

FACT SHEET #5

December 2002

<u>Frequently Asked Questions About the</u> <u>Pratt & Whitney Brain Cancer Cluster Investigation</u>

This Fact Sheet addresses some frequently asked questions about the Pratt & Whitney Brain Cancer Cluster Investigation, with answers from the researchers and the Connecticut Department of Public Health (DPH).

Background

In May 2000, the DPH began an investigation of a suspected cluster of brain cancer at the Pratt & Whitney (P&W) jet engine manufacturing plant in North Haven, CT. A preliminary analysis of brain cancer incidence conducted by the DPH was inconclusive since information on the number of workers at risk was not readily available. DPH recommended that a more comprehensive and rigorous investigation be undertaken by an independent research group. The study that is being conducted at P&W consists of two parts:

Epidemiology and Biostatistics. This component of the study will be conducted by the University of Pittsburgh (UPitt), with Dr. Gary M. Marsh as the Principal Investigator. The UPitt investigation will include a study of mortality and cancer incidence studies at the seven current and former production plants in Connecticut. Another part of the study that will be done by UPitt is a study of factors that may be related to the brain tumors. In this part of the study the work history and exposures of people with brain tumors will be compared to people who worked at the plant during the period 1942 through 2001 who did not have brain tumors. Workers with, and without tumors, or family members will be interviewed.

Exposure Assessment. The UPitt investigation will be complemented by a companion exposure assessment project, which will be conducted independently by investigators at the University of Oklahoma (UOK), with Dr. Nurtan A. Esmen as Principal Investigator. This comprehensive exposure assessment will attempt to characterize the historical work practices and exposures that occurred in each P&W study plant. UPitt will use this work history and exposure information to examine whether there is a relationship between brain cancer mortality and incidence and the past working environment of the P&W study plants. Workers who have information relevant to exposures or work practices will be interviewed.

The previous Fact Sheets #1 and #2 described the early phases of the investigation, which had been centered on the North Haven Facility. Fact Sheet #3 described the researchers who are conducting this more formal study. Fact Sheet #4 presented detailed outlines of the study. All of these Fact Sheets and further information about the study are posted on the DPH website, <u>www.dph.state.ct.us</u>.

Frequently Asked Questions About the Epidemiology Component of the Study Gary Marsh, Ph.D gmarsh@pitt.edu

How will the study be conducted?

The epidemiology part of the study will begin with identifying all workers who worked at any of the P&W plants from personnel records. It will include: (1) a comprehensive study of all causes of *mortality and brain cancer incidence* for former and current workers, and (2) a *case-control study of malignant and benign brain cancer*. This second part of the study will include interviews of persons, based on those who worked at the plants and did <u>not</u> have brain tumors, for each case of brain tumor identified.

Who will choose the people to be interviewed for the epidemiology study?

For each identified case of brain cancer, the researchers will identify a selected number of controls (this number depends on ultimate number of cases) from the study population who match the case on age, time period, race,

and sex. If more controls are available than needed, the researchers will randomly select the required number of controls from the pool of available controls. All cases and controls have the option of not participating, but participation is vital for the success of the case-control study.

How will the people be interviewed for the epidemiology study?

The case-control information is collected via a structured *telephone interview* with living cases and controls, or with a knowledgeable informant for deceased cases and controls.

Will the names of the people being interviewed and the results be made public?

The names of interviewees will <u>not</u> be made public. The rules of confidentiality do not allow this information to be shared. The results of the interviews will be incorporated into the analysis. From the published information, it will not be possible to tell who was interviewed and what was said in the interview.

Will the Communications Facilitation Workgroup be involved in the process?

The Communications Facilitation Workgroup comprises representatives from the International Association of Machinists, Pratt & Whitney, the University of Connecticut, family representatives of brain cancer victims and DPH. The group is charged with keeping all interested parties aware of any developments with regard to the study. The Communications Facilitation Group will be informed through progress reports of the type and scope of interviews conducted. However, the group will not be involved in the interview process.

What are the epidemiology studies going to find?

