Task Force on Cancer Clusters In New Jersey

Report to the Commissioner

New Jersey Department of Health and Senior Services

April 2004

James E. McGreevey
Governor

Clifton R. Lacy, M.D.
Commissioner

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Executive Summary

Task Force on Cancer Clusters in New Jersey

Cancer clusters have been of significant concern to New Jersey citizens. Over the past several decades, residents and workers have reported suspected cancer clusters to the New Jersey Department of Health and Senior Services (NJDHSS). In light of New Jersey Governor, James E. McGreevey's focus on cancer, the Commissioner of Health and Senior Services, Clifton R. Lacy, M.D., established the Task Force on Cancer Clusters in New Jersey (the Task Force). In January 2003, Commissioner Lacy issued Executive Order 197 (Appendix A) establishing the Task Force with charges to:

- evaluate current trends in cancer incidence and mortality;
- evaluate cancer cluster investigation policies, procedures, guidelines and best practices;
- develop a set of priority strategies to develop and implement best practices in New Jersey;
- delineate the roles and responsibilities for the State and its partners to implement the priority strategies; and
- report the findings and recommendations to the Commissioner of Health and Senior Services.

Commissioner Lacy subsequently appointed fourteen Task Force members with Dr. Eddy Bresnitz, M.D., M.S., Senior Assistant Commissioner and State Epidemiologist, as the Chairperson and, Jane Lewis, Dr.P.H., University of Medicine and Dentistry of New Jersey (UMDNJ) School of Public Health, Assistant Professor, as Vice-Chairperson. The Task Force convened in April 2003, met ten times and sponsored two conferences with presentations by national experts. One conference focused on cancer clusters and the other on risk communication issues. The Task Force reviewed and discussed

- detailed information about the New Jersey State Cancer Registry;
- cancer incidence and mortality in New Jersey and the U.S.;
- key definitions and concepts of cancer clusters;
- cancer cluster response protocols and practices in New Jersey and other jurisdictions;
- cancer cluster surveillance in New Jersey and other jurisdictions;
- risk communication relating to cancer clusters; and
- the role of the State and its partners in cancer cluster response and surveillance.

Findings

The New Jersey State Cancer Registry (NJSCR)

The NJSCR has been collecting data on cancer patients in New Jersey for over 25 years and maintains a database of over one million records. It is the largest database on cancer in the state and serves as a strong foundation for cancer cluster inquiries. The database contains high quality incidence data as well as important medical, treatment and survival data. Geocoding of this database, which is 97 percent completed, will improve its applicability to analysis of temporal and spatial clustering of cancer. Rigorous attention to national standards and quality control make the NJSCR data indispensable to cancer cluster inquiries.

However, NJSCR data are not sufficient for answering cancer concerns of citizens. While the NJSCR may be used to assess spatial and temporal patterns, estimate the magnitude of observed excesses or deficits and provide time trends, the data do not contain sufficient detail on many other aspects important to cluster investigations. For example, only the residence at time of diagnosis is recorded, while a lifetime residential history could be more informative. Occupational information is sparse and is limited to “usual” occupation and industry. Work addresses are not included. There are many known risk factors associated with the development of different cancers, yet they are not collected by the NJSCR. Furthermore, environmental exposures such as air pollution and contaminated drinking water that are often a source of concern to citizens cannot be systematically linked to individual cancer patients.

Evaluation of Current Trends in Cancer Incidence and Mortality

The Task Force reviewed tables and graphs of annual age-adjusted incidence and mortality rates and counts by gender for New Jersey and the U.S. for the years 1979-2001 (New Jersey incidence) or 1979-2000 (New Jersey mortality, U.S. incidence and mortality) for all cancers combined and eleven types of cancer - prostate, female breast, cervical, lung, colorectal, melanoma, non-Hodgkin lymphoma, bladder, oral, brain, and childhood. Tables of the incidence and mortality rates for men and women for 1979-2001 are included in Appendix C.

In general, the New Jersey annual incidence rates were higher than the U.S. annual incidence rates for all cancers combined, cervical, lung, colorectal, bladder, and childhood cancer, while the New Jersey annual incidence rates for melanoma and oral cancer were usually lower than the U.S. rates. New Jersey prostate cancer annual incidence rates generally were lower than the U.S. rates until 1992-2000 when the New Jersey annual rates were higher than the U.S. rates. New Jersey female breast cancer annual cancer incidence rates were higher than the U.S. rates through 1997, after which the New Jersey and U.S. rates were similar. New Jersey non-Hodgkin lymphoma and brain cancer annual incidence rates were lower than U.S. rates in some years and higher in other years. The New Jersey annual mortality rates were very similar to the U.S. annual mortality rates.

Cancer Clusters – Key Concepts

The Task Force studied key concepts in assessing cancer clusters including definitions of a cancer cluster, cancer cluster response and cancer cluster surveillance, types of cancer clusters, how cancer cluster response and surveillance are initiated, possible explanations for cancer clusters and the challenges of cancer cluster response and surveillance.

The Centers for Disease Control and Prevention’s (CDC’s) *Guidelines for Investigating Cluster Health Events* (Appendix D) defines a cluster as “…an unusual aggregation of health events that are grouped together in time and space.” Since the publication of the CDC guidelines in 1990, this definition has been expanded. For example, discussions of responses to cancer cluster inquiries at the 1997 annual meeting of the Council of State and Territorial Epidemiologists included the acknowledgement that the terms “cluster” or “excess” may be used to mean people’s *perception* about excess disease, as well as a *confirmed* statistically significant excess.

There are several important biological, statistical and practical reasons why cluster response and surveillance are difficult to do. Cancers tend to aggregate in space and time within populations. Clustering may be due to chance, or it may be due to the interplay of factors in the population that increases the risk of disease. These factors may be demographic (age or sex), genetic, behavioral (tobacco smoking or diet), environmental (such as occupation or pollution), or may be related to the health care system (access to screening services). Without further study, it is not possible to distinguish between cancer clustering due to chance alone and clustering that may be due to underlying demographic, genetic, behavioral, environmental or health care system factors.

Responding to Suspected Cancer Clusters

The NJDHSS has used a standard cancer cluster response protocol, the *Interim Cluster Response Protocol* (the *Protocol*), based on CDC’s *Guidelines for Investigating Cluster Health Events*, since 1997 to respond to public inquiries about potential cancer clusters. The *Protocol* outlines the procedure for responding to cancer cluster concerns by the public, including:

- handling initial responses to inquiries;
- additional activities undertaken if needed;
- the criteria for conducting an incidence analysis;
- criteria for types of further investigation activities;
- criteria for conducting an in-depth study; and
- the role of the local health department.

The *Protocol* also establishes the goals for responding to cancer clusters, stating that staff responses should be:

- timely, courteous, empathetic;
- efficient at triaging and communication;
- informational for citizens, their representatives and health care providers; and
- efficient for maintaining electronic documentation to facilitate future responses.

A central place within the NJDHSS, the Cancer Epidemiology Services (CES), has been designated to respond to cancer cluster inquiries. In addition to developing the *Protocol*, CES has developed standard operating procedures (SOPs) to ensure an appropriate response to all inquiries, an electronic tracking system, and partnerships with other programs within the NJDHSS and with external partners such as local health officers. However, the *Protocol* has not been updated since 1997, many SOPs are not written, and most New Jersey citizens are not aware of the NJDHSS’s cancer cluster response protocol.

Surveillance for Cancer Clusters

A second approach to cancer cluster inquiry is cancer cluster surveillance. Surveillance is defined as "the ongoing systematic collection, analysis and interpretation of outcome-specific data for use in the planning, implementation and evaluation of public health practice." The NJDHSS has had limited involvement in this approach, which also rarely has been used by other states or agencies. An important reason to consider performing cancer cluster surveillance is that waiting for communities to notice clustering may not be a sensitive or a timely way to find those clusters in most need of attention. Communities may never become aware of a real spatial or temporal cluster, or may be hesitant to express concerns even if they have them. Furthermore, most community concerns about cancer incidence that are reported and investigated show no actual elevation in cancer incidence in the community.

Follow-up investigations of suspected increases in local cancer incidence may lead to the identification of risk factors that may be preventable or the identification of environmental conditions that can be remediated. Systematic cancer cluster surveillance may also facilitate response to community concerns, by reducing response time and demonstrating a comprehensive evaluation of existing data.

Delineation of Partner Roles

Members of the community are instrumental in bringing cancer concerns to the attention of the NJDHSS and their local health departments. New Jersey citizens provide valuable information regarding cancer incidence in their neighborhood and workplaces. The public can provide the NJDHSS with valuable feedback and opportunities for further information sharing. The more information the public brings to the attention of NJDHSS, the better the NJDHSS can respond.

In responding to a suspected cancer cluster, CES contacts the *New Jersey Department of Environmental Protection (NJDEP)* on an "as needed" basis regarding residents' specific concerns about environmental contamination. The NJDEP provides information regarding hazardous waste sites and dumps and monitors drinking water, radiological hazards, air pollution, and soil contamination. Related to cancer cluster surveillance, the NJDEP maintains extensive databases to track facility releases to the air, water and soil, and measured levels of contaminants in these environmental media. The NJDEP also tracks the quantity of pesticides applied for various uses in the state. The NJDEP is planning to develop an integrated, spatially and temporally coded database for the development of environmental exposure metrics. Potentially, this database can be used in conjunction with cancer cluster surveillance. However, specific exposure data collected by NJDEP cannot be linked to individual cancer cases with routine surveillance approaches.

The NJDHSS and *local health departments* work together to respond to cancer cluster inquiries. When cluster inquiries are brought to the attention of Local Health Officers (LHOs), the NJDHSS and the LHOs coordinate cluster investigation and collaborate in bringing concerns to resolution. To facilitate the process of communication and response to cancer clusters, the NJDHSS has conducted training seminars. The *Interim Cluster Response Protocol* has been distributed to all local health departments along with appropriate documentation and NJDHSS contact numbers. Additionally, the departments work together to educate the community and individuals on cancer risk factors and to encourage healthier lifestyles and early detection.

New Jersey's *academic community* also plays an important role in cancer cluster inquiries. The academic community serves as a vital resource to the NJDHSS by providing expertise in a wide variety of subjects including the environment, medicine, working with communities, biostatistics, exposure modeling, epidemiology, geographic information systems (GIS), toxicology, and communications. The academic community often provides valuable input in community meetings on technical issues. They are often effective as a voice of authority that is independent of government. Their rich breadth of knowledge and willingness to become involved with cancer cluster issues has been an asset to the NJDHSS and the citizens of the State.

Often the concerns of citizens regarding cancer clusters are brought to the attention of *local, state, or federal elected officials*. These officials, in order to respond to their constituents concerns, turn to the NJDHSS for information and assistance. It is always helpful when elected officials have knowledge of the issues surrounding cancer clusters and understand the known causes of cancer and which cancers are most common in New Jersey. Developing such an understanding will help elected officials to pass citizen concerns to the NJDHSS with realistic expectations as to the analysis and results they may expect.

Recommendations:

Cancer Incidence Data – the NJSCR:

- Explore the feasibility of collecting complete residence history, especially for children.
- Maintain adequate funding for the NJSCR as a resource for cluster inquiries and analysis in addition to its other public health functions.
- Continue to fund expanded Behavioral Risk Factor Surveillance System data collection.
- Provide additional support to CES to improve GIS capabilities to further spatial and temporal analytic support of cancer registry data.

Responding to Suspected Cancer Clusters:

- Update and modify the *Interim Cluster Response Protocol* and SOPs to reflect changes in the *Protocol*, in the statistical tools available for cancer cluster response, and in the NJSCR (e.g. geocoded residential addresses). Especially consider including qualitative criteria in addition to p-values to trigger further investigation.
- Prepare a cancer cluster response procedures manual to accompany the *Protocol*.

