



FEASIBILITY OF COMMUNITY-WIDE EPIDEMIOLOGIC STUDIES OF DRINKING WATER AND HEALTH: ST. LOUIS PARK AND NEW BRIGHTON

FINAL REPORT TO THE MINNESOTA LEGISLATURE DECEMBER 31, 1985

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INTRODUCTION

Origin and Purpose of Study

In the spring of 1984, the Minnesota Legislature authorized funding for the Minnesota Department of Health (MDH) to evaluate the <u>feasibility</u> of conducting community-based epidemiologic studies in the cities of New Brighton and St. Louis Park (1984 Minnesota Session Laws, Chapter 654, Article 5, Section 4, and H.F. 1318). In St. Louis Park, six of fourteen municipal wells were removed from service between 1978 and 1981 due to trace levels of polynuclear aromatic hydrocarbons (PAHs). The contamination is believed to have originated from the former operation of a creosote and coal-tar distillation plant in St. Louis Park. In New Brighton, six of eight wells were modified or removed from service following the detection in 1981, of low levels of several volatile organic compounds (VOCs), primarily trichloroethylene (TCE) and trichloroethane (TCA). A major source of the contamination is believed to be the Twin Cities Army Ammunition Plant. Both sites have been ranked in the highest priority group of federal Superfund sites.

The discovery of contaminated municipal wells in these communities resulted in considerable concern among the residents that they may be at increased risk of adverse health effects, particularly cancers, as a result of their potential exposure to contaminated drinking water. Subsequently, several efforts were made to examine available disease statistics to determine whether a public health problem could be identified. These efforts were not able to resolve community or scientific concerns, and the possibility of large-scale community studies was considered. However, such

epidemiologic studies can pose serious technical difficulties, often require significant resources, and may be incapable of resolving specific concerns. In light of these issues, the MDH undertook an 18-month evaluation of the feasibility of conducting environmental epidemiologic studies in these communities that would address health outcomes that may be related to well water contamination. The goal of this study was to develop recommendations to the State concerning whether, or how, such studies should be conducted. It was also the goal of this study to provide a more general and socially useful assessment of the difficulties in evaluating the human health impacts of long-term exposure to low levels of chemicals present in community drinking water.

Some of the issues that were considered in this feasibility study include the following:

- the availability and usefulness of existing morbidity and mortality data;
- 2. the ability to estimate individual exposure to drinking water contaminants (based on environmental and hydrologic data, biological markers, tissue burdens, residence history, etc.);
- 3. evidence on the biochemical, toxicological, and carcinogenic properties of identified contaminants;
- 4. existence of highly exposed subgroups within the communities that could serve as sentinel populations for the entire community;
- 5. the willingness of individuals, communities, industries, medical providers and other agencies to participate;
- 6. determination of potential epidemiologic study methods, their advantages, and their costs; and
- 7. determination of criteria by which to evaluate the feasibility of environmental epidemiologic studies of contaminated drinking water.

In July, 1984, the Chronic Disease and Environmental Epidemiology Section of the MDH, in consultation with faculty of the University of Minnesota School of Public Health, began the feasibility study with the goal of producing a final report with recommendations to the Legislature by January, 1986.

Approaches Used in the Study

Several approaches were taken to evaluate the feasibility of epidemiologic studies in the two communities.

- A computerized literature search of appropriate biomedical and toxicological bibliographic databases was conducted to identify published reports pertaining to specific contaminant compounds, health effects related to drinking water, and environmental epidemiology in general;
- 2. Information relevant to this study was solicited from federal agencies, including the Environmental Protection Agency, the Centers for Disease Control, and the National Institute of Environmental Health Sciences;
- 3. Information was solicited from all fifty state epidemiologists concerning efforts in their states to address health effects related to waterborne environmental contaminants;
- 4. Other agencies within the state (local, state, and federal) were contacted to determine the availability and quality of various environmental, hydrogeologic, water supply and other engineering data;

- 5. All existing health-related information that had been generated as a consequence of the contamination problem was identified and reviewed;
- 6. A special two-day workshop with national experts was held to address issues related to development of a model of historical exposure to contaminants in drinking water. Many different areas of expertise were represented by workshop participants (see Appendix A);
- 7. Additional review of cancer incidence data for St. Louis Park was conducted, including a critical review by an outside expert in statistical epidemiology; and
- Outside experts in epidemiology and toxicology were asked to review the final report.