The comprehensive study of all workers (the cohort study) will address rigorously the basic question of *whether the number of observed brain cancers overall and in each study plant is greater than would have been expected* had the death or cancer incidence rates of the general population prevailed on the P&W study population at risk. The study will also enable a comparative mortality analysis of cause of death categories other than brain cancer.

The *case-control study of malignant and benign brain cancer* will afford a more comprehensive and focused *evaluation of brain cancer occurrence in relation to demographic, work history and occupational exposures* while controlling for potential confounding factors. The case-control analysis will be used to compare cases and controls with respect to the frequency of the various occupational factors of interest. Occupational factors occurring more frequently among cases than controls (after adjustment for potential confounding factors) are *potential occupational risk factors* for brain cancer.

Frequently Asked Questions About the Exposure Component of the Study

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How will the exposure study be conducted?

The exposure analysis is an exposure assessment companion project that will be conducted independently by investigators at the University of Oklahoma. This comprehensive exposure assessment will attempt to characterize the historical work practices and exposures that occurred in each P&W study plant. Part of this assessment will involve interviewing knowledgeable persons about past practices and potential exposures at the plants. The University of Pittsburgh will use this work history and exposure information to determine if there is an association between brain cancer mortality and incidence and the past working environment of the P&W study plants.

What is the process for picking the people to be interviewed for the exposure study?

The researchers will choose the people to be interviewed from a list of current and former employees identified by the company and the union, based on their direct knowledge of plant processes and work practices over the time periods covered by the study. Interviewees will be selected based on their knowledge of a specific operation or task, or to answer specific questions. Workers' accounts of how materials were handled, based on their long-term experience, are a very important part of the exposure reconstruction process. The interviews are conducted one-on-one between an investigator and the interviewee. No one else will be present, unless the interviewee requests a family member to accompany him or her.

Where will the interviewer hold the meetings for the exposure study?

The meetings are held at a location that is convenient for the researchers and the interviewees.

Will the names of the people being interviewed and the results be made public?

The names of interviewees will <u>not</u> be made public. The rules of confidentiality do not allow this information to be shared. The results of the interviews will be incorporated into the analysis and the results of the process analysis will be published. From the published information, it will not be possible to tell who was interviewed and what was said in the interview.

Is Dr. Esmen going to recreate multiple processes in the same general area?

Yes, to the extent possible, the group at the University of Oklahoma, which is headed by Dr. Esmen, will recreate the processes in a manner that is reflective of how they were organized in the plants.

What chemical or other exposures will be looked at?

At the outset of the study, <u>all</u> agents present in the workplace will be treated as potentially causative. The selection of exposures will have to be based on the plausibility of the effect, the ability to differentiate the exposures and the availability of data to reconstruct exposures.

Will the exposures include PCBs, oil mists, asbestos, electromagnetic fields?

To the extent that data are available and the processes reasonably suggest their inclusion, *PCBs, oil mists, and other chemicals* will be included as agents that will be studied. However, not all exposures will be analyzed with the same degree of detail. For example, *asbestos* is not a plausible causative agent for brain cancer; in that respect, while its presence might be noted in the data bank of measured exposures, it would not be studied specifically.

Some previous occupational epidemiology studies have shown a possible association between brain cancer and *electromagnetic fields*, but taken as a whole, the results of these studies have been inconsistent and, in the words of a major National Research Council report "have failed to establish an association with a high degree of certainty." Research in this area is further complicated by the lack of a known, physically plausible mechanism by which electric and magnetic fields could cause cancer. This makes it impossible to define the most appropriate measure of exposure. It is only reasonable to take all these facts into account as the researchers go through the process of focusing the study on the most plausible agents. Accordingly, exposure to electromagnetic fields will be considered to the extent possible.

<u>Could the tar wooden blocks cause damage to the body because they were treated with tar and other chemicals?</u>

Although we do not know the precise answer to this question, it is surmised that any adverse health effect due to the presence of tarred blocks is a very unlikely event. In addition, researching this question within this study would not lead to any answers, as the entire plant populations were exposed in a non-differentiated fashion.

Will all environmental issues be in question?

For the purposes of this study, only environmental issues that relate to occupational exposures of P&W will be addressed.

Will the issue of chemicals transferred from the work environment to homes/vehicles be looked at?

This will not be included in the study.