- Offer additional training opportunities to the LHOs and other partners.

- Prepare a *Citizen's Guide to Cancer Clusters in New Jersey*.

- The NJDHSS should develop and implement a written protocol and procedures to address cancer cluster risk communication issues. The protocol and procedures would address risk communication with individuals, the media, elected officials, community representatives and at public meetings.

- Develop a mechanism for the public to request an independent review of NJDHSS response to a cancer cluster inquiry. Public entities such as the New Jersey Public Health Council or ATSDR should be considered as the agency to conduct such a review.

Surveillance for Cancer Clusters:

- NJDHSS should develop a proposal for assessing the feasibility of cancer cluster surveillance based on cancer incidence data, on an appropriate geographic and temporal scale.

- NJDEP should develop integrated, geographically based and time-specific environmental exposure metrics based on permitting, monitoring and modeling. Environmental data should be linkable to cancer surveillance data to facilitate follow-up investigations and epidemiologic research studies.

Delineation of Partner Roles:

- Designate an office within NJDEP (as in NJDHSS) to be contacted by the public about cancer and other health-related concerns.

- Develop methods to disseminate the latest research on cancer and cancer clusters to the local level.

- Foster communication and collaboration among academic institutions, public health officials, and communities regarding the development of best practices for cancer cluster response and surveillance.

Continued Role of the Task Force on Cancer Clusters:

- The Task Force has addressed the issues of the Commissioner's charge; therefore, the Task Force activities *per se* are completed. However, it will be useful to reappoint the original members or a smaller committee with some of the original members of the Task Force, to oversee the progress of the implementation of the recommendations of the Task Force. In addition, there should be an annual review of cancer cluster response outcomes.

SECTION I: Introduction

New Jersey, the nation's most densely populated state, is home to 8.5 million people of diverse backgrounds. For many years, the State has had some of the highest cancer rates in the country. Cancer affects thousands of New Jersey residents and their families each year and represents a significant burden and impact on the health-related quality of life within the Garden State. New Jersey Governor James E. McGreevey has recognized this impact and has designated a focus on cancer as one of his highest priorities.

Commissioner of Health and Senior Services, Clifton R. Lacy, M.D., initiated a Task Force on Cancer Clusters to address suspected cancer clusters, which have been of significant concern to New Jersey citizens. Over the past several decades, residents and workers have reported suspected cancer clusters to the New Jersey Department of Health and Senior Services (NJDHSS). Members of the community or workers may suspect a cancer cluster when family members, friends, neighbors or co-workers are diagnosed with cancer and they perceive that the number of cases observed is unusually large. Questions regarding the presence of environmental pollution in the neighborhood or hazardous conditions in the workplace are often asked, with citizens wanting to know if environmental pollutants are instrumental in causing the cancer.

The nature of cancer clusters remains an enigma to both the community and to scientists. Many factors make investigations of suspected cancer clusters problematic. Cancer includes over 100 different diseases, many with different causes and risk factors. It cannot be assumed that the different types of cancer in a community or workplace share a common cause, although this may be the case. The role of environmental contaminants in cancer etiology is often entangled with other risk factors and may be difficult to resolve. Furthermore, there may be many years between the initiation of cancer and its diagnosis, so the residence and/or exposures at the time of diagnosis may or may not be related to the onset of disease.

There are several important biological, statistical and practical reasons why cluster response and surveillance are difficult. Cancers, like many diseases will tend to aggregate in space and time within populations. The clustering may be due to chance, or may be due to the interplay of factors in the population that increase the risk of disease. These factors may be demographic (age or sex), genetic, behavioral (tobacco smoking or diet), or environmental (such as occupation or pollution), or may be related to the health care system (access to screening services). Without further study, it is not possible to distinguish between cancer clustering due to chance alone and clustering that may be due to underlying demographic, genetic, behavioral, environmental or health care system factors.

Responding to cancer concerns raises many complex and wide-ranging questions. What criteria determine the presence of a cancer cluster? What procedures and guidelines will best serve the citizens of New Jersey? Can the potential for a cancer cluster be predicted and prevented? It is the responsibility of the NJDHSS to provide the expertise to guide the public and local officials through public health concerns. The scope of this document is to discuss these questions and recommend a course of action to identify and address potential cancer clusters.

Chapter 1:

Creation of the Cancer Cluster Task Force – Executive Order No. 197

In January 2003, Commissioner Clifton R. Lacy, M.D., issued Executive Order 197 (Appendix A) establishing the Task Force on Cancer Clusters in New Jersey (henceforth known as the Task Force). Commissioner Lacy subsequently appointed fourteen Task Force members. The specific charges to the Task Force were to:

- Evaluate current trends in cancer incidence, morbidity and mortality.
- Evaluate cancer cluster investigation policies, procedures, guidelines and best practices used in New Jersey and other states.
- Delineate the respective roles and responsibilities for the State and each of its partners in implementing the priority strategies identified pursuant to this Executive Order.
- Develop an integrated set of priority strategies to develop and implement best practices in New Jersey to investigate potential cancer clusters.
- Report the findings and recommendations to the Commissioner of Health and Senior Services within 12 months of its organizational meeting and annually thereafter.
- Annually review the findings of cancer cluster investigations to further goals of continuous quality assessment and improvement.
- Annually evaluate the continued role and need for the Task Force.

The Commissioner appointed a Chairperson, Senior Assistant Commissioner and State Epidemiologist, Dr. Eddy Bresnitz, M.D., M.S., and a Vice-Chairperson, University of Medicine and Dentistry of New Jersey (UMDNJ) School of Public Health, Assistant Professor Jane Lewis, Dr. P.H., to direct Task Force activities. The Task Force committee members represent a wide range of health-related occupations and specialties, each bringing a unique background and expertise to the study of cancer clusters. Since April 2003, the Task Force convened on ten occasions to conduct further study and address the charges of the executive order. In addition, the Task Force sponsored two conferences; one that examined best practices in the study of cancer clusters and the other concerning risk communication issues.

Chapter 2:

Background

• Cancer Epidemiology Services (NJDHSS)

Cancer Epidemiology Services (CES) has been the source of cancer data for New Jersey for over 25 years. Housed within the Center for Cancer Initiatives, CES is comprised of the New Jersey State Cancer Registry (NJSCR) and the Cancer Surveillance Program. The NJSCR collects, edits, and compiles data on newly diagnosed cancer cases in New Jersey. The Cancer Surveillance Program has over 25 years of experience in conducting epidemiologic research and analyzing data from the NJSCR for cancer control purposes and cancer cluster response.

Cancer prevention and control have long been goals of the New Jersey Department of Health and Senior Services (NJDHSS). Publication in the 1970’s of cancer mortality maps by the National Cancer Institute (NCI) (Mason 1975) showing New Jersey's very high cancer mortality was a catalyst for legislative interest and program development in public health, and among private and voluntary organizations throughout the state. The statute establishing the NJSCR in 1977 was a milestone in the development of cancer surveillance and control as a critical mission of the NJDHSS. In subsequent years, the NJDHSS has been involved in projects that have continued to expand on the cancer surveillance foundation including research, primary prevention, screening, and cancer cluster response.

The establishment of the NJSCR made cancer a reportable disease. The NJSCR was designated as the authorized agent to collect cancer incidence data for the population. The initial legislation mandated reporting of all newly-diagnosed cancer cases by hospitals, physicians, and laboratories, reporting of cancer diagnoses within six months of diagnosis or three months of discharge whichever is sooner, and permitted access to medical records for case finding and cancer research purposes. The legislation was strengthened in 1996, and again in 2001, to assign penalties for non-reporting of cancer cases, and to require that data be abstracted at health care facilities by certified tumor registrars. A copy of the NJSCR statute and regulations appears in Appendix B.

From 1983 to 1988, the NJSCR received funds from the NCI to collect data for its Surveillance Epidemiology and End Results (SEER) Program. Since 1994, the NJSCR has received funding from the Centers for Disease Control and Prevention (CDC) to participate in its multi-state National Program of Cancer Registries (NPCR). The NCI SEER funding was reinstated in 2001. SEER has been considered the “Gold Standard” for cancer incidence data collection for 30 years. The NJSCR maintains data on over one million case records representing 25 years of continuous data collection and analysis. Analyses of New Jersey cancer incidence and mortality have been published by the NJDHSS in descriptive reports, some tailored to specific topics such as breast, colorectal, childhood cancer and prostate cancer and in scientific journals, by both NJDHSS staff and external researchers.

The NJDHSS has had a strong commitment to cancer epidemiologic research over the past 25 years. Cancer research studies, including etiologic research, studies of outcomes of treatment regimens, and access to care studies have been conducted since the 1970's. During the late 1970's and 1980's, the NJDHSS was under contract with the NCI to collaborate on a number of nationwide case-control studies of cancer. Since that time, the Cancer Surveillance Program has participated in dozens of collaborative research studies utilizing cancer registry data as the foundation. In the past 25 years, over 100 reports and scientific publications have been produced by NJDHSS researchers, often in collaboration with researchers from other agencies and organizations. Expanded state funding since 1996 has permitted the establishment of a Cancer Surveillance Program, staffed by epidemiologists and a statistician to monitor cancer incidence trends, disseminate data, and respond to citizens' concerns about cancer. The Cancer Surveillance Program staff has been instrumental in the publication of various NJSCR reports within the past several years. The Cancer Surveillance Program is also implementing a geographic information system (GIS) with the capability for mapping cancer data for cancer control and research purposes.

• Cancer Incidence Data: The New Jersey State Cancer Registry

Data Reported to the NJSCR

The NJSCR collects data on all newly diagnosed cancer cases. The data include the following types of information: personal identifiers (age, date of birth, address at diagnosis, gender, race, ethnicity), and medical information (type of cancer including primary site and morphology, laterality, extent of disease at diagnosis, first course of cancer treatment, stage at diagnosis, behavior, grade, date of last contact or death, cause of death). All data are edited and checked for accuracy. Data on any subsequent cancers are linked to the patient to guarantee epidemiologic integrity. All identifying information on individual cases must be kept strictly confidential.

Data Collection

The NJSCR began as an incidence-only registry in 1978. With the advent of SEER funding (1983), the NJSCR adapted the database to be SEER compatible from 1979 forward. Expansion to a SEER compatible database added information on first-course of cancer-directed therapy, more detailed stage at diagnosis data and annual vital status information. The data collected between 1989 and 1994, however, does not contain first-course of treatment or SEER extent of disease (EOD). With the initiation of CDC funding, first-course of treatment was added back into the variable requirements. The NJSCR has continued to collect summary stage of disease and vital status from the earliest years and meets all NPCR and North American Association of Central Cancer Registries (NAACCR) requirements.

The majority of the annual 80,000 cancer case reports to the NJSCR are reported by hospitals throughout the state. As required by law, all health care facilities must report cancer cases within three months of discharge or six months of diagnosis, whichever is sooner, or face a penalty for non-reporting. A Certified Tumor Registrar (CTR) must complete cancer abstracting. This is a statutory requirement aimed at guaranteeing data quality standards. Timely case reporting has improved greatly since the mid-1990’s. New Jersey now publishes data well within national standards. It is usually one of the first states to have data available for use. For example, 2001 data were posted to NJDHSS website in August 2003, well in advance of NCI and CDC data releases for the same time period. Hospitals are required to report all cases of cancer, regardless of in-patient or outpatient status. The facilities also report autopsy-only cases, consults and cases with a history of cancer. Cancer patients seen in multiple health care settings are reported multiple times to assure complete case ascertainment, and patient records are consolidated to ensure epidemiologic integrity of the data. Of the approximately 80,000 annual case reports, 47,000 new tumor records are used in annual reports.