Organization of the Report

This report consists of five sections which address the principles of epidemiology and their application to the study of potential health effects resulting from contamination of groundwater supplies. Section 1 provides a brief summary of epidemiologic methods, how epidemiologic associations are judged, and the kinds of data frequently used to describe health. A brief overview is provided of the methods and findings of studies that have examined water and health issues. Section 2 describes several nonepidemiologic approaches for assessing potential human health risks from environmental exposures. Section 3 outlines several major criteria for the conduct of meaningful community-based epidemiologic studies of environmental contaminants. Section 4 reviews available information regarding the well water contamination in St. Louis Park and in New Brighton. Information presented includes when contaminants were first

detected, the nature and magnitude of the contamination, the possible sources of contamination, various aspects of the municipal water supply that relate to potential community exposure, existing studies and available data that relate to community health, and the general environmental and toxicologic aspects of the contaminants. Section 5 outlines a series of epidemiologic options for addressing potential health effects as a result of well contamination in St. Louis Park and New Brighton. Proposals for studies or monitoring of both mortality and morbidity are provided, along with discussion of study strengths, limitations, costs, and recommendations.

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FINDINGS AND CONCLUSIONS

Listed below is a summary of the major findings and conclusions of this feasibility study. General findings are presented first, followed by more specific findings for St. Louis Park and for New Brighton. Specific recommendations arising from these findings are presented elsewhere. The Section(s) of the full report that refer to a particular finding or conclusion are indicated in parentheses.

It is important to recognize that the findings and recommendations of this study, although, of some applicability to other or future situations of water contamination, should not be interpreted as a statement of the appropriateness of water quality criteria, the type of remedial actions that should be taken to relieve water contamination problems, or the acceptability of particular levels of risk arising from such contamination. The scientific uncertainties in estimating human health risks, the nature of the risks (cancer risks or other risks, voluntary or involuntary, etc.) aesthetic values, public perceptions, and many other factors are extremely pertinent to the water quality issue. The right of a community to the best available water supply is a long established and accepted principle of public health and should be viewed separately from the issue of whether epidemiologic studies are warranted in particular instances of water contamination.

General

 There have been many published epidemiologic studies that have attempted to examine cancer risks in relation to drinking water source. Most of these studies have serious design limitations that make interpretation of their findings very difficult. The major flaw has generally been the absence of individual measures of

exposure. Neither their findings nor their methodology serve as useful models for St. Louis Park or New Brighton. (Section 1)