How will the question of the wearing of Personal Protective Equipment (PPE) be looked at?

PPE usage will be documented to the extent possible and reliable. The interviews will be a critical source of information about actual usage of PPE throughout the study period. It should be kept in mind that any exposure

reconstruction must be based on characteristics of <u>groups</u> of workers. It would be impossible to delineate individual differences for the cohort.

Other Frequently Asked Questions

Where can the publications that Drs. Marsh and Esmen previously wrote be found?

The list of all publications of Drs. Marsh and Esmen can be found on the DPH website.

What is a cancer cluster?

A cancer cluster is a larger than expected number of people diagnosed with one type of cancer occurring during a limited time period in a specific geographical location. To determine if a cluster is real, it must be determined whether the number of cancers that occurred in a population in a defined time period is greater than would normally be expected. Clusters may occur by chance, especially when many comparisons are made, therefore it is important to assess the strength of the comparisons that are made.

Is there a disease cluster at Pratt & Whitney?

That is a question that can only be answered after the researchers have gathered sufficient data and conducted at least some preliminary epidemiologic analysis. Clusters can be described as "disease occurrence that is not uniform in time, across populations, etc." This type of observation can only be made when sufficient data are available for analysis.

When do we define a cluster?

When sufficient data have been gathered to determine if there is a non-random distribution of cases, it may suggest a cluster. Non-random occurrence of disease is more likely in an occupational epidemiology study to indicate differences in exposure patterns (different substances, processes, etc.) or magnitude.

What are the differences between malignant and benign brain tumors, and metastatic brain tumors?

Malignant brain tumors are cancerous, involving a growth with a tendency to invade and destroy nearby tissue and spread to other parts of the body. A *benign* brain tumor is non-cancerous, a growth that does not invade nearby tissues or spread. A *metastatic* brain tumor is one that does <u>not</u> originate in the brain, but has spread from other parts of the body. In the case-control investigation, malignant and benign brain tumors will be analyzed further, but not metastatic brain tumors.

Can I be screened for Brain Cancer and if so, should I be screened?

This question was answered in the third fact sheet. Since there are still questions regarding this issue we are reprinting the answer provided by Dr. Michael Grey of the University of Connecticut Department of Occupational and Environmental Medicine.

In order to be effective, screening for a particular disease or health condition should result in early detection <u>and</u> improved outcomes, such as lower mortality. Examples would be screening for elevated blood pressure or blood sugar screening for diabetes. Early detection in both instances results in treatment and better outcomes (fewer heart attacks, strokes, etc.) Because early detection of brain cancer has not been shown to lower the mortality or morbidity associated with malignant brain cancers, screening for brain cancer cannot be recommended. Even in industries where the risk of developing brain cancer has been better documented, mass screenings are not done, nor is routine testing with imaging studies such as CAT scanning or MRI recommended. There are several reasons for this, but in general the cost versus benefit of screening has not been shown to favor testing. Not to be discounted is that most medical tests have potential downsides in terms of cost, risk of injury, and unnecessary tests, worry and anxiety in the event of false positive testing. In addition, we do not yet know the level of risk for current and past P&W employees. In fact, getting a handle on this risk is the goal of the study being conducted by Dr. Marsh. As the study progresses and if new information becomes available on the possible benefits of screening, this recommendation would be reviewed.

Frequently Asked Questions About Brain Tumors

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WHAT ARE THE SYMPTOMS OF A BRAIN TUMOR?

Brain tumors cause problems by invading and injuring normal brain tissue and by pressing on normal brain tissue. As brain tumors enlarge, they may also cause symptoms by taking up so much space inside the head that pressure rises.

The brain is organized so that different parts of the brain are responsible for different functions. For example, one part of the brain is devoted to vision, another to controlling movement of the opposite side of the body. Tumors may cause different symptoms depending on where in the brain they arise.

For any of the symptoms that may be caused by a brain tumor, it is important to remember that there are other more common causes as well. No one symptom usually means that the patient has a brain tumor. The key difference between symptoms caused by brain tumors and other causes, is the steady worsening of brain tumor symptoms over time. Although individual symptoms may come and go, a growing brain tumor will lead to increasingly severe symptoms over time.