All New Jersey hospitals report to the NJSCR on a monthly basis via modem to a closed bulletin board system. Fifty-two of these facilities are American College of Surgeon (ACoS) approved hospitals which account for about two thirds of cancer reports. ACoS approved facilities tend to be larger hospitals and have a wide variety of cancer related services including active patient follow up and compliance with stringent standards set by the ACoSs. Of the remaining facilities, 42 are non-ACoS approved hospitals and four are military hospitals.

The proximity of New Jersey to prestigious cancer centers in major metropolitan areas in neighboring states enables many New Jersey residents to seek diagnosis and treatment outside of the State. Over 9,000 case reports are received annually from out of state sources through reciprocal reporting agreements with other states including New York, Pennsylvania, and Delaware as well as Florida, Maryland, and North Carolina. These cases represent about 5-10 percent of the 80,000 cancer reports. These reports are often second reports of an existing cancer and must be carefully evaluated to ensure that duplicate cases are not created. Data from other states are often sparse, and follow-back queries are problematic. In the late 1990's the NJSCR conducted a special study to evaluate reciprocal reporting between New Jersey and New York. This study identified cases in each state that had not been reported to the state of residence. Results indicated that of the two states, New York’s percentage of reciprocal reporting was lower than New Jersey’s. Since that time, New York case reporting has improved and now about 4,500 cases among New Jersey residents are reported from New York facilities each year.

Reporting from non-hospital facilities accounts for a small but growing percentage of annual cancer cases. Ten independent pathology laboratories report the majority of non-hospitalized cases. Other non-hospital sources of reporting include surgery centers and freestanding radiation treatment centers. The NJSCR also receives reports from nursing homes, psychiatric facilities and rehabilitation facilities. Physicians and dentists are also required to report non-hospitalized cancer cases. The NJSCR has begun to accept electronic pathology reports from independent laboratories, and is currently expanding the program to hospitals to assist rapid case ascertainment.

Other non-traditional sources of case reports for the NJSCR include other data bases located within the NJDHSS. Matching of the NJSCR database with the Department’s AIDS registry and the New Jersey Cancer Education and Early Detection Program (NJCEED) have resulted in the identification of cases. (These matching initiatives occur on an annual basis as resources permit.)

Completeness of cancer data from these data sources is excellent. SEER or NAACCR methods produce completeness estimates of 100 percent. Only about 1.5 percent of case reports annually are cases for which we have information only from the death certificate.

Case-finding Activities

Data collection activities are supplemented when necessary by specific case-finding activities. Case-finding audits to ensure completeness of reporting are conducted in hospitals reporting less than 90 percent of their expected number of cases for a diagnosis year. The NJSCR has maintained data for 25 years on hospital-specific case finding. Staff is frequently in contact (at least monthly) with hospital tumor registrars to monitor case reporting and discuss administrative changes (such as the opening of radiation facilities, departure of key oncologists) that may affect hospital reporting. When case reports fall below what is expected, specially trained auditors conduct an on-site audit and review 100 percent of the pathology reports, cytology reports, bone marrow reports, and autopsy reports. This is in addition to reviewing radiation therapy logs and outpatient clinic records for the entire diagnosis year. Secondly, an electronic copy of the disease index containing all cancer cases is also requested of the facility that is being audited. The electronic audit matches cases against those already in the master database. Upon completion of the on site and electronic audit processes, a list of unreported cases is generated and sent to the hospital. Hospitals are then required to report all outstanding cases within thirty days. Hospitals have the option of contracting with the NJSCR on a cost reimbursement basis to help them submit these cases in a timely manner.

Abstracting and Electronic Data Submission

Abstracting, coding and data entry for the NJSCR are conducted at the hospital level by CTRs directly from source records and reported electronically. In 1996, New Jersey was the first state to require that all hospital abstracting be completed by a CTR. This provision ensures a high level of competency in data abstraction at the hospital level. CTRs must have specific training in areas of cancer abstracting, coding, case finding, and registry operations and supplement this training with on the job training under the tutelage of a CTR specializing in tumor registration education. In order to facilitate adequate training of hospital personnel, the NJSCR has collaborated with the Oncology Registrar’s Association of New Jersey (ORANJ) to establish a premier training program. This program, entitled *Basic Education,* provides monthly opportunities for NJDHSS staff to interact with hospital registrars, discuss difficult abstracting and coding issues, and improve the quality of data submitted to the NJSCR. Experienced hospital registrars also attend *Basic Education* to review and improve their skills. This program has been instrumental in improving the data abstracting skills and the consistency of abstracting at the hospital and the central registry. It has also produced many additional CTRs. There are currently over 100 certified tumor registrars working in New Jersey.

As part of on-going quality-control activities, hospital abstracting is reviewed by NJDHSS staff when cases are received at the central registry. After passing through computerized edits, cases are visually edited for consistency, and supporting text is reviewed to determine if it justifies the recorded codes. Inconsistencies and discrepancies are followed up with the reporting hospital registrar for resolution or correction. Additionally, NJDHSS conducts annual re-abstracting studies on a sample of New Jersey health care facilities to verify and audit the accuracy of submitted data. These audits serve as a measure of data accuracy and a tool to discuss abstracting technicalities with hospital tumor registrars.

Case Processing and Editing at the NJSCR

The NJSCR maintains a well-integrated system to ensure the timely flow of data from the time it arrives at the central office to incorporation into our master file for analysis and reporting. Data are received in monthly submissions from the hospitals via a secure bulletin board system (BBS), are uploaded to one subdirectory on the network and then automatically scanned for viruses. Submitting facilities are blocked via network rights, as well as the BBS software, from examining any data submitted by another facility. The BBS is also set to disallow upload of duplicate file names so that NAACCR files once received, cannot be overwritten. The NJSCR uses a case management and data processing system by Rocky Mountain Cancer Data Systems (RMCDS). RMCDS is a benchmark system and supports many other state cancer registries across the country.

Senior NJSCR staff examines the holding subdirectory in order to log each batch of records to a tracking database, where any problems are noted. Each new file is examined for: 1) invalid file sizes, record lengths or line counts; 2) corruption of data; 3) acceptable NAACCR format and version; and 4) adherence to NJSCR file naming conventions.

Approximately 6,700 records are submitted each month. A batch process scans the subdirectories for new records and processes them into a RMCDS holding area. At the end of the submission, several quality control and data characterization reports are run on the data to determine whether the batch is acceptable. A standardized edit report summarizes errors by type. This process identifies problem cases, cases requiring consolidation of data to existing patients, and possible duplicate cases. If necessary, quality-control staff resolves any problems by contacting the reporting source.

Cases are then merged and uploaded to the main system via a second batch process into the main RMCDS database. Quality-control and data characterization reports are then rerun on these newly added records which now have their permanent accession number assigned in the master database. The report is printed for quality-control staff to review. All matches to existing records are identified for review rather than automatically merged with another record. This process safeguards the database from false merging of data to the wrong patient. All matches found are reviewed by experienced registry staff, who decides whether a possible match is a new case or belongs to a previously reported individual. At this time, staff also reviews the case thoroughly for consistency and accuracy. Staff may contact the reporting source to obtain additional or clarifying information at this time. At this point, approximately one third of all submitted records are reviewed to ensure accurate and complete data.

Newly added records are subjected to a social security number match against the rest of the master file. Matching cases for de-duplication and research purposes utilize both deterministic and probabilistic matching routines. Deterministic matches are included in RMCDS and in programs written by NJSCR staff. These programs are supplemented by utilization of proprietary software that uses probabilistic matching and is essential for determining within-file duplicates. A merge report, run after each batch, reduces the amount of staff time needed to de-duplicate the full file. The raw data files that were imported into RMCDS holding area are compressed and archived for any future investigations and quality assurance.

Assessing Patient Survival

Since 1979, the NJSCR has collected data to assess patient survival. The extent of these efforts has varied over time in response to budget constraints. In some years, only matching the NJSCR with New Jersey vital records was affordable. In more recent years, efforts have expanded to be much more comprehensive. Many of these methods have been applied to the entire data set. The NJSCR is currently using the data collected to analyze New Jersey cancer survival data and to assess the validity for publication.

The NJSCR utilizes a variety of data sources to maintain patient follow-up status. Vital status is obtained through matching with a variety of sources including state and national death files, state taxation files, and motor vehicle registration records. Additionally, hospitals are required to submit annual vital status updates.

The NJSCR performs quarterly record linkages between the master file and the state death file with over 70,000 annual deaths. Definite matches automatically update the following death information on the cancer registry record: date of death, death certificate number, patient status (alive/dead), cause of death, and state of death. Possible matches to death certificate file require manual review to determine if the cancer registry record should be updated with the death information.

A process termed “follow-back” is performed to reduce the percentage of cases reported only by death certificate (death certificate only cases or DCO). A report of all death certificates with a cancer cause of death not matched to an existing cancer registry record is printed. NJSCR staff retrieves copies of these death certificates and contacts tumor registrars for additional information at the hospitals listed on the death certificates. Other reporting sources such as nursing homes and physicians are also contacted for missing information. Any additional information reported back to the NJSCR is recorded and updated on the cancer registry record and the reporting source is changed from death certificate only report to the appropriate source. These intensive procedures are essential to maintain a death certificate only rate of less than 2 percent, below the SEER quality control standard of 3 percent.

The National Death Index (NDI) at the National Center for Health Statistics is also used to gather death information for cancer registry cases. The NJSCR first applied to use the NDI's services in 1985 to search for death information for registry cases who may have died out of state or been missed in New Jersey death match runs. Annual NDI repeat searches are performed in an effort to improve upon our follow-up rate.

State taxation returns are also used as a source of passive follow-up. In New Jersey, an annual linkage is performed between the registry’s master file and the State of New Jersey Division of Taxation. Records are matched based upon the social security number and the first four letters from the last name. The matched cases are updated on our master file as alive on the filing date. Records are not updated if the vital status of the registry case is deceased or if there is a more recent date of last follow-up on our master file.

The New Jersey Division of Motor Vehicles is used to access driver's license renewal records as a source of follow-up information and linked on a quarterly basis. The Centers for Medicare and Medicaid Services (CMS) files have also been annually used as a source of follow-up for cases aged 65 and over.

NJSCR Geocoding Process

All available resident street addresses of the patient at the time of cancer diagnosis are geocoded for future spatial analysis using a process implemented by the New Jersey Office of Information Technology (OIT). The data, consisting of the complete street address, are abstracted from the NJSCR master patient database. The data are cleansed and standardized by the geocoding system and then matched against a street level reference file. Street addresses that successfully match the reference file are returned with the following geocoded information:

- latitude and longitude coordinates
- U.S. 2000 census tract and block group numbers
- standardized street, city, ZIP code, state, and county

Records that fail to geocode are placed in a suspense file for further processing, including manual review.

The processing decision tree for geocoding the data is as follows:

- Match the complete standardized address with the street reference file to obtain the X-Y latitude and longitude coordinates.
- If unsuccessful, or if a PO Box or Rural Route is the only address, use the ZIP code (ZIP +4, ZIP +2, etc.) to geolocate the centroid of the ZIP code boundaries.
- If unsuccessful, place the record in a suspense file for later review.

All geocoded addresses are assigned a census tract certainty code that reflects the accuracy of the geocoded census tract value. Additional details about the geocoding of the NJSCR data may be found in Chapter 6: Surveillance for Cancer Clusters.

Quality Assurance

New Jersey has submitted 1995-2000 data to the NAACCR Certification Committee for evaluation. Each year New Jersey has received Gold Certification status, an accomplishment shared by only a handful of registries across the country. Data must meet stringent quality standards for the NAACCR gold medal. According to these standards, data must be at least 95 percent complete 23 months after the close of the diagnosis year; 100 percent of data must pass NAACCR edits; less than 3 percent of cases may be reported by death certificate only; the duplicate case rate must be less than 1 per 1,000; and less than 2 percent of cases may have unknown data on age, sex, and county of residence, while less than 3 percent may have unknown race information.