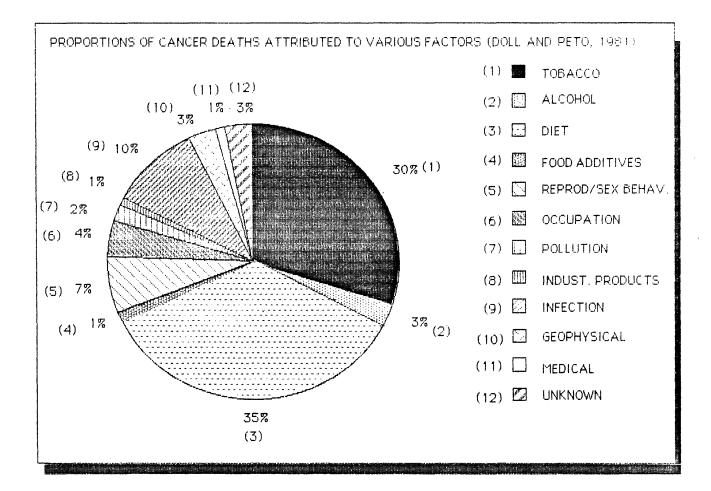
- 2. Several studies have examined potential associations between particular health effects and contaminated well water. These studies have varied widely in their assessment of exposure, general study design, health outcomes examined, and many other factors. For a variety of reasons, these studies have not shown clear evidence of a causal association between water contamination and adverse health effects. Neither can these studies rule out such an association. (Section 1)
- 3. Major difficulties in almost all epidemiologic studies of environmental carcinogens include (a) long latency periods for most cancers; (b) lack of information on relevant exposures that may have occurred many years or decades ago; (c) the existence of multiple risk factors for most cancers; (d) multiple exposures to potential carcinogens; (e) population mobility; and, (f) the need for large study populations due to the relative infrequency of specific cancer types. (Sections 1, 3)
- 4. Quantitative risk assessment (bioassay) is a process for estimating human cancer risks based on animal experiments. The basic premise of this process is that substances that are carcinogenic in experimental animals may also be carcinogenic in humans. Mathematical models are used to extrapolate from high dose animal exposures to low dose human exposures. Although there are many assumptions and large uncertainties involved in this approach, bioassay offers a practical and objective means for identifying

potential health risks. It is generally accepted that in the absence of direct epidemiologic evidence of a health risk, substances shown to be carcinogenic in experimental animals should be treated as if they represented a carcinogenic risk to humans. (Section 2)

- 5. Current epidemiologic methods are not generally capable of identifying or validating the excess cancer risks that are typically projected from animal bioassays for environmental exposure levels. These risks are commonly expressed in terms of the exposure level that would result in one additional cancer per 100,000 persons with lifetime exposure $(10^{-5} \text{ risk level})$. Since the cumulative lifetime cancer risk in the population is approximately 30%, that one additional case would have to be detected among the 30,000 other cases. (Sections 1, 5)
- 6. There appears to be a growing concern among the public that cancer incidence is largely the result of chemical contaminants in drinking water, ambient air, or other environmental media. One factor that has probably contributed to this belief is a misunderstanding of statements made by scientists that a significant portion of cancer incidence is related to environmental factors. "Environment" in this sense should usually be interpreted to mean all non-genetic factors, and includes significant lifestyle characteristics such as smoking, alcohol consumption, type of diet, reproductive history, and occupation, in addition to ambient environmental exposures. The extent to which personal or lifestyle factors contribute to occurrence of a particular type of cancer varies, but may be extremely large (e.g., 90% of lung cancer and

30% of all cancer deaths are attributable to tobacco). An estimate of the proportions of all cancer deaths that are attributable to various factors is summarized in Figure E-1. It should be noted that these estimates have a large uncertainty and are intended to apply to the U.S. population in general. In particular subgroups of the population, these estimates would differ.

Figure E-1



The large contribution of "lifestyle" to many cancers does not imply that society should be less vigilant about reducing or eliminating exposures to identified environmental carcinogens (e.g., asbestos). Another factor that may contribute to public concerns regarding cancer and the environment is the lack of public knowledge regarding the natural history of cancers. For example, it is not always understood that cancer is not a single disease, but many different diseases with different risk factors and generally long latency periods. Continuing efforts are needed to inform the public of the many issues related to cancer and the environment, including information on the known or suspected causes of cancer, the magnitude of actual or potential cancer risks, and the methods used to identify cancer risks (e.g., animal bioassays, cytogenetic tests, and epidemiologic studies). (Section 1)

St. Louis Park

A substantial amount of information has been generated in relation to the water contamination that resulted in several well closings between 1978 and 1981 in St. Louis Park. This information includes environmental, hydrogeologic, water supply, and limited health data. In addition, much general information is available regarding the environmental and toxicological aspects of the contaminants found in the wells. The following findings and conclusions are based on review of this information.

