

# **QUESTIONS & ANSWERS**

Hanford Thyroid Disease Study (HTDS)

MAY 1999

# 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.

**Q:** WHO WAS INCLUDED IN THE STUDY?

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

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/ OR http://www.cdc.gov/nceh/programs/radiation/

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 be sent by July 1, 1999. All comments will be given consideration in preparation of the final report.

**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, 3441 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 Hanford and be most at risk of developing thyroid disease as a result of their exposure. Previous studies have shown that the risk of thyroid disease after exposure to radiation is greater in persons exposed at earlier ages. The birth years 1940 through 1946 were chosen to ensure that participants in the study were very young children during the times of the largest releases of radioactive iodine, and therefore subject to the highest doses and highest potential risk.

**Q:** Is it possible that people who chose not to participate could have changed the outcome of the study?

A: There were some people who were located for the study who declined to participate in the study or were not able to be evaluated for a variety of reasons, such as incomplete residential histories. With the exception of 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 would have been more likely to participate. Therefore, it is highly unlikely that the study results would change 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 to estimate radiation doses that persons may have received from Hanford, provided the mathematical models needed to allow the HTDS to calculate estimates of radiation doses to the thyroid received by individual study participants. These calculations were based upon information collected from personal interviews with the participants and their close relatives. A second analysis was conducted by estimating radiation exposure based upon where a participant lived when the releases of I-131 were highest as well as whether or not they drank milk.

**Q:** Who had input into how the study would be done?

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 before 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.

**Q:** What do you mean by dose response?

A: When using the term dose response, we usually mean that people with lower exposures have less risk of disease, and people with higher exposures have more risk of disease. In some situations this may be reversed, having more exposure to a substance may be protective and lead to less risk of disease.

Q: EVERYONE NEAR HANFORD WAS EXPOSED - WHY DIDN'T YOU USE A CONTROL GROUP WITH NO EXPOSURE?

A: In many epidemiologic studies an appropriate unexposed control group is not available for comparison. In these instances, comparisons are made within the study population between groups of people who have different levels of exposure (such as low, medium, and high exposure). This is called an internal control group and can make the results of an epidemiologic study more meaningful. In the case of the HTDS, if we had used a population from some other part of the country as a control group, we could not be sure whether any differences in the disease risk between the two groups was due to a difference in exposure levels or due to some other risk factor that was different between the two populations. A population living around Hanford with respect to many different health related factors such as exposure to natural background radiation, lifestyle, or diet. Comparable national data on the cumulative incidence of thyroid disease in the U.S. population do not exist and cannot be used as a substitute for a control group.

**Q:** Why did you use a dose response to evaluate the relationship between thyroid disease and I-131?

A: Dose response relationships are often used to help answer questions about causation. In other words, we would like to know whether or not Hanford radiation caused thyroid disease in the population. Dose response relationships are frequently demonstrated in biologic systems (i.e. more exposure to a harmful substance often leads to a greater impact on the organ or gland) and have been identified studies of human populations exposed to radiation. In general, the presence of a dose response relationship can provide strong evidence for the existence of a cause-effect relationship.

### HANFORD THYROID DISEASE STUDY FINDINGS

**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. That is, 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. 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. In addition, there was an elevation in deaths related to congenital anomalies and conditions that occurred before or shortly after birth. The reasons for this higher death rate are not known. 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 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.

**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.

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 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.

#### **Q:** IS THYROID DISEASE ELEVATED IN THIS POPULATION?

A: The participants in the HTDS were extensively tested and examined for the presence of thyroid disease whether or not they had any noticeable symptoms of thyroid disease. Cases of thyroid disease, including thyroid cancer, often go undetected for many years because they do not cause symptoms which lead people to go to a physician. When a population is thoroughly examined or screened for thyroid disease many cases of disease will be identified that would not otherwise have been detected. The amount of diagnosed thyroid disease in a population that has been screened will be much higher than in an unscreened population. For this reason, comparisons between the HTDS study participants and other general populations are not appropriate. In addition, there are no national or state statistics for thyroid disease in a population similar to the study participants which has been screened for thyroid disease that can be used for comparison.

**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 possible in an epidemiologic study to determine whether an individual case of disease is due to radiation. 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 the preliminary study findings do not show 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 are available on the Internet. 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.

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 <u>certain</u> 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 fact sheets that summarize the findings of the study in an easy to read format. These materials 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 SCIENCES' 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 AFFECT 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 **A**..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 AFFECT 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 before 1950, the total release for the period December 1944 through December 1957 will increase approximately 2.9%. This error will affect some individual dose estimates, but HTDS staff do not expect it to greatly affect the HTDS results. CDC is currently evaluating the affect of this error. All HTDS doses will be recalculated and all statistical analyses will be repeated using these recalculated doses 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. 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.