The NJSCR employs a program known as the *NJSCR Data Quality Assurance Program* to ensure results of this caliber. This program is a continuous multi-faceted program of checks and balances. Fundamental to the program is staffing by highly skilled CTRs with years of quality-control experience. Staff members employ methods using consistent application of computerized edits, systematic review of problem cases, reabstracting and recoding studies centered in hospitals, feedback and training programs for hospital staff, documentation of policies and procedures, and case finding audits. Standard computer edits, visual editing, and de-duplication processes as discussed are utilized as well as additional quality assurance discussed below.

Computerized programs are utilized to identify cases for review with multiple primaries to ensure the proper application of complex rules related to such cases. All cancers related to a single patient are linked to the patient and contain complete information about each primary. These cases are often used in special studies including those examining causes of multiple primaries such as risk from previous treatment. Edits are also run to verify gender and to verify Hispanic ethnicity on a quarterly basis throughout the year.

Re-abstracting and re-coding studies are conducted annually in hospitals. The purpose of such studies is to verify that the abstracted information was properly coded and the data submitted to the NJSCR represent the most accurate and complete information available in the reporting facility. During re-abstracting studies, NJDHSS and/or SEER staffs review medical charts in healthcare facilities and re-abstract cases while blinded to the data submitted by the facility. Answers are compared and discrepancies noted. The results of these studies have been used to build training programs presented at both State training workshops and the ORANJ annual meeting. Training programs have been developed to improve submission of text information, improve feedback to hospital tumor registrars, and to educate hospital tumor registrars on issues facing population-based registries.

The NJSCR has a strong commitment to providing excellent training opportunities to both central registry and hospital tumor registrars in an effort to improve data quality and increase the number of CTRs in New Jersey. Central Registry staff is provided with numerous in-house educational opportunities throughout the year. Through these seminars, an average of 25 continuing education credits are granted by the National Cancer Registrars Association (NCRA) and made available to NJSCR staff and hospital registrars. Topics are selected based on suggestions from staff or recommendations from the staff in the Quality Assurance Unit specifically targeting cancer types that are difficult to code or noted problem areas. The NJSCR also sponsors a three-day pre-certification workshop each year to prepare tumor registrars for the certification examination. This program has been designed to assist individuals planning to take the certification examination, and is intended to provide an overview of the skills and knowledge necessary to complete the examination successfully. In addition to these activities, the NJSCR annually hosts training workshops for hospital and central registry tumor registrars. Various topics have been addressed in these programs.

Staff from the NJSCR has played a key role in the development and implementation of educational workshops sponsored by NAACCR and ORANJ. Staff members have also served as chairpersons and committee members of both organizations.

External Assessments of Data Quality

Each year the NJSCR is subject to a least four formal external assessments. Data are submitted annually to NAACCR for registry certification and publication in *Cancer in North America*. Each year the certification has been offered, New Jersey has obtained the Gold level, an accomplishment achieved by only a few registries nationwide. Data are also submitted to the NPCR for publication in the *United States Cancer Statistics,* and formal quality assurance tests are run. Data are submitted one or two times a year to the NCI SEER Program as a contract deliverable for a number of applications at the NCI including *Cancer Statistics Review,* posting on the website Cancer Planet, use in NCI research studies, and data linkage projects. Additionally, the SEER Program annually audits the NJSCR data through on-site quality control audits. SEER sends auditors to New Jersey health care facilities to conduct extensive case-finding audits in these facilities and compares the data to the NJSCR case listing. While at the facility, SEER reabstracts a sample of cases from hospital charts and compares the data to that in the NJSCR. When necessary, the NJSCR has convened an external advisory panel to assess specific issues. For example, a panel was convened to review the NJSCR reportable list. Since joining SEER, the NJSCR has participated in an annual reliability study sponsored by the NCI. A standard set of cancer case records are given to participants across all SEER registries. All staff involved in data collection and processing abstract and code the cases. Results are compared across registries. New Jersey fares very well in these studies and has received an award for excellence in this area.

Special Studies and Rapid Case Ascertainment

The NJSCR participates in a variety of special studies to assess the causes and burden of cancer in New Jersey. These studies range from international collaborative case control studies, to cohort studies of various occupational exposures, to patterns of care and survivorship. Some of these studies involve record review and others require patient contact for interviews and sometimes the collection of biological specimens (blood, buccal swabs). Rapid case ascertainment is necessary in some studies when patient contact is essential soon after diagnosis. In these studies, NJSCR personnel conduct case finding audits at selected facilities at pre-determined intervals to maximize the probability of identifying the study participants in the interval required for the study protocol. The Cancer Surveillance Program and the NJSCR then process these cases.

Rapid case ascertainment was first used in 1978 when the NJSCR participated in the National Bladder Cancer Study. At that time, pathologists were asked to phone in new bladder cancers within 24 hours of diagnosis. After that initial study, CES staff has audited health care facilities on a frequent (often monthly) basis to identify specific types of cancer included in special studies. CES has used this method for a wide variety of case control studies including cancer of the lung, liver, breast, endometrium, multiple myeloma, esophagus, and many others. This methodology is currently employed in an Agency for Toxic Substances and Disease Registry (ATSDR) funded study of mesothelioma.

• Summary - Chapter 2: Background

The NJSCR has been collecting data on cancer patients in New Jersey for over 25 years and maintains a database of over one million records. It is the largest database on cancer in the state and serves as a strong foundation for cancer cluster inquiries. The database contains high quality incidence data as well as medical, treatment and survival data. Geocoding of this database, which is 97 percent completed, will improve its applicability to analysis of temporal and spatial clustering of cancer. Rigorous attention to national standards and quality control make the NJSCR data indispensable to cancer cluster inquiries.

NJSCR data are not sufficient for answering cancer concerns of citizens. While the NJSCR may be used to assess spatial and temporal patterns, estimate the magnitude of observed excesses or deficits and provide time trends, the data do not contain sufficient detail on many other aspects important to cluster investigations. For example, only the residence at time of diagnosis is recorded, while a lifetime residential history could be more informative. Occupational information is sparse and is limited to “usual” occupation and industry and does not include a work address. There are many known risk factors associated with the development of different cancers, yet they are not collected by the NJSCR. Furthermore, environmental exposures such as air pollution and contaminated drinking water that are often a source of concern to citizens cannot be systematically linked to individual cancer patients.

Strengths:

- The NJSCR provides a solid foundation for cancer cluster inquiries by producing complete, accurate and timely data. NAACCR, the NCI and the CDC have recognized the quality of NJSCR data.

- The NJSCR complies with all standards set by national cancer data standard setters, making the data appropriate for comparison on state, local, national and international levels.

- Cancer surveillance data may be used for a wide variety of applications including public health planning and evaluation, research into causes of cancer, patterns of care, and quality of life.

- The NJSCR is the most comprehensive population-based dataset on cancer in New Jersey, with over one million records and 25 years of data.

Weaknesses:

- Registry data are reported with a minimum of a 6-month delay, to allow for collection of complete first course of treatment data and staging data. When a community is concerned about clusters, they are often concerned about cancers that have occurred in the last 6 months, which have not yet been reported to the registry.

- Changes in national standards often create substantial delays in reporting cancers from hospitals, and from the central registry. These changes require massive programming changes by numerous software vendors, even when national groups develop the logic.

- Data on cancer cases that are diagnosed and/or treated out of state are reported first to the other state’s central registry and then to New Jersey via reciprocal reporting. This further delays the reporting of these cancers and New Jersey law does not apply.

- Geocoding of residence data in New Jersey has proven expensive, time-consuming, and difficult.

- Occupation and residence history data are not included in the NJSCR database. For cluster analyses, residence at diagnosis may not be sufficient, given the latency of many cancers.

- NJSCR data do not contain many variables of interest for cluster investigation such as common risk factors and individual environmental exposure data.

Recommendations:

- Explore the feasibility of collecting complete residence history, especially for children.

- Maintain adequate funding for the NJSCR as a resource for cluster inquiries and analysis in addition to its other public health functions.

- Continue to fund expanded Behavioral Risk Factor Surveillance System data collection.

- Provide additional support to CES to improve GIS capabilities to further spatial and temporal analytic support of cancer registry data.

SECTION II: Task Force Activities

Chapter 3:

Evaluation of Current Trends in Cancer Incidence and Mortality

• Description of Current Trends

At the Task Force meeting on October 14, 2003, the Cancer Epidemiology Services staff presented "Trends in Cancer Incidence and Mortality," using data from the New Jersey State Cancer Registry (NJSCR) and the National Cancer Institute (NCI). The presentation included tables and graphs of annual incidence and mortality age-adjusted rates and counts by gender for New Jersey and the U.S. for the years 1979-2001 (New Jersey incidence) or 1979-2000 (New Jersey mortality, U.S. incidence and mortality) for all cancers combined and eleven types of cancer - prostate, female breast, cervical, lung, colorectal, melanoma, non-Hodgkin lymphoma, bladder, oral, brain, and childhood. Tables of the incidence and mortality rates for men and women for 1979-2001 are included in the following pages and in Appendix C.

Between 1979 and 2001, the New Jersey incidence rates increased for all cancers combined (with a small peak in 1992 for men), prostate cancer (with a large peak in 1992), female breast cancer, female lung cancer, melanoma, and non-Hodgkin lymphoma. The 1992 peak in prostate cancer incidence reflects the beginning of wide use of prostate-specific antigen (PSA) blood testing. The incidence rates for cervical, male lung, colorectal, and oral cancer decreased in the same time period. The bladder, brain, and childhood cancer annual incidence rates remained relatively stable from 1979-2001.

Between 1979 and 2000, New Jersey mortality rates of all cancers combined declined among men and remained stable among women. Female breast, cervical, male lung, colorectal, female melanoma, male bladder, oral, male brain, and childhood cancer mortality rates declined from 1979-2000. Prostate cancer, male melanoma, female bladder cancer, and female brain cancer mortality rates remained stable, while female lung cancer and non-Hodgkin lymphoma mortality rates increased.

In general, the New Jersey annual incidence rates were higher than the U.S. annual incidence rates for all cancers combined, cervical, lung, colorectal, bladder, and childhood cancer, while the New Jersey annual incidence rates for melanoma and oral cancer were usually lower than the U.S. rates. New Jersey prostate cancer annual incidence rates generally were lower than the U.S. rates until 1992-2000 when the New Jersey annual rates were higher than the U.S. rates. New Jersey female breast cancer annual incidence rates were higher than the U.S. rates through 1997, after which the New Jersey and U.S. rates were similar. New Jersey non-Hodgkin lymphoma and brain cancer annual incidence rates were lower than U.S. rates in some years and higher in other years. The New Jersey annual mortality rates were very similar to the U.S. annual mortality rates.