If some new problem worries you, you should consult your physician. You should tell your doctor that you are concerned the problem may mean you have a brain tumor.

Examples of symptoms that would raise concern:

- 1. Headache: New headaches or a change in the type and pattern of headaches may be a symptom of brain tumor. There are many other less serious causes that are more common, for example migraine headache or tension headache. A headache that is present on waking up in the morning, wakes the person from sleep, or which worsens in severity when the patient lies down, requires investigation. Headaches associated with black outs or greying out of vision are especially worrisome.
- 2. Weakness: New weakness of an arm or leg or one side of the body which worsens over time requires investigation.
- 3. Numbness: Loss of feeling in an arm or leg, or one side of the body that worsens over time.
- 4. Vision problems: Loss of vision to one side of space that worsens over time. Black outs or grey outs of vision with standing up, especially if there is also headache, require investigation.
- 5. New problems with walking, such as loss of balance or coordination, unsteadiness and falling.
- 6. Problems with thinking, memory or concentration that worsen over time.
- 7. Problems with speaking, understanding or thinking of words that worsen over time.
- 8. Change in behavior or personality.
- 9. New onset of seizures: Seizures result from abnormal electrical activity of nerve cells in the brain. When seizures appear for the first time in an adult, MRI imaging is always necessary. Brain tumors usually cause focal seizures, meaning that the abnormal electrical activity in the brain arises from one specific spot. The electrical activity may spread, with blacking out. Seizures may have several different patterns:
 - a) Generalized seizure: loss of consciousness with shaking of all the arms and legs
 - b) Focal motor seizures: shaking of one arm or leg or twitching of one side of the face. Focal seizures may spread to involve one entire side of the body
 - c) Focal sensory seizures: tingling or numbness of one arm or leg or of one side of the face. Focal seizures may spread to involve one entire side of the body
 - d) Partial complex seizures: loss of awareness of surroundings without falling down or shaking of limbs. There is no memory of what happens during the actual seizure. These seizures may begin

with smelling strange smells or a feeling of being sick to the stomach.

e) Seizures may occur during sleep. If you sleep with a spouse or significant other, he or she may report that you have shaking of the arms or legs during sleep. Waking with unexplained muscle soreness, bitten tongue, or wetting or soiling the bed or bedclothes may be symptoms of a seizure occurring during sleep.

It is important to remember that many healthy people have headaches, weakness, or numbness that goes away, and that these types of symptoms do not necessarily mean you have a brain tumor, or any serious neurologic disease. If you are afraid that you have symptoms similar to those listed, or other symptoms concern you, the best course of action is to consult your physician.

HOW ARE BRAIN TUMORS DIAGNOSED?

The most sensitive and reliable test for identification of a brain tumor is Magnetic Resonance Imaging (MRI). MRI does not use x-rays, and gives very detailed pictures of the brain. MRI scanning can identify abnormalities as small as one centimeter (approximately ½ inch) reliably. Injection of the drug gadolinium, which leaks out of the leaky blood vessels that feed growing tumors, can help identify tumors that are likely to grow rapidly (high grade). If an abnormality is seen on MRI scan that suggests the presence of a tumor, a biopsy is required to prove whether or not the abnormality is a tumor, and if so, exactly what type of tumor.

If you have additional questions about this investigation, or would like more information, you may contact: IAM District and Lodges for all sites: Deb Belancik – District 26 EH&S Coordinator – 860-565-4766 Paul Dickes – Middletown LL 700 Chief EH&S Rep – 860-704-7142 John Tronier – East Hartford LL1746 – Chief EH&S Rep – 860-565-3738 Al Virelli – Cheshire LL 1746A – Chief Rep – 860-620-1975 or P&W Medical Department

(860) 565-5872

If you would like to report cases you may be aware of, or if you would like to request the previous Fact Sheets, or if you have questions about this investigation, please contact: Connecticut Department of Public Health Division of Environmental Epidemiology and Occupational Health 410 Capitol Avenue, MS #110SP, PO Box 340308 Hartford, CT 06134-0308 Phone: (860) 509-7744 Fax: (860) 509-7785 Previous fact sheets and additional information are posted at: http://www.dph.state.ct.us/