meaning that it could have been due to chance. Small growth abnormalities of this type, which can be detected by sensitive ultrasound equipment but not by a physician during an examination, are very common in the general population.

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**Questions & Answers, cont'd**

**Q: What if my dose was high?**

A: The results of the study cannot rule out the possibility that an individual exposed to Iodine-131 from Hanford might have suffered some type of health effect as a result. No epidemiologic study is capable of doing so. If you are concerned about your health or the radiation dose you may have received, you should discuss your concerns with your health care provider.

**Q: Were there other health effects from Hanford radiation releases?**

A: The results of this study are limited to the effects of I-131 exposure and thyroid disease, associated laboratory tests and ultrasound results, and hyperparathyroidism in persons who were infants and children at the time of exposure. They do not answer questions about effects from other types of radiation released from Hanford, or other types of diseases in relation to Hanford exposures.

**Q: Why were the study results released early?**

A: CDC's commitment to conduct the study in complete openness, together with the intense interest about the study results on the part of the affected citizens, led to the release the Draft Final Report at this stage. The same public process has been used to release CDC reports at other nuclear weapon production sites.

The original HTDS Communications Plan, approved by the federally chartered HTDS Advisory Committee in February 1998, called for a report of the study results after the peer review process was complete. The purpose of this type of independent, expert peer review is to help ensure that the final results are accurate and complete. However, due to the high level of public interest in the results, the CDC and FHCRC decided jointly to make the Draft Final Report available to the public while the peer review process was still underway, and before CDC or others made any revisions. By doing so, all interested parties were given the opportunity to review the unedited findings at the earliest possible time. ❖

#### *How the Study Was Conducted, Cont'd*

It is generally believed that most of these do not indicate thyroid disease.

The preliminary results of the study indicate that hyperparathyroidism was no more common in people with higher radiation doses from Hanford than those with very low doses. Hyperparathyroidism was evaluated using a measurement of calcium in the blood. Higher levels of serum calcium are associated with hyperparathyroidism. There was evidence from the study that the level of calcium in the blood (serum calcium) was slightly lower in people who received higher radiation doses from Hanford, but there was no increase in the proportion of persons with below-normal calcium levels in relation to thyroid radiation dose. Even among study participants with the highest doses, the levels of serum calcium were well within normal limits. ❖

### **CALL FOR COMMENTS**

The complete text of the HTDS Draft Final Report and summary public information materials are available on the web at: [www.fhcrc.org/science/phs/htds](http://www.fhcrc.org/science/phs/htds) and at [www.cdc.gov/nceh/programs/radiation](http://www.cdc.gov/nceh/programs/radiation). Individuals who would like to provide written comments on the Hanford Thyroid Disease Study Draft Final Report are encouraged to do so. Please send comments to: Centers for Disease Control and Prevention; Radiation Studies Branch (attn: HTDS); MS-F-35; 4770 Buford Highway; Atlanta, GA 30341. CDC would like to receive all comments by July 1, 1999. CDC plans to post all review comments on its web site: [www.cdc.gov/nceh/programs/radiation](http://www.cdc.gov/nceh/programs/radiation). Specific questions and/or requests for more information will be handled on an individual basis by either telephone (770-488-7040) or written response. All comments will be given consideration in preparation of the final report, which is expected to be available in late 1999. ❖

## **Evaluation of Mortality in the HTDS Study Population**

Of the 5,199 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 disease. Information from the death certificates was obtained for 502 of the 541 deceased individuals. An analysis of the causes of death revealed no indication that thyroid disease or thyroid cancer was responsible for any of these deaths. However, some individuals may have had thyroid disease when they died. These cases of thyroid disease would not have been identified by the examination of death certificates. Overall mortality (death) rates in the HTDS study group were somewhat higher than what would be predicted based on mortality rates in the State of Washington for the same time period. In addition, there was an elevation in deaths related to birth defects, complications of pregnancy and delivery, and premature birth. Preliminary results from the HTDS indicate that the increase in mortality was evident before releases from Hanford began and continued after the Hanford facility started operation. The reasons for this higher death rate are not known. The HTDS was not designed to evaluate mortality in the population around the Hanford facility. Consequently, the amount of information that can be gained from this study about mortality is limited. However, a 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 the 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. ❖

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**For More Information:**

Visit the HTDS websites at:

**[www.fhcrc.org/science/phs/htds](http://www.fhcrc.org/science/phs/htds)**

and

**[www.cdc.gov/nceh/programs/radiation](http://www.cdc.gov/nceh/programs/radiation)**

**Or Contact:**

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