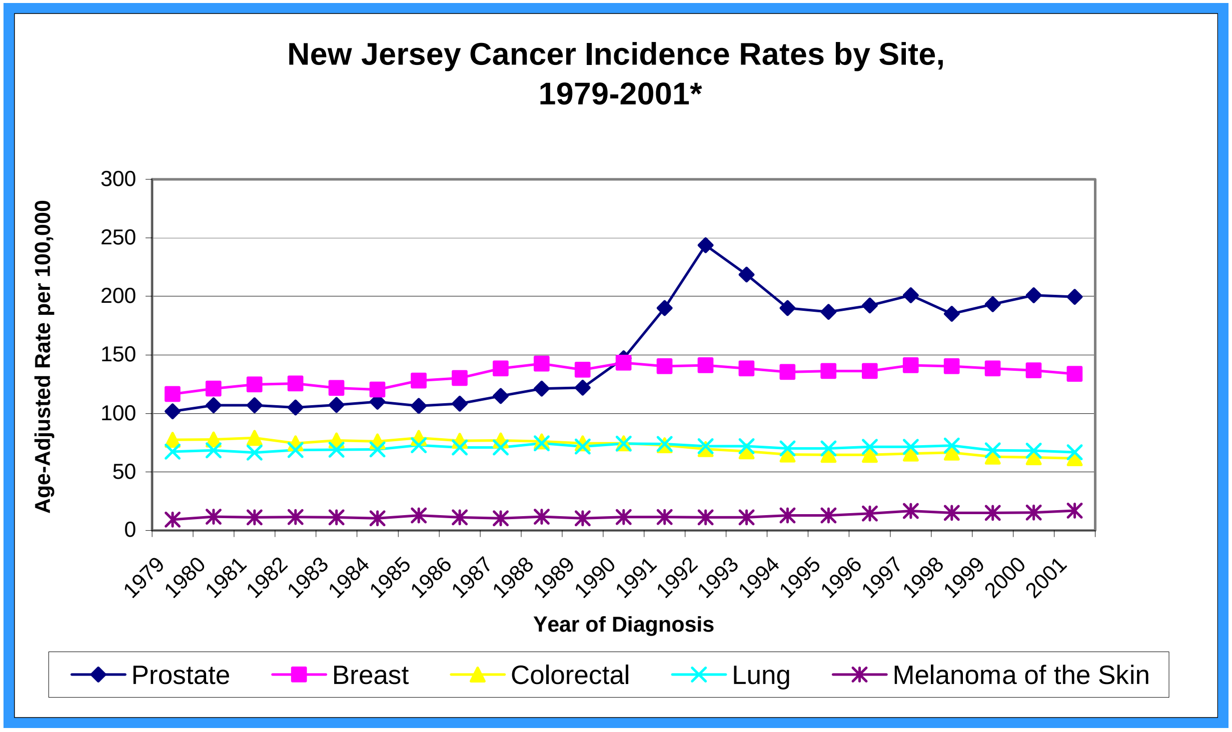
Additional compiled statewide data are contained in the annual reports, available in hardcopy or on the New Jersey Department of Health and Senior Services (NJDHSS) website, beginning with the 1992-1995 report and ending with the 1997-2001 annual report. The NJDHSS website also includes two sets of tables with state-level data for the years 1979-1996 for 60 cancer sites by gender: 1) annual age-adjusted incidence rates and counts and 2) annual age-specific incidence rates and counts. Special reports with more detailed data and information on specific cancer types (breast, prostate, colorectal) or in specific populations (counties, children, Hispanic, older adults) of interest are available in hardcopy and on the NJDHSS website. Cancer Epidemiology Services (CES) staff provides compiled data upon request and a database is available for researchers' use. CES staff is participating on a Centers for Disease Control and Prevention (CDC) committee to set federal guidelines for the release of data.

The CES is finalizing an agreement to prepare maps and tables of NJSCR incidence data to be accessible through the cancer area of the NJDHSS's website (http://www.state.nj.us/health/cancer). Maps will be drawn at the county level using four mapping colors to display the range of age-adjusted rates by year. Data tables will show the population denominator, total case count, crude incidence rates, and age-adjusted incidence rates by county and the entire state, gender, race, and year for all the major and minor types of cancer.

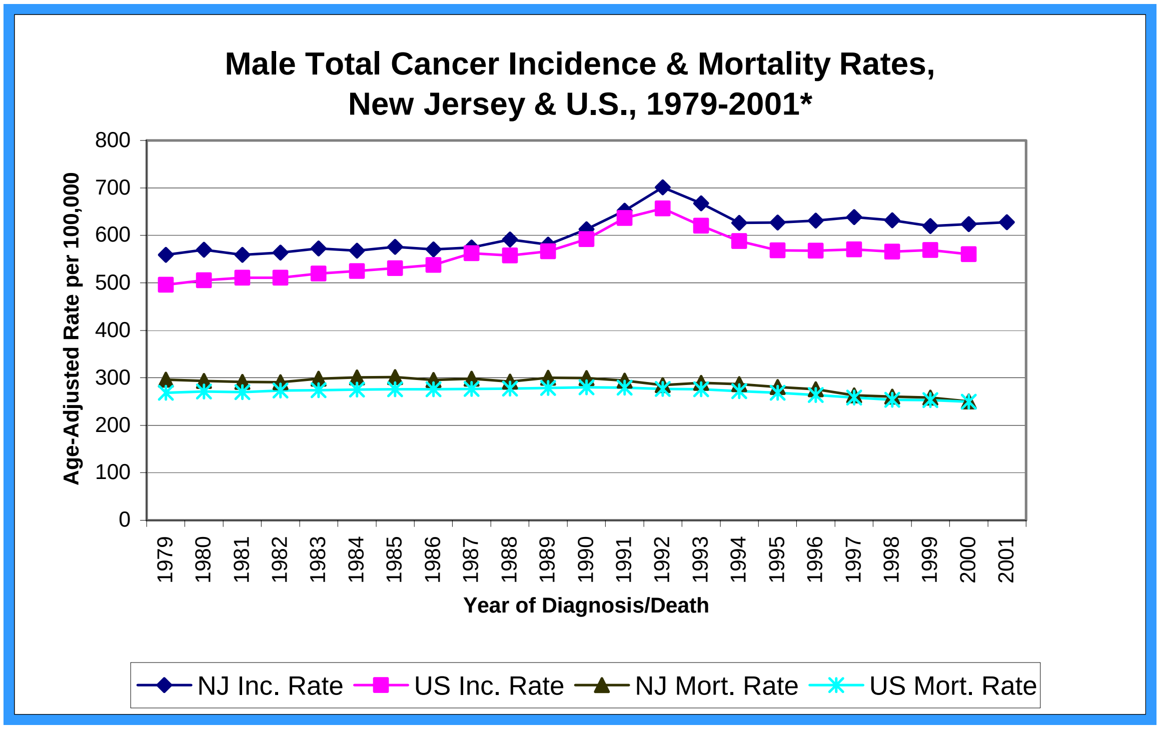
In addition, several federal agencies including the NCI, CDC and American Cancer Society (ACS) have developed a "portal" website called Cancer Control PLANET (http://cancercontrolplanet.cancer.gov). Cancer incidence data from the NJSCR are included at the state and county levels for eight major cancers. Cancer mortality data for New Jersey are also included for the state and each county.

Some members of the Task Force asked for municipal level data, which was not possible to produce due to the current incompleteness of diagnosis address geocoding and lack of staff resources. Also, time trends would not be meaningful for smaller municipalities due to small numbers.

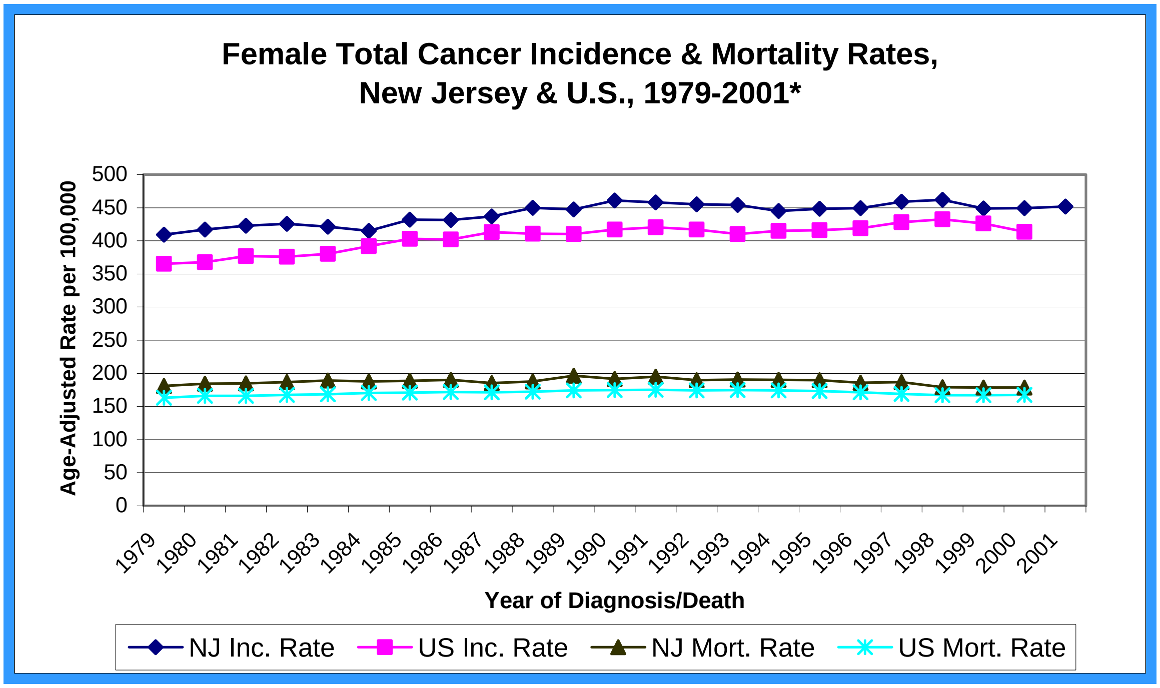
*2001 data are preliminary



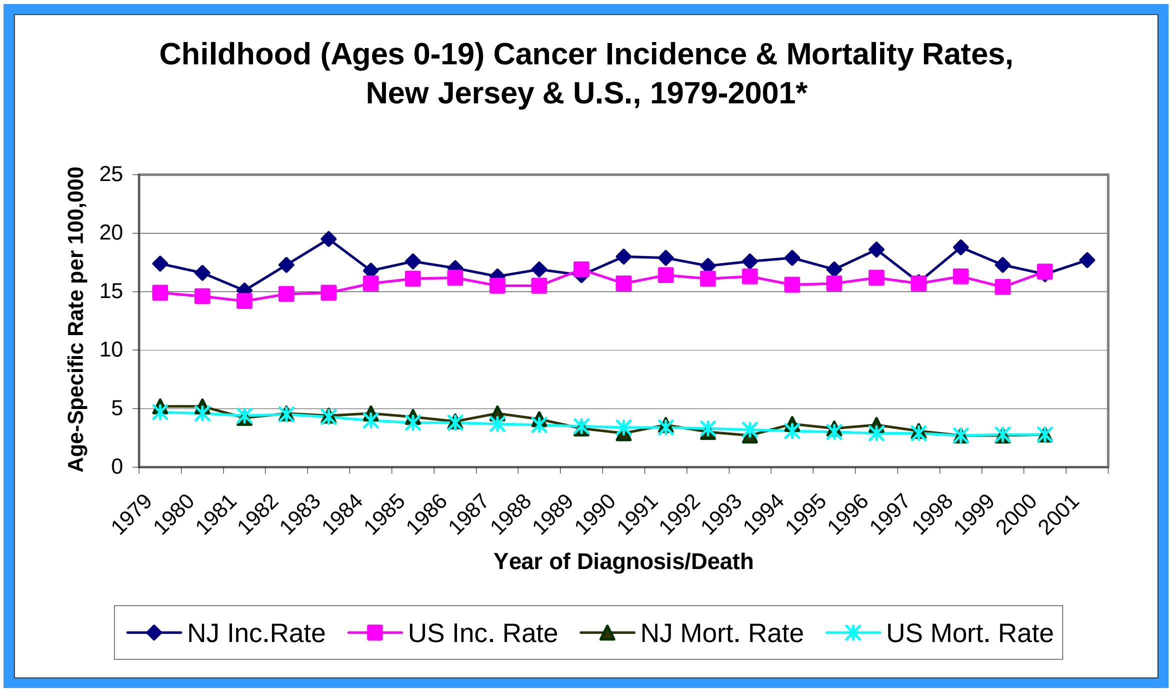
New Jersey Cancer Incidence Rates by Site, 1979-2001*



*2001 data are preliminary



*2001 data are preliminary



*2001 data are preliminary

Chapter 4:

Cancer Clusters: Key Concepts

• Approaches to Cancer Clusters

There are two general approaches to addressing cancer clusters - cancer cluster response and cancer cluster surveillance. Currently, the New Jersey Department of Health and Senior Services (NJDHSS) is involved with cancer cluster response, which is described in Chapter 5. The Department has had only limited involvement with the second approach, cancer cluster surveillance, which is described in Chapter 6. Cancer cluster surveillance rarely has been conducted by states or other agencies for a variety of reasons that are discussed in detail in this chapter and Chapter 6. The following key concepts are generally relevant to both approaches.