1. A valid contaminant-exposure model for use in epidemiologic studies in St. Louis Park cannot be established. That is, it is not possible to classify individuals or residences within St. Louis Park according to their relative degree of historical exposure to PAH contaminants in drinking water. At the outset of this study, it had been thought that a crude surrogate for exposure might be

length of residency in St. Louis Park between 1947 and 1978. However, neither this nor any other approach would avoid the potential for serious misclassification of exposure. This conclusion is based on the following factors: (Section 4)

- a. The pattern and history of municipal well contamination in St. Louis Park prior to 1978 are not known. The installation dates for contaminated municipal wells range from 1947 to 1969, long after the beginning of operation of Reilly Tar and Chemical Corporation (1917) and long after the first evidence of contamination of the major bedrock aquifer (early 1930s). Available information strongly suggests that the migration of groundwater contaminants has been complex. It is also possible, then, that the history of well contamination was complex, with some periods of well contamination and other periods with little or no contamination. The net effect of such variability, in addition to the effects of seasonal and long-term variations in well use, is that over different periods of time, it is possible that none, some, or most of the St. Louis Park water supply was provided by contaminated wells.
- b. Additional insights into the history of contaminant migration (and well contamination) might be gained by further computer simulations using groundwater flow models developed for the St. Louis Park area by the U.S. Geological Survey. Such efforts might require several years, and it could not be known in advance whether these simulations would be capable of establishing time periods in which specific wells were likely to have been (or not have been) contaminated. The validity of computer groundwater flow models in predicting historical contaminant migration is unknown.
- c. Contaminant levels were measured at the well head, and it is not known to what extent the usual water treatment, storage, and distribution processes would affect contaminant levels at the tap at various locations in the city.
- d. Measurements of PAH residues in the water distribution system would not likely serve as a useful index of cumulative exposure. Much of the distribution system was installed many decades ago when the use of asphaltic or coal-tar liners in water mains was common in the U.S.
- e. Polynuclear aromatic hydrocarbons (PAHs) are rapidly metabolized and eliminated from the body. They do not accumulate in human tissues; consequently, tissue residues cannot be used to estimate historical exposures.

- 2. It has long been established that certain PAHs and PAH-containing mixtures are potent animal carcinogens, capable of producing tumors in most animal species tested by most routes of exposure. Depending on the animal species used, the experimental conditions, and the specific PAH, tumors can be produced in many different tissues. Although PAHs commonly produce tumors in rodents at the site in which intake occurs (stomach, lungs, skin), some can also produce tumors at remote body sites, such as mammary glands. (Section 4)
- 3. PAHs are produced from most combustion processes and are ubiquitous in the environment. The general population is exposed to PAH in the air, in foods and beverages, and in drinking water. Smoking and certain occupational settings produce significant additional exposures. Estimates of PAH intake in the general population indicate that foods are the primary source of exposure to carcinogenic PAH. It is probable that exposures from food would significantly exceed exposures from contaminated St. Louis Park well water. Exposure to carcinogenic PAHs would also be much greater through smoking than through contaminated well water. For noncarcinogenic PAH, however, consumption of water with PAH levels found in the most highly contaminated wells could equal or exceed estimated intake from food sources. Since some noncarcinogenic PAH can act as "promoters" of carcinogenesis, while others have no effect or even act as inhibitors, the significance of increased exposure to noncarcinogenic PAH is not clear, but cannot be (Section 4) discounted.

