Prologue and Summary

CANCER MORTALITY AND MORBIDITY (INCIDENCE) AROUND TMI

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More than six years have elapsed since the March 1979 accident at the Three Mile Island (TMI) nuclear facility. During this period, concerns about low level radiation as a possible cause of cancer have been a subject of considerable attention. These concerns have been heightened by a review of radiation dose assessment sponsored by the TMI Public Health Fund and a survey of cancer mortality by a group of local volunteers in selected communities near TMI.

The Pennsylvania Department of Health has conducted an epidemiological study to determine if there is evidence of unusual cancer mortality and morbidity in communities around TMI, and if so, to determine if the findings are consistent with what is currently known about cancer caused by radiation.

Cancer caused by radiation generally has a long latency period before diagnosis can be made (10 to 20 years or more). Even leukemia, which is known to have a relatively short latency period, is usually not detectable earlier than five years following radiation exposure.

The present study examines both cancer mortality (deaths) and morbidity (incidence, i.e., the number of newly diagnosed cancer cases) and the results presented include: (a) comparison of the observed and expected numbers of cancer deaths, (b) comparison of the observed and expected numbers of newly diagnosed cancer cases (incidence), and (c) followup of the incidence of cancer among specific groups of mothers and fetuses presumably exposed to radiation as a result of the TMI accident.

ANALYSIS OF CANCER MORTALITY IN TMI AREAS:

Direct comparison of cancer rates before and after the TMI accident would have been desirable. However, such comparisons require adjustments for population changes and for the influences of the age-sex compositions of area populations under study. Because total and age-sex specific population data for the time prior to the accident are not available, such comparisons are not possible on a scientifically valid basis.

Under the circumstance, an observed vs. expected number method was used. The expected numbers of cancer deaths computed for the post-TMI period (1979-1983)[a] are those which would have been anticipated, based on the 1980 population, if the communities under study had the same age-sex cancer mortality experience as Pennsylvania had during the 1979-80-81 period (average). The observed numbers of cancer deaths for the period prior to TMI (1974-1978) have been included in the study to provide some indication of whether or not unusually high or low cancer mortality may have occurred in areas surrounding TMI prior to the accident. It should be noted that in areas of population increase, the expected numbers for the pre-TMI period would tend to be "overestimates" while for the post-TMI period they would tend to be "underestimates."

a) For purposes of this report the post-TMI period is January 1, 1979 through December 31, 1983 and the pre-TMI period is January 1, 1974 through December 31, 1978.

The reader should also be aware that one may expect to see more cancer cases, living or deceased, in the post-TMI period regardless of the accident because of the following:

* General increase in cancer cases in Pennsylvania and elsewhere.
* Population increases over time in many areas under study.
* Better cancer reporting system.
* Improved diagnostic techniques and opportunities.
* Cancer patients now live longer than previously.
* Increased longevity (older persons are more susceptible to cancer).

ANALYSIS OF CANCER MORBIDITY IN TMI AREAS:

In addition to analyzing the number of deaths due to cancer, the Department also analyzed cancer morbidity (newly diagnosed cases or incidence) in the TMI area. Incidence data are more useful than mortality data in assessing possible connections between radiation exposure and cancer.

It is well established that there is a long latency period between radiation exposure and the diagnosis of cancer. There is an even longer time lag between exposure and death from cancer. Accordingly, if radiation exposure from TMI had resulted in any increase in the number of cancers, it will be observed in the incidence data long before being observed in mortality data.

Cancer morbidity (incidence) data used in this study were obtained from the Pennsylvania Cancer Registry which became operational in July 1982 for the TMI area. The data gap from the time of the accident through June 1982 is not considered serious in view of the fact, as previously noted, that radiogenic cancers

are not expected to be observable within a few years post exposure. These missing years, however, were well covered by the Department of Health's comprehensive analysis of the mortality data (see Summary of Major Findings).

ANALYSIS OF CANCER INCIDENCE AMONG MOTHERS AND FETUSES PRESUMABLY EXPOSED TO RADIATION FROM TMI:

The method of analyzing cancer incidence data in a given population as of a given year does not consider the fact that, since the accident, some individuals have moved out while others have moved into the study areas. In order to take this migration factor into account, a special analysis was conducted involving nearly 4,000 pregnant women living in the TMI area at the time of the accident.

Subsequent to the accident, pregnant women residing within 10 miles of TMI were entered into the Pennsylvania Department of Health Mother/Child Registry. The mothers and children they were carrying at that time have been monitored systematically to determine if they have experienced an unusual increase in cancer incidence.

The analysis of cancer morbidity (incidence) among this group living in the area at the time of the accident complement the Department's analysis of cancer mortality data. The results of this special analysis are discussed in the Summary of Major Findings.