• Definition of a Cancer Cluster

The Centers for Disease Control and Prevention's (CDC's) *Guidelines for Investigating Cluster Health Events* (Appendix D) defines a cluster as "…an unusual aggregation of health events that are grouped together in time and space". Since the publication of the CDC guidelines in 1990, this definition has been expanded. For example, discussions of responses to cancer cluster inquiries at the 1997 annual meeting of the Council of State and Territorial Epidemiologists included the acknowledgement that the terms "cluster" or "excess" may be used to mean people's *perception* about excess disease, as well as a *confirmed* statistically significant excess.

• Cancer Cluster Types

There are three types of cancer clusters, spatial, temporal and spatial-temporal.

***Spatial*:** Spatial clustering means that the incidence or mortality of cancer is higher in some places than in others. One reason may be that random events are not uniform. Other factors that affect spatial distribution are socioeconomic, behavioral, environmental and genetic variation within a population (Rothman 1987).

Temporal: Temporal clustering means that cancer incidence or mortality occurs with a higher rate at some times than at others. Temporal clustering also includes cyclic variation, in which the temporal changes in an incidence rate recur in regular cycles. Variations over long periods of time may be explained by numerous factors including changes in diagnostic practice and changes in the gene pool (Rothman 1987).

Spatial-Temporal: Clustering that takes place in both space and time, known as spatial-temporal or space-time clustering, occurs when, for a given period of time, incidence, prevalence or mortality rates of cancer are higher in some places than in others. For example, spatial-temporal clustering may be seen when environmental agents move from place to place or suddenly appear in identifiable locations. These agents can include infectious organisms (e.g.viruses) or toxic chemicals.

• Initiating Cancer Cluster Response and Surveillance

Cancer clusters generally come to the attention of public health officials in one of three ways. Most commonly, spatial-temporal clusters begin with a report to the public health department of a suspected increased frequency of cancer cases or deaths by some observer, often a person with the disease or a relative of a case, or, less frequently, a physician (Neutra et al.1992). These clusters are often reported in conjunction with a phone call or letter to a state health department (Greenberg and Wartenberg 1991). Disease clusters are most commonly reported in neighborhoods, schools or at the workplace (Caldwell 1990). Another form of cancer cluster initiation occurs in the presence of known environmental hazards, such as a Superfund site, when members of neighboring communities request a review of death certificate or cancer registry incidence data to see if particular cancers have occurred at an excessive rate. Sometimes, an epidemiologist or statistician has access to death records or cancer registry incidence data and decides to explore geographical data looking to confirm the presence of "statistically significant clusters" (cancer cluster surveillance).

• Explanations for Cancer Clusters

When an unusual number of cases of cancer is noticed in a particular place and time period, there are four likely explanations for the excess. The first is chance, the second is an aggregation of persons with an age, race, gender or other factor distribution that puts them at inherently higher risk, the third is the prevalence of enhanced risk lifestyle/behavior factors, and the fourth is the appearance of a biologically active factor which subsequently caused cancer (Neutra et al. 1992). A spatial-temporal cluster may be the result of normal variation because random events do not occur in a perfectly uniform pattern (Rothman 1990). The important distinction to be made between a cluster that is a potential health concern and one that is not, is whether there is a common etiology among cases. If a common etiology can be determined, the causative factors may be identified and, if necessary, prevented or remediated so that the adverse outcome does not occur in the future.

• Common Concern: Exposure to Environmental Contamination

Throughout the United States, people are concerned about common scenarios pertaining to cancer clusters. The primary concern with cancer clusters seems to be in establishing an association with environmental contamination or occupational hazards. When carcinogens are found in the air, soil, water, or the workplace, the news is often widely publicized, resulting in speculation linking the exposure to various diseases, especially cancer (Caldwell 1990). Attention focusing on the contamination of rivers and tributaries has also resulted in heightened public perception and concern over carcinogens in the drinking water (Devier 1990). The great public concern about the drinking water during the childhood cancer cluster investigation in Dover Township is an example.

The types of cancer with known environmental or occupational etiologies include bladder, lung, skin, gastrointestinal, leukemia, lymphoma, nasal, larynx, liver, brain, testicular, bone, kidney and thyroid (National Toxicology Program, 2002). However, most environmental health scientists currently believe that a relatively small proportion of all cancers are related to hazardous substances. In order for environmental contaminants to cause cancer, or any other disease, there must be a completed pathway through which the contaminants could travel from their source, through the environment, to enter the human body through air, water, food, or direct contact with the skin.

There are, however, other often more important, risk factors for these cancers. Behavioral factors, such as smoking, would be one example. In fact, cancer is a diverse group of more than 100 diseases, each characterized by uncontrolled growth and spread of abnormal cells. Different types of cancers have differing rates of occurrence and different causes. It cannot be assumed that all types of cancers in a community or workplace share a common cause.

• Challenges of Cancer Cluster Response and Surveillance

There are several important biological, statistical and practical reasons why cluster response and surveillance are difficult to do. Cancers will tend to aggregate in space and time within populations. The clustering may be due to chance, or it may be due to the interplay of factors in the population that increase the risk of disease. These factors may be demographic (age or sex), genetic, behavioral (tobacco smoking or diet), environmental (such as occupation or pollution), or may be related to the health care system (access to screening services). Without further study, it is not possible to distinguish between cancer clustering due to chance alone and clustering that may be due to underlying demographic, genetic, behavioral, environmental or health care system factors.

Latency and Migration

Consider a situation in which there is an exposure factor that increases the risk of cancer over a defined period of time in a distinct geographic area. Cancers do not develop immediately after exposure. There is a *latency* period between cancer-initiating exposure and recognition of clinical disease (diagnosis of cancer) that may be many years or decades long. When considering environmental or occupational factors, latency is important because people move frequently. Rates of specific cancers in the exposed population may not appear elevated in adults for decades after the exposure occurred. But this increase may not be observed in the geographic area since persons at higher risk of disease may have moved out and been replaced by others not at increased risk.

Latency periods for cancers developing in childhood are generally shorter than latency periods for cancers arising in adults. For this reason, population migration is not as likely to affect the detection of a childhood cancer cluster due to a geographic exposure factor.

Information on Confounders

When evaluating the incidence of cancer in a population, it is important to consider important factors that affect the rate of cancer. The most important factor that affects the rate of cancer is age. For most cancer types, there is a marked increase in the rate with increasing age. If two populations are of different age compositions, then the incidence of cancer is expected to be quite different. For example, the rate of cancer in a community composed of young families will be lower than an otherwise similar community of retired persons. When comparing the rates of cancer in two populations, cancer rates are usually adjusted to take into account differences in age, so that differences due to a factor of interest (such as an environmental exposure) may be revealed. Adjustments may also be made for other demographic factors such as sex or race for which data are readily available.

There are other important confounding factors, however, for which data are not readily available and cannot be easily adjusted for in a comparison of cancer rates in populations. For example, tobacco smoking is an exposure factor responsible for a high percentage of lung and many other types of cancers. However, information on tobacco smoking history is not available for cases registered in the NJSCR, nor is there detailed data on smoking frequencies in small geographic units across the state. The NJDHSS Center for Health Statistic's Behavioral Risk Factor Surveillance System (BRFSS) has collected data on smoking frequency for the state as a whole, and has recently begun collecting data to provide statistically stable frequency estimates at the county and major city level. Other examples of potentially important confounding information that are not readily available include genetics, family history, occupational history, reproductive history and other behavioral factors such as diet, exposure to sunlight and exercise.

The lack of information on important confounding factors limits the interpretation of most analyses to detect clustering of cancer. Separate analyses of childhood cancers are not likely to be as strongly influenced by confounding due to occupational, reproductive or behavioral risk factors that are common in adults.

Variability and Stability of Rates of Rare Diseases

It is important to consider the natural variability in cancer rates when evaluating geographic or temporal patterns of possible clustering. The smaller the number of cases upon which a rate is based, the more variable that rate will be from place to place or time to time by chance alone. For example, suppose a large population is divided into equal groups such that five cases of a type of cancer are expected to occur in each group each year. The number of cases that would actually be observed in each population would average about five, but, by chance, there would be a variable number of cases occurring in the groups. In fact, the actual number of observed cases would be between one and nine for 95 percent of the groups, based on the assumption of a Poisson distribution. This would mean that an observation of 10 cases, or a doubling of the usual number, might be considered unusual. If the expected number were 18 instead of five, then the observed values would range between 10 and 26 in 95 percent of the groups. This would mean that an observed value of 27 might be considered unusual, which is an increase of only 50 percent. The following table shows the range of observed numbers of cases that would occur 95 percent of the time for differing numbers of expected cases.

Expected Number	**Range of Observed Numbers in 95% of Groups**
3	0 – 6
5	1 – 9
7	2 – 11
9	4 – 14
12	6 – 18
18	10 – 26

Three factors contribute to the number of cases upon which a rate is based: the size of the population, the length of observation time, and the frequency of the disease. Cancer rates in smaller populations will be more unstable than in large populations, and rates over short time periods will be subject to more variability than rates over long periods of time. Some types of cancer occur far more frequently than other types, although all are considered rare diseases for statistical purposes (see table on next page). Therefore, it follows that chance fluctuations will be relatively smaller in the rates of the more common cancers such as prostate, breast, lung and colorectal, than in the less common cancers, such as Hodgkin disease or brain.

Incidence Rates of Selected Cancers in New Jersey by Gender, 2001

Males		Females	
Cancer Type	**Rate per 100,000***	**Cancer Type**	**Rate per 100,000***
Prostate	199.5	Breast	133.8
Lung and bronchus**	84.2	Lung and bronchus**	54.9
Colon and rectum	72.5	Colon and rectum	53.8
Urinary bladder**	46.3	Corpus uteri	28.2
Non-Hodgkin lymphoma**	26.3	Ovary	16.2
Melanoma of the skin**	21.7	Non-Hodgkin lymphoma**	17.4
Kidney**	19.2	Thyroid**	14.4
Leukemias**	15.7	Urinary bladder**	12.4
Pancreas	14.1	Melanoma of the skin**	13.8
Stomach	13.6	Pancreas	10.1
Esophagus	8.4	Cervix uteri	10.1
Brain and other nervous system**	7.5	Leukemias**	8.8
Larynx**	8.2	Kidney**	9.2
Liver**	8.6	Stomach	5.8
Multiple Myeloma	7.0	Brain and other nervous system**	5.2
Testis**	5.8	Multiple Myeloma	5.3
Thyroid**	4.4	Hodgkin disease**	3.1
Soft tissue (including heart)	3.7	Soft tissue (including heart)	3.0
Hodgkin disease**	3.6	Esophagus	2.4
Nasopharynx**	.8	Liver**	2.5
Bones and joints**	1.4	Larynx**	1.6

*age-adjusted to the U.S. 2000 population standard, 2001 rates are preliminary
** have occupational or environmental risk factors
source: New Jersey State Cancer Registry, New Jersey Department of Health and Senior Services

Analytic Considerations

Because of the diverse and complicated nature of clusters, there is no omnibus statistical test for assessing them. Different methods have different inherent weaknesses as well as strengths. Additionally, different tests are sensitive to different types of clustering. The development and use of statistical tests for clustering is constantly evolving. Tabulating frequencies of health events and examining related descriptive statistics can be a useful step in the evaluation of reported clusters.