- 4. Cancer incidence data for the Minneapolis-St. Paul metro area are available from a national survey conducted in 1969-71. Examination of these data in 1979 indicated that none of the forty-five types of cancer analyzed were elevated in men who resided in St. Louis Park at the time of diagnosis. Among women, however, elevated cancer incidence rates were found for several types of cancer, as well as for all cancers combined. The largest excess was for breast cancer (45% higher than the Metro area). The finding of elevated breast cancer in St. Louis Park in conjunction with the ability of several PAHs to induce mammary and other tumors in rodents raised both public and scientific concerns, and led to additional efforts to examine this issue. Evaluation of this issue requires recognition of the following factors:
 - a. The specific PAHs that have been shown to induce mammary tumors in rodents were either not present in contaminated wells or were detected very rarely even in the most highly contaminated wells. In general, the level of carcinogenic PAH in contaminated wells was relatively low in relation to other environmental levels (atmospheric and dietary). These other sources of exposure to PAH would have to be estimated and taken into account before attributing effects to PAH in water. (Section 4)
 - b. The many published case-control and cohort studies of breast cancer have not demonstrated clear evidence of an association between breast cancer and smoking (a substantial exposure to PAHs and other compounds occurs from smoking).
 - c. Epidemiologic studies of breast cancer have identified a number of risk factors that account for some of the observed variations in rates among different groups of women. The population in St. Louis Park differs from that in the general Metro area with respect to several of the factors that are known to influence breast cancer rates. Previous efforts by the MDH to determine the extent to which these known risk factors account for the observed excess of breast cancer in St. Louis Park are not conclusive. (Sections 4, 5)

- d. Epidemiologic evidence to date linking consumption of high-PAH foods with gastrointestinal cancer is weak. However, smoking and intense occupational exposures to PAH-containing mixtures have been strongly associated with a variety of human cancers, including lung, esophageal, kidney, bladder, and skin. (Section 4)
- e. There are many known factors (e.g., selenium, certain vitamins and other dietary constituents) that are powerful inhibitors of PAH-induced carcinogenesis (including mammary carcinogenesis) in animals. The extent to which these factors might affect PAH-induced carcinogenesis in humans is unknown. (Section 4)
- f. Although effects of mixtures of PAH compounds are generally assumed to be additive, synergistic or antagonistic effects cannot be ruled out. In experimental systems, cocarcinogenic, promotional, synergistic, additive, and antagonistic interactions have all been observed. (Section 4)
- g. Studies of radiation exposure, an established initiator of breast cancer, suggest that there is a long latency period (at least 10 years) between onset of exposure and diagnosis of disease. Latency periods for most other cancers are also typically 10-30+ years. Thus, breast (and other) cancer cases observed in St. Louis Park in 1969-71 may be related to events that occurred several decades earlier. (Sections 1, 4)

In light of these and the other findings noted above, it does not appear likely that the observed excess of breast cancers in St. Louis Park in 1969-71 could be related to water contaminants. Nevertheless, further definition of this issue would be useful to determine whether this excess was a result of normal statistical variability; whether an excess rate still exists or has increased; whether any other cancer rates have increased or decreased; and, if an excess does exist, the portion of the excess that could be accounted for by known risk factors. Some of these important unknowns could be addressed by further study or epidemiologic monitoring; however, it is very unlikely that any type of study would be capable of directly addressing the health impact from contaminated wells.

- 5. Employee data provided by Reilly Tar and Chemical Corporation showed that the vast majority (>80%) of their St. Louis Park employees between 1950 and 1972 were employed for less than five years. The average duration of employment was slightly over three years. This observation, along with the small number of workers involved (<800) over this time period, suggests that a study of Reilly workers as a more highly exposed subgroup would have little power to detect important increases in cancer rates. Furthermore, it would not address the issue of breast cancer in women. (Sections 3, 4)
- 6. There appears to be little basis for expecting health effects other than cancers to result from low level environmental exposures to PAH. (Section 4)

New Brighton

There is a considerable and growing body of information concerning the well contamination problem in New Brighton. Information includes well monitoring, hydrogeologic, water supply, and some mortality data. There is also much available information regarding the general toxicological and environmental aspects of the contaminants. The findings and conclusions below are based on this information.