ADDITIONAL CONSIDERATIONS/LIMITATIONS:

1. CORRECTION OF ERRORS IN PLACE OF RESIDENCE

For selected small geographic areas, particularly those located north, northwest, and west of the TMI facility (down-wind during the early period of the accident), a special effort was made in this study to insure the accuracy of the place of residence reported for each of the identified cancer cases. Such care is necessary because mailing addresses are often incorrectly reported as residential addresses on mortality and cancer records.

2. FLUCTUATING STATISTICS FOR SMALL AREAS

One should be aware that it is difficult to draw conclusions based on small area statistics because of the inherent variability in the data and thus the increased probability of error in making inferences. In fact, mortality and morbidity rates for small areas can and do fluctuate markedly from one area to another and from time to time within the same area. This normal fluctuation may create false impressions among lay observers about the importance of different rates from one time period to another or between one area and another.

3. CANCER CLUSTERS

"Cancer Clusters" are frequently observed in community settings such as churches, schools, factories, or along certain streets. This is because cancer is a common disease in the United States, with a life-time incidence of one case for every four to five people. With such a high frequency, it is not difficult to observe apparent "clustering" depending upon how a geographic boundary is delineated or how the small area population at risk is identified and selected.

4. CAUSE AND EFFECT RELATIONSHIPS

It is tempting to attribute high cancer death rates or an increase in cancer morbidity to those potential causative agents that would seem to be most apparent in a given place or time. The radiation releases from TMI are a case in point. However, cancer can be caused by one or more of a variety of environmental and genetic factors such as: diet, tobacco, micro-organisms, radiation, food additives, occupational/industrial exposures, host susceptibility, etc. Because of the complexity of cancer etiology, one should not draw quick conclusions about cause and effect relationships.

SUMMARY OF MAJOR FINDINGS:

1. The results of mortality analyses provide no evidence that cancer mortality in the TMI area was significantly different from expectation after the accident. On the contrary, the area covering a 20-mile radius from the plant was found to have had fewer cancer deaths than expected during the 5-year period post-TMI (7,924 observed versus 8,177 expected). Analyses of data for several smaller geographic areas, regardless of distance and direction from the TMI facility, also showed no observed numbers significantly higher than expected. While in some instances the observed numbers of cancer deaths post-TMI were higher than expected, others were lower than expected, a sign of random variation.

2. TMI area cancer mortality data were also analyzed according to eight major anatomical site classifications. While recognizing the presence of random variations, there were no significant increases in any cancer sites, including leukemia and other radiogenic cancers. The nine leukemia deaths reported during the period January 1, 1979 through December 31, 1983 in four selected MCDs (Fairview and Newberry Townships and Goldsboro and York Haven Boroughs), compared to the three leukemia deaths of the pre-TMI period

might be viewed by lay persons to be of importance. However, neither nine nor three deaths were significantly different from the expected number of six for the area. It should be noted that one of the nine patients actually died before the accident and, of the remaining, two were diagnosed as having leukemia prior to the accident (in 1976 and 1978). In still another case, the available clinical data suggest that the apparent onset of leukemia was noted by a physician well before the accident.

3. In addition to analyzing deaths caused by cancers, the Department also analyzed the number of newly diagnosed cases of cancer. According to Pennsylvania Cancer Registry data for the July 1982-June 1984 period, there is no indication that the number of newly diagnosed cases of cancer was significantly higher than expected for the four MCDs. The differences between the observed and expected numbers of cases for these areas could have occurred by chance alone. Furthermore, the total number of radiogenic cancer cases observed in the four communities was not significantly greater than expected. In particular, leukemia, the most likely cancer that could be detected as early as 5 to 6 years following exposure to radiation, was diagnosed in only two area residents while approximately four cases might have been expected. Again, these differences are not statistically significant.

4. The TMI Mother/Child Registry includes a study group of nearly 4,000 pregnant women who delivered between March 28, 1979 and March 27, 1980. These women were residing within a 10 mile radius of TMI and most of them were pregnant at the time of the accident. This Registry is updated continuously and is linked to the Pennsylvania Cancer Registry file. During the July 1982-December 1983 period, four of the 3,582 mothers (most of whom were residing in 14 southcentral Pennsylvania counties) were diagnosed as having cancer. Based on the national cancer registry data for females in the 10-44 year age group, 3.9 mothers might have been expected to be so diagnosed during this time period. Of the mothers' children, two were diagnosed with cancer, while one case was expected. Neither of these differences is statistically significant. Thus, available information based on mothers and children presumably exposed to TMI radiation gives no indication of a significant increase in cancer incidence at this time.