Mapping the data is also helpful. The most commonly used statistic to evaluate variation in cancer rates in small populations is the comparison of the observed to expected number, expressed as a standardized incidence ratio (SIR). The SIR is calculated by dividing the observed number of cases, usually in a specified geographic area by an expected number for the surveyed population over the time period reviewed. Other commonly used statistical approaches include Chi-square tests of observed versus expected frequencies based on the Poisson distribution for low-frequency data, and Poisson regression used for comparison of rates. Confidence intervals are calculated for point estimates. Statistical tests to detect clustering around a point source (focused tests) include Fixed Cut Off Isotonic Regression, Lawson–Waller's Score Test, Bithell's Linear Rank Score Test and Diggle's method (Kulldorff M, 2004).

For cancer cluster surveillance, there are two types of tests for spatial randomness – global clustering tests and cluster detection tests. Global clustering tests evaluate whether clustering exists throughout a geographic area (e.g. New Jersey) without pinpointing the location of specific clusters. These include Moran's I, Mantel-Bailor's Test, Cuzick-Edwards K-NN Test, Tango's Maximized Excess Events Test, Grimson's Method, Ripley's K Function, Besag and Newell's Method and Rogerson's Method. Cluster detection tests determine the location and statistical significance of clusters, not just whether clustering occurs. These tests include Turnbull's CEPP and the Spatial Scan Statistic (Kulldorff M, 2004).

Necessary Data

The data needed for cancer cluster response and surveillance are cancer incidence and mortality data, population data, and in some instances, survival data. The problems with the cancer incidence data, discussed in Chapter 2 of this report, include reporting delays, correctly geocoding the addresses at diagnosis, and small numbers of cases, especially of the less common cancers. Generally, Census data are used for the populations at risk but these data can be unreliable for small geographic areas, especially if further categorized by gender, age and race, all important factors in cancer cluster analysis. Additionally, Census data for small geographic areas have been demonstrated to be unreliable in intercensal years. The further the time period of analysis is from the Census year, the lower the reliability of denominator data in small areas. Also important is the geographic "unit of analysis". The use of geopolitical units such as counties or municipalities can be problematic because they may be too large. Clusters that are in a smaller area than a county or municipality or cross county or municipal boundaries may be missed. To avoid this problem, Census tracts are often used as the geographic unit of analysis, although this may not completely solve the problems.

Multiple Comparisons

Multiple comparisons are not usually a problem in cancer cluster response, but can be a problem in cancer cluster surveillance. Neutra, et al. demonstrated that in the course of surveillance for cancer clusters, a large proportion of statistically elevated SIRs are expected to be due to chance alone, i.e. false positives. The number of false positives is determined by the number of SIRs calculated, the significance level (p-value, e.g. 0.05) chosen, the size of the population, and the expected frequencies of the cancers involved (Weinstein and Klotz, 2000). This problem could result in following up identified clusters that are not related to any etiologic or demographic factors. This is discussed further in Chapter 6: Surveillance for Cancer Clusters.

On the other hand, if there is insufficient statistical power, “real” cancer clusters may be missed. Power is the ability to discern an effect, in this case a cancer cluster, given that there is one. Power relates to the numbers of cases of disease; small numbers result in low power. Power also relates to the significance level; a high significance level, for example 0.001, also contributes to low power.

Confidentiality

The legislation that established the New Jersey State Cancer Registry (NJSCR) requires that the identity of any person who appears in the NJSCR be maintained as confidential. Any information that could identify an individual such as name, social security number, address, telephone number, birth date or any other combinations of factors that could reveal someone’s identity cannot be released to anyone. The exception is for *bona fide* research by a qualified researcher with a protocol and confidentiality procedures approved by an Institutional Review Board (IRB). The NJSCR strictly adheres to this requirement and there has never been a breach of confidentiality. Precautions are taken with aggregated data to protect against inadvertent disclosure of identity. For example, cancer incidence counts less than five generally are not published. Therefore, any cancer cluster response and surveillance activity must ensure that confidentiality is maintained; for example, dot maps of cancer should not be fine enough to reveal the street segment of a case.

Chapter 5:

Responding to Suspected Cancer Clusters

• History of Cancer Cluster Response in New Jersey

Since the inception of data collection efforts of the New Jersey Cancer Registry (NJSCR) in 1978, the New Jersey Department of Health and Senior Services (NJDHSS) has responded to cancer cluster concerns in New Jersey. Prior to the collection of cancer incidence data by NJDHSS in 1978, mortality data was used to assess cancer excess at the state, county, or local level. In 1981, Cancer Epidemiology Services (CES) published New Jersey's first cancer mortality atlas, *Descriptive Epidemiology of Cancer Mortality in New Jersey 1949-1976, Volume I Discussion and Analysis, and Volume II Statistical Appendix* that described the cancer mortality burden in the state.

In the early 1980's NJDHSS investigated several notable reports of cancer clusters including a childhood leukemia and Hodgkin disease cluster at the Pierpont School in Rutherford (Halperin et al. 1980), a testicular cancer cluster in Garfield (Slade et al. 1980), and an occupational cluster at Smith Hall, an academic/laboratory building at Rutgers, Newark (NJDHSS, Division of Epidemiology and Disease Control, 1981). These investigations were difficult to conduct since an adequate baseline of cancer incidence data had not been accumulated, making the evaluation of cancer excesses problematic. Consequently, the results of these investigations were inconclusive.

From the mid-1980s until 1996, the Environmental Health Service (EHS), now Consumer and Environmental Health Services (CEHS), handled most cancer cluster responses, since inquiries were often related to community environmental concerns. A standard procedure for cluster response was developed in cooperation with a Centers for Disease Control and Prevention (CDC) Epidemic Intelligence Service (EIS) officer. When appropriate, additional information was requested from the caller using a standardized form, and cancer incidence data was requested for analysis from the NJSCR. About 50 cluster inquiries and responses were logged per year over this time period by one staff epidemiologist.

In 1988, an epidemiologist in the Occupational Health Service (OHS) began responding to occupational cancer cluster reports, while epidemiologists in the EHS continued to respond to community cancer cluster reports. In 1990, the OHS epidemiologist developed the *Protocol for Investigating Occupational Cancer Clusters* along with the *Occupational Cancer and Response to Reports of Cancers at Work* fact sheet and forms on which to report information about cases of cancer and the worker cohort at workplaces of concern.

In 1996, cancer cluster response was moved to the Cancer Surveillance Program within CES. By 1997, the *Interim Cluster Response Protocol*, the *Cancer Cluster Inquiry Intake Form*, fact sheets on *Inquiries about Cancers in Communities* and *Cancer Risk Factors*, and an electronic database for tracking cancer cluster inquiries were developed. Reference materials such as *Cancer Rates & Risks* (National Cancer Institute, 1996), *Cancer Facts and Figures* (American Cancer Society), *Cancer Epidemiology and Prevention* (Schottenfeld & Fraumeni, 1996) and lists of persons and programs to contact for information were collected. Literature shelves were stocked with fact sheets and pamphlets from other services within the NJDHSS, the New Jersey Department of Environmental Protection (NJDEP), American Cancer Society (ACS), National Cancer Institute (NCI), and other organizations. A NJDHSS Cancer Investigation Review Panel was organized with staff from the CES, CEHS, OHS, and Family Health Services. In 1997, a series of three one-day educational seminars entitled "Risk Assessment and Investigation of Non-Infectious Disease Clusters for Health Professionals," was provided to the Local Health Officers (LHOs). Since then, the fact sheets prepared by CES, the electronic database, the stock of literature, and lists of contact people and programs have been continuously updated and expanded. Use of various government and organizations' websites to access information pertinent to individual cancer cluster inquiries has become routine.

Childhood Cancer in Dover Township (Toms River), New Jersey

The most recent suspected cancer cluster that resulted in an in-depth study was the childhood cancer investigation in Dover Township (Ocean County). The investigation was prompted by community concerns. In 1996, the NJDHSS and the federal Agency for Toxic Substances and Disease Registry (ATSDR) developed a comprehensive plan to evaluate childhood cancer statistics and to examine potential exposures to hazardous chemicals in the environment. The cancer incidence analysis showed that leukemia was elevated in the township, particularly among female children, and that leukemia and brain cancers were elevated in female children in the Toms River section of the township (Berry and Haltmeier, 1997a). Environmental exposure assessments found exposures in the past through contaminated public drinking water supply wells and air emissions from a chemical manufacturing facility in the township (NJDHSS and ATSDR, 2001a; NJDHSS and ATSDR, 2001b; NJDHSS, NJDEP and ATSDR, 2001). Based on these findings, the NJDHSS and ATDSR designed and conducted a case-control epidemiologic study to assess whether children who developed cancers were more likely than other children to have been exposed to environmental contaminants in the past. The study involved complex, detailed computer modeling of historic water-distribution system and atmospheric flow patterns to assess exposures to children and their mothers (ATSDR, 2001; EOHSI, 2001). The study found that female children who developed leukemia were five times more likely to have been exposed during the prenatal period to water from one of the two contaminated well fields than were comparison children. Female children with leukemia were also more likely to have been exposed to air pollutant emissions from the chemical manufacturing plant. Environmental factors did not appear to be associated with brain and central nervous system cancers (NJDHSS and ATSDR, 2003). In 1996, the contaminated wells were taken out of service, and the chemical manufacturing plant ended operations. Between 1996 and 2000, childhood cancer incidence remained elevated, but incidence among the youngest children was lower than expected, suggesting that childhood cancer may be decreasing (NJDHSS, 2003). The NJDHSS continues to monitor closely the incidence of childhood cancer in Dover Township.

• Response Protocols: New Jersey

NJDHSS's Interim Cluster Response Protocol

In 1997, the Cancer Epidemiology Services (CES) prepared the *Interim Cluster Response Protocol* (the *Protocol)* (Appendix E). This *Protocol* was based upon the CDC's *Guidelines for Investigating Clusters of Health Events* (Appendix D). The *Protocol* outlines the procedure for responding to cancer cluster concerns by the public, including:

- handling initial responses to inquiries;
- additional activities undertaken if needed;
- the criteria for conducting an SIR analysis;
- criteria for types of further investigation activities;
- criteria for conducting an in-depth study; and
- the role of the local health department.

The *Protocol* also establishes the goals for responding to cancer clusters, stating that staff responses should be:

- timely, courteous, empathetic;
- efficient at triaging and communication;
- informational for citizens and their representatives and health care providers; and
- efficient for maintaining electronic documentation to facilitate future responses.

The *Protocol* incorporates the principles of risk communication throughout. These principles are described in more detail in Appendix F. In addition, the confidentiality of any individual level cancer information provided to or by the CES or the NJSCR is paramount and must be maintained.

Initially, a CES staff person speaks with the concerned person(s) to discuss their concerns. Every attempt is made to contact the concerned citizen within a day of their call. Specific information about the cancers of concern and any environmental, occupational or other exposures of concern is elicited and recorded on the *Cancer Cluster Inquiry Intake Form*. In most cases, information about cancer and risk factors for the cancers of concern is provided by the CES staff person (e.g. information from the fact sheets *Inquiries about Cancers in Communities* and *Cancer Risk Factors)*. Information and referrals relating to environmental and occupational exposures of concern may also be provided over the phone. The staff person explains the next steps and encourages the concerned citizen to call again with any additional information or concerns. The inquiry is given a number and entered into the database.

The CES staff person then follows up on the conversation by collecting additional information. Information is gathered from pertinent reference materials and Internet websites. Knowledgeable people within the NJDHSS (e.g. CEHS and the Public Employees Occupational Safety and Health Program (PEOSH)) and in other agencies such as the New Jersey Department of Environmental Protection (NJDEP), the federal Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH) are consulted about exposures of concern. The LHO may be contacted to obtain more information about the cancers and exposures of concern, as well as to discuss any specific source(s) of potential exposure in the community; e.g. the drinking water, a factory in the neighborhood, a hazardous waste site in the area, a particular chemical used at a workplace.

Generally, after this initial investigation, and within one to two weeks, a letter is sent to the concerned person. The letter restates the concerns expressed by the inquirer, provides general information about cancer, information on the specific cancers of concern, information on the environmental or occupational exposures of concern and referrals to other programs within the NJDHSS (e.g. PEOSH Program), other agencies such as NJDEP, an OSHA regional office, and/or the LHO. The importance of addressing environmental or occupational hazards and ensuring that all federal and state environmental and occupational regulations are followed is stressed. Communicating this point is essential, even though there may not be a connection between the cancers of concern and the exposures of concern. An invitation to re-contact the CES staff person with additional information or questions is extended. Enclosed with the letter is a packet of information including the NJSCR's brochure, the fact sheets *Inquiries About Cancers in Communities, Cancer Risk Factors,* and/or *Occupational Cancer Clusters* as appropriate, excerpts from *Cancer Rates and Risks* and/or *Cancer Facts & Figures*, other publications, brochures and fact sheets about the cancers and environmental or occupational exposures. Occasionally, compiled data from the NJSCR is also included. Staff is very careful that all information provided is from established scientific sources such as the NCI, the CDC, the ACS, and the National Toxicology Program.

The letter is written by the CES staff person who spoke with the concerned person. The Cancer Surveillance Program Manager and the Cancer Epidemiology Services Director each review the letter. Copies of the letter and the enclosures are sent to the LHO, other NJDHSS or NJDEP staff, local officials and staff as appropriate.

For residential cancer cluster inquiries, if the initial information provided by the concerned person suggests an unusual pattern regarding number and types of cancer, gender, or ages at diagnosis or there is a high level of community concern, staff cross-check the cases reported by the caller in the NJSCR and/or may compare the numbers and patterns of cancer in the area of concern to county and state-level data. If indicated by the results of this analysis or if community concern remains high, a standardized incidence ratio (SIR) statistical analysis is performed to see if a statistically significant excess of cancer is present. A written report with the results of the SIR analysis and any other information about the cancers and environmental or occupational exposures of concern is sent to the concerned person(s), the LHO, and other involved agencies. Sometimes a public meeting(s) is held, often organized by the LHO, with staff from the local health department, NJDHSS, NJDEP and other agencies as appropriate in attendance.

Occupational Cancer Cluster Inquiries

Additionally, the NJDHSS's PEOSH Program refers occupational cancer cluster inquiries involving public workplaces to the CES. These inquiries come to the PEOSH Program's attention via a phone call or through a formal complaint by an employee or an employee representative. In the case of a complaint, the NJDHSS PEOSH Program sends a copy of the complaint to CES and CES copies their response letter to PEOSH. The CES staff assigned to the inquiry then coordinates the CES response with the PEOSH investigator assigned to the complaint. The PEOSH investigator inspects the workplace, focusing on carcinogens and any other workplace hazards mentioned in the complaint such as poor indoor air quality or lead exposure. The PEOSH investigator sends a copy of the investigation report to the CES. By law, the name of a PEOSH complainant must be kept confidential. The NJDHSS, through the PEOSH Program, has the "right of entry" for public workplaces only. Federal OSHA regulates private workplaces in New Jersey. Public schools are considered public workplaces and are regulated by the PEOSH Program, while employees of private schools may be under the jurisdiction of OSHA.

A cohort of workers may be matched to the NJSCR to ascertain workers diagnosed with cancer. This has occurred for several public workplaces and one private workplace, upon the request of management. In these cases, meetings with the management and concerned workers and/or their representatives are usually held. For the private workplace, the worker cohort is annually matched with the NJSCR for a researcher hired by the employer to monitor the situation. It is not possible to search the NJSCR for all workers with cancer in a specific occupation, industry, or workplace because this occupational information is not complete for each cancer case in the NJSCR. NJSCR only collects usual occupation and industry as it appears in the medical record. Even a match of a worker cohort with the NJSCR may miss workers with cancer, for example, workers who were diagnosed before October 1978, or very recently, or were not New Jersey residents at the time of diagnosis. Occupational cancer cluster investigations and cancer studies also are hampered by incomplete information on the worker cohorts (e.g. years worked at the workplace for each worker), incomplete information on worker exposures especially before the OSHA Act of 1970, and information on other risk factors among the workers.

In-depth Study

Currently, **the minimum criterion** for an evaluation of the need and feasibility of an in-depth study (e.g. a case-control study) is **one** of the following:

- SIR for one observation period (e.g. several years) is statistically significantly elevated at the $p<0.001$ level; **or**
- SIRs for two consecutive observation periods are each statistically significant at the $p<0.05$ level; **or**
- there is an increasing trend of rates over several timeframes of an unusual cancer; **or**
- there is a plausible hypothesis regarding a particular factor or exposure and a statistically significant SIR at the $p<0.05$ level for any period.

The evaluation of the need and feasibility of an in-depth study may include more detailed case characterization, review of existing information on environmental exposures, interviews with health care providers and local government officials, and discussions with community leaders. The criteria for an in-depth study are:

- sufficient cases of cancer,
- a biologically plausible hypothesis with documented exposure pathways; and

- residency and latency characteristics consistent with the timeframes of exposures and diagnoses of cases.

Role of the Local Health Departments

The role of the local health departments or the LHOs in cancer cluster response may include:

- initiating the inquiry, for example, when citizens have contacted the LHO with their concerns;
- conducting or assisting with the initial response;
- evaluation of environmental and other factors of concern including characteristics of the population;
- evaluation of local sensitivities, history, key informants;
- public education;
- coordination of local meetings, if any;
- communication with the public and media, if necessary; and
- communication with the NJDHSS and other agencies, as needed.

The level of the LHO's involvement depends on the particular cancer cluster inquiry and the LHO's experience and comfort in responding to this type of public concern.

Staffing

The CES staff members who work on cancer cluster inquiries are doctorate or master's level epidemiologists or related professions. Other CES staff assisting the epidemiologists include a statistician and an information specialist. The NJDHSS's Office of Communication handles all contact with the media and elected officials, usually with input from CES. The Office of Communication is also involved in public meetings, particularly if the media will be there. The Office of Governmental Relations is notified about inquiries from legislators.

Summary of Recent Cancer Cluster Inquiries

Information on CES's response to cancer cluster inquiries was presented at several Task Force meetings. The numbers of inquiries in a year has varied from a low of 36 to a high of 73:

Year	1997	1998	1999	2000	2001	2002	2003
Inquiries	73	50	50	41	36	67	61

Currently, thirteen of the total 378 cancer cluster inquiries (as of December 31, 2003) are reviewed annually. Five involved SIR analyses. As new data become available each year, the latest incidence counts are factored in. The cancers of interest included in these annual reviews are: childhood (6), brain (2), breast (2), leukemia (2), bladder (1), gallbladder (1), and thyroid (1).

Of the 61 cancer cluster inquiries in 2003, 72 percent were considered to be residential (i.e. involving the home, neighborhood or community) and 26 percent were occupational (i.e. involving the workplace). The remaining 2 percent involved schools. Private citizens initiated most inquiries (42 inquiries or 69 percent of the total), while the remaining initiators included 7 employees (including 1 who filed a complaint with the NJDHSS PEOSH Program), 2 consultants, 2 hospital staff, and 2 local officials. The counties with the most inquiries were:

Counties	**Monmouth**	**Mercer**	**Bergen**	**Essex**	**Atlantic**	**Camden**	**Middlesex**
Inquiries	9	7	6	6	4	4	4

The response to each of the 61 inquiries included at least one phone conversation and a personalized follow-up letter with enclosures (e.g. informational materials about cancer and cancer clusters). Most inquiries also involved obtaining pertinent environmental and occupational information, referrals to other agencies and the LHO, and/or verification of reported cases in the NJSCR. The response to one inquiry also entailed a comparison of NJSCR incidence data for the residential area of concern with the county and the state as a whole. None of the inquiries resulted in a Standardized Incidence Ratio (SIR) analysis, a public meeting, or an evaluation for the need and feasibility of an in-depth epidemiology study.

• Response Protocols: Other Jurisdictions

The Task Force sponsored a one-day conference, "Current Practice in the Investigation of Disease Clusters," on July 11, 2003 in New Brunswick to learn about practices in other states and within the CDC. Experts from the CDC, California Department of Health Services, Cancer Institute of New Jersey, University of Missouri, University of Connecticut, and Boston University gave presentations on the investigation of cancer clusters, perceptions and communication about cancer clusters, and statistical analysis of clusters. A summary of the conference is in Appendix G. Dr. Rubin's and Dr. Reynolds' presentations on cancer cluster response protocols are summarized below.

CDC Perspective

Dr. Carol Rubin, of the CDC, presented information on the cancer cluster activities at the CDC, beginning with the development of the *Guidelines for Investigating Clusters of Health Events* (Appendix D) and the National Conference on Clusters of Health Events in 1990. In the 1990's, the CDC participated in very few cancer cluster investigations, advising that these be handled on a local level. In 2000, CDC cancer cluster activities were consolidated within the National Center for Environmental Health (NCEH). The NCEH initiated five projects related to cancer clusters:

- a uniform CDC inquiry system, the Cancer Cluster Triage System;
- a review of state cancer cluster protocols;
- a review and description of media coverage of cancer clusters;
- in-depth site visits to three states with recent cancer cluster investigation experience

  (one of the 3 states was New Jersey, see Appendix H for a CDC summary of the site visit); and
- two workshops with other states to obtain detailed information about their experiences.

As part of its review of state cancer cluster protocols, NCEH requested documentation related to cancer cluster investigations from all the U.S. states and territories and, in collaboration with Research Triangle Institute International, developed a tool to compare the state cancer cluster protocols. Fifty states and territories sent their protocols and other documents; six states did not respond. The 1990 CDC *Guidelines for Investigating Clusters of Health Events* was the only uniform baseline that could be used for comparing the protocols, as there is no gold standard for cancer cluster protocols. The protocols were compared on level of detail, education provided to the callers, responsibility for investigation and gathering information, decision tree, sequence of activities, available data resources, and delineation of responsibilities.

A report has not been released yet, but findings indicate:

- level of detail varied significantly among states;
- many states followed the 1990 CDC *Guidelines for Investigating Health Events*;
- every state provided some education about cancer (e.g. common, not a single disease, risk increases with age, most known risk factors are related to lifestyle, environmental exposures often blamed but seldom verified) although the amount of information varied;
- the responsibility for gathering information/investigation included
  - the caller provides information about cancer type(s), number and location of cases, and potential exposure(s),
  - the responsible state official is the chief medial officer, cancer registry director, environmental health personnel, county/LHO, or state epidemiologist,
  - the majority of states were not specific about roles and responsibilities,
- similar decision trees with pivotal criteria such as a single cancer type, biological plausibility/adequate latency, political climate, common cancer in an unusual age group, rare cancer and strong potential for carcinogenic exposure; but there is great variation among states in the sequence of activities usually depending on available resources;
- available data resources varied among states, but all used their central (population-based) cancer registry; and
- communications or community liaison plans were not included in the majority of states' protocols.

From two workshops held in March 2003, the CDC learned that states' limitations in responding to cancer cluster inquiries include:

- inadequate scientific methods
- insufficient staff
- unpredictable data quality
- lack of appropriate control or reference populations
- inherent limitations such as small numbers and latency
- public distrust
- difficult media relations

- politics.

The CDC also learned that states need:

- validation of what they are doing
- funding
- staff training
- information and data sharing
- assistance with complex investigations
- enhanced credibility with the