 The development of a valid exposure model for epidemiologic studies in New Brighton is not currently possible. That is, it is not possible to classify individuals or residences on the basis of historical exposures to water contaminants. This conclusion is based on the following factors: (Section 4)

- a. The history of municipal well contamination prior to 1981 is not known. Installation dates for contaminated wells range from 1955 to 1971. Available information suggests that many of the likely sources of contamination are located within the Twin Cities Army Ammunition Plant (TCAAP). This facility was put into operation in the early 1940s. The six municipal wells initially found to be contaminated are in close geographic proximity to each other, and (in 1981) were all drawing water from essentially the same bedrock aquifer. These six wells provided the vast bulk of the yearly municipal water pumpage in New Brighton back to at least 1971.
- b. Additional insights into the history of contaminant migration (and the onset of well contamination) could probably be gained by further computer simulations of groundwater flow and contaminant transport using models developed for the New Brighton area by the Minnesota Pollution Control Agency. The validity of computer groundwater flow models and contaminant transport models in predicting details of historical contaminant migration is unknown.
- c. Contaminant levels were only measured at the well head, and it is not known to what extent water treatment, storage, and distribution processes would affect contaminant levels at the consumer tap at various locations within the city.
- d. Volatile organic compounds (VOCs) found in New Brighton wells are rapidly metabolized and eliminated from the body; they do not persist or accumulate in tissues. Consequently, tissue burdens cannot be used as a measure of historical exposure. (However, VOC levels in expired air or VOC metabolites in urine can be used to monitor current or very recent exposures.)
- 2. The contaminants found in New Brighton wells (TCE, TCA, among others) in 1981 are among the most commonly detected contaminants in ground water supplies in Minnesota as well as in the U.S. (Section 4)
- 3. Carcinogenic risks from exposure to environmental levels of the major contaminants in New Brighton wells (TCE, TCA) appear to be very slight. In contrast to several PAH compounds, studies to date have shown that these compounds are very limited in their ability to induce tumors in animals. Based on carcinogen bioassay data,

metabolic data, mutagenicity assays, and limited epidemiologic data, it appears unlikely that an observable increase in cancer would result from exposures to low (parts per billion) levels of these compounds in water. (Section 4)

- Overall cancer mortality for New Brighton over the five-year period 1976-1980 did not differ from expected mortality, based on Metro area or statewide rates. (Sections 4, 5)
- 5. TCE, TCA and DCE (dichloroethylene) have not produced significant teratogenic or other reproductive effects in animal studies. (Section 4)
- 6. VOCs such as TCE and TCA are widely used in many industries, and are found in a number of consumer products. They have become widespread environmental contaminants and can be found in the air, water, and in some foods. In urban areas, atmospheric as well as indoor concentrations for individual VOCs are commonly in the microgram per cubic meter range, resulting in a daily uptake that may be comparable or greatly exceed uptake from consumption of contaminated well water. Occupational exposures can be many orders of magnitude greater than general population exposures. Thus, additional significant exposures, other than drinking water, would have to be evaluated in epidemiologic studies involving these (Section 4) compounds.
- 7. Levels of VOCs in several production wells at TCAAP were much higher (10-100 fold) than in New Brighton municipal wells. This suggested the possibility that employees at TCAAP might represent a subgroup with higher exposures. General information about the

number of employees, periods of employment, etc., were solicited from the two largest contractors at TCAAP -- Honeywell Corporation and Federal Cartridge Corporation. Discussions with Honeywell representatives suggested that it would be difficult to construct an occupational cohort with sufficient definition of exposures and with sufficient person-years of experience to allow reliable Federal detection of increased mortality rates. Cartridge Corporation did not provide any information concerning their employees during the time this study was conducted. Consequently, the suitability of this employee group as a useful sentinel population could not be assessed. However, it does not appear that a study of TCAAP employees would offer useful insights into potential community health issues due to the following factors: (a) occupational studies of other worker populations exposed to these VOCs have not to date shown increased health risks; (b) the TCAAP employee population would differ from the general New Brighton population in many important respects (e.g., age and sex distribution, general health status) that would make any findings difficult to extrapolate; and (c) the size of the employee population and the period(s) of employment would probably be too small to detect even modest elevations in risk. (Sections 3, 4)

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RECOMMENDATIONS

Specific information is presented in this report concerning the feasibility of community-based epidemiologic studies in St. Louis Park and New Brighton. The finding of contaminated municipal wells in each of these communities raised public concerns over potential adverse health effects. Such studies would address the question of whether there is an excess risk of adverse health effects in these communities that could be attributed to contaminated drinking water. The following recommendations are based on an 18-month intensive review of available information regarding the contamination problem in these communities and on generally-recognized strengths and weaknesses of available epidemiologic methods.

General Recommendation

A statewide cancer surveillance system should be instituted to enable the systematic collection and analysis of cancer incidence data.

There is considerable societal concern over cancer, especially in relation to potential environmental factors. The water contamination problems and resulting public concerns in St. Louis Park and New Brighton are certainly not unique to these communities. Similar situations have occurred elsewhere in the state, and will continue to occur in the future. Public health agencies are increasingly being called upon to respond to the concerns of environmentally-related The availability of statistical data on cancer incidence disease. derived from a surveillance system, in addition to many other uses, would permit the state to respond to these issues more completely, and in a more scientifically-useful manner. A cancer efficiently, surveillance system would collect data on newly-diagnosed (incident)

cancer cases and would permit routine monitoring of the rate of cancer occurrence in the population. This information is quite different from cancer mortality and is of greater value when attempting to identify causative factors. (A feasibility study of a state cancer surveillance system was mandated by 1981 Session Laws, Chapter 340 and completed in December, 1985). Since it is not known how long wells were contaminated in these communities, or to what extent contaminants were present at the consumer tap, the monitoring of cancer incidence should continue for a sufficient period of time (many years and perhaps decades) to account for the long latency of many chronic diseases.

Recommendations - St. Louis Park

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1. Existing state-collected mortality data should be monitored for possible excesses and/or time trends that are suggestive of an existing or emerging public health problem in this community.

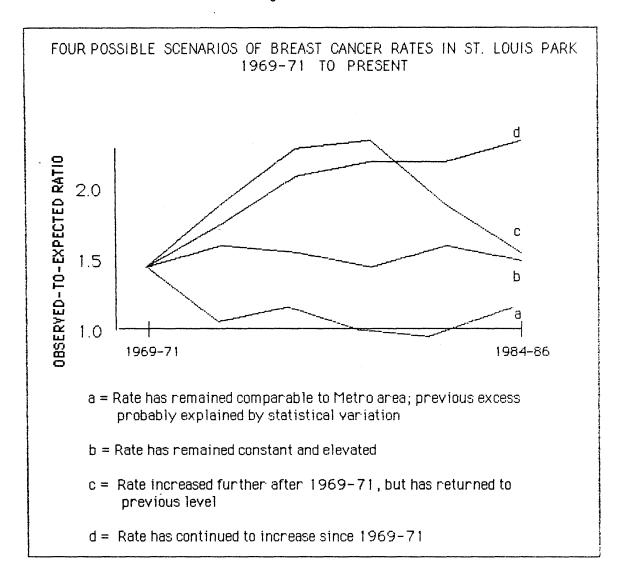
The State routinely collects mortality data and it would be relatively inexpensive to monitor these data for any excesses or trends in causes of death. Although there are limitations to mortality data, and their findings must be interpreted cautiously, they can provide useful insights into the mortality experience of a population. Analyses of mortality could identify, for example, unusual trends of disease, which would provide the focus for any future study. It should be noted that such analyses, in and of themselves, would not be able to identify the actual causes for observed patterns.

2. The need for additional epidemiologic monitoring or detailed studies will depend on the observed patterns of cancer mortality and on the implementation and findings of a statewide cancer surveillance program.

Data from the Third National Cancer Survey in 1969-71 indicated the overall cancer rate was elevated in St. Louis Park women that compared to the Metro area. The greatest excess was for breast No cancer sites were found to be elevated in men. cancer. Several interpretations of these findings are possible, including normal statistical variability and a higher prevalence of established cancer risk factors in the St. Louis Park population. It is not known if, or how, breast cancer or other cancer rates in St. Louis Park have changed since the time of the 1969-71 survey. As an example, several scenarios are possible with respect to breast cancer rates. Some of these possibilities are shown Figure E-2 below. These scenarios have different public health implications, and it is important to determine whether any changes in cancer incidence have occurred. Such information would be provided by a statewide cancer surveillance If such a statewide system is not implemented, a specific system. effort will be required to update the cancer incidence in St. Louis Park.

The need for, and the design of, additional analytic studies (case-control or cohort) will depend on trends or patterns observed from the monitoring of mortality and/or cancer incidence. This would apply to any population in which disease surveillance data were available. If, for example, breast cancer incidence in St. Louis Park has remained high or has increased, there would be substantial justification for undertaking further epidemiologic study to identify

Figure E-2



the factors associated with the increased risk. Since cases would already have been identified by cancer surveillance, a case-control study would represent the most cost-effective approach. Although it is unlikely that a case-control study could directly resolve the water contamination question (due to the lack of a valid exposure model), it could reveal the extent to which other known risk factors account for the breast cancer rate and would have considerable public health value. Due to their enormous expense, time requirement, and social invasiveness, cohort studies of the entire community should not be considered unless the following conditions are satisfied:

- a. There are unambiguous findings of a statistically significant excess of disease in the community;
- b. Further information becomes available that permits assessment of individual exposures to water contaminants. This would involve additional efforts (i) to develop or refine computer models of groundwater flow, contaminant transport, and the water distribution system, and (ii) to define the relationship between contaminant levels at the well head and at the tap; and
- c. Other significant sources of exposure to the contaminants (e.g., ambient atmosphere, foods, many workplace environments, various consumer products) can be assessed and taken into account.

Recommendation - New Brighton

Community-based epidemiologic studies in New Brighton are not justified at this time based on existing information.

In response to requests from state officials following identification of well contamination, the Minnesota Department of Health in 1983, conducted an analysis of cancer mortality in New Brighton for the five-year period 1976-1980. This study found that the number of observed cancer deaths among New Brighton residents was essentially identical to the number expected, based on Metro area or state rates. Specific types of cancer that are of conceivable interest (e.g., liver cancer) are exceedingly rare in the population

and cannot be meaningfully studied in populations of this size. The low and variable number of reproductive events (e.g., births, fetal deaths, infant deaths) in New Brighton, in addition to other technical difficulties, prohibits a meaningful examination and interpretation of adverse reproductive outcomes. Although scientific uncertainty still exists, the weight of the available evidence (toxicologic and epidemiologic) suggests that observable human risks of cancer or other adverse health outcomes are not likely to be associated with low-level environmental exposures to the major contaminants identified in New Brighton wells.

Finally, it is not currently possible to determine the magnitude or duration of actual exposure to water contaminants at the tap, or to distinguish these exposures from other major sources of individual exposure (outdoor air, indoor air, food, consumer products, and occupation).

In light of the available information and the costs, social intrusiveness, and probable yield of community-wide epidemiologic studies, such studies are not scientifically justified at this time and are not recommended. More intensive epidemiologic monitoring or special studies of mortality or cancer incidence is not required at this time. Routine monitoring of future cancer occurrence among New Brighton residents through a statewide cancer surveillance system, when available, will be sufficient.