CONCLUSIONS:

The results of our epidemiologic study, including both mortality and morbidity data, do not present evidence of an increased risk of developing cancer by local residents living near the TMI nuclear facility.

In view of the known long latency period from exposure to a cancer-causing agent and the development of cancer, however, and the persistent dispute over the amount of radiation releases from the damaged TMI nuclear reactor, it is prudent to continue epidemiologic surveillance of cancer around TMI. The Pennsylvania Department of Health established the mechanism for such an effort shortly after the 1979 accident and several long-term followup studies of those who presumably were exposed to TMI radiation are in progress.

SUMMARY OF EVALUATION OF THE AAMODT SURVEY:

The results of a health survey conducted by a group of local residents (Aamodt survey) were made public on June 21, 1984. The Aamodt survey concluded that cancer mortality has markedly increased around TMI and implicated the 1979 nuclear accident at Three Mile Island (TMI) as being responsible. It covered three separate, small geographic areas northwest of the TMI facility, but provided little information regarding the survey design or methodology. The demographic and cancer mortality data in the survey were very limited and incomplete.

Following its release, the Centers for Disease Control (CDC), U.S. Public Health Service, reviewed the Aamodt document at the request of the U.S. Nuclear Regulatory Commission. CDC identified a number of epidemiologic deficiencies in the data presented and concluded that the Aamodt survey does not present "convincing evidence of increased cancer incidence; increased cancer mortality; or adverse pregnancy outcome in the TMI-area residents following the accident." In November, 1984, the Pennsylvania Department of Health was requested by the Advisory Panel for Decontamination of TMI Unit 2 to further evaluate cancer data presented in the Aamodt Survey.

The Division of Epidemiology Research of the Pennsylvania Department of Health was able to ascertain some additional information regarding the reported cancer cases. This enabled the Department to conduct a more thorough assessment of the Aamodt survey of cancer mortality.

A re-analysis of the data originally presented in the Aamodt survey, as well as additional data for the same general area procured by the State Health Department, does not support the claim that the TMI accident caused an increase in cancer deaths. A number of methodological defects was noted in their survey. These defects and related comments are summarized as follows:

1. The most important and serious defect in the Aamodt survey is the selection bias which was introduced early in data collection by the inclusion of only specific geographic areas (streets), households and individual residents while ignoring others equally qualified for inclusion. More specifically, there is evidence that such selection was influenced by the pre-existing knowledge of cancer deaths, i.e., only those streets where cancer deaths were known to be present were chosen, ignoring other streets in the same area where no cancer deaths were reported. Because of this selection bias, the results of the Aamodt analyses are invalid.

2. The Aamodt survey claims a causal relationship between radiation resulting from the March, 1979 accident at TMI and cancer in the areas they surveyed. This claim, however, is based on mortality data, which, by themselves, are of limited value in establishing such a relationship. The

Aamodt survey provides very little information regarding essential cancer incidence data.

3. The Aamodt survey differed with the concept of latency in radiogenic cancer. Yet, leukemia is probably the only cancer for which one reasonably could expect to see an increased incidence within five or six years post-TMI (even if the disputed doses of radiation releases were in fact high enough to cause it). Other forms of radiogenic cancers may not be observable for at least 10 to 20 years or more after the initial exposure to high doses of radiation.

4. Existing epidemiologic studies indicate that certain specific forms of cancer are more likely to occur following exposure to high-dose radiation. When many different types of cancer are observed, as is the case with the Aamodts' reported cancer deaths, it suggests an absence of a single causal relationship.

5. Age and sex distributions of the local populations under study are important factors to consider when evaluating cancer mortality. The Aamodts' survey did not take these sensitive factors into account.

6. Unless supplemented by other data, cross-sectional mortality data are not adequate for establishing a causal relationship between cancer and TMI radiation because many people have moved out of and into the area since the accident. The former residents should be included, and the newcomers excluded in any scientific attempt to determine whether there is a connection between cancer mortality and the accident at TMI. The Aamodt survey did not address this problem.

7. The expected numbers of cancer deaths presented in the Aamodt survey are for a five-year period. The 20 "actual cancer deaths" reported by the Aamodts, however, include persons who died during a five year ten and a half month time period - a discrepancy, which given the limited population survey could have had a significant impact on their claimed death rate.

8. The Aamodt survey attributed an alleged increase in cancer mortality to the TMI accident. Of the 20 originally reported deaths, one died before the accident in 1978; one who died of a cause other than cancer was apparently confused with a relative who died of cancer prior to the accident; six were diagnosed as having cancer prior to the accident, and two were long-term heavy smokers who died of lung cancer. The remainder represented a variety of cancers normally found in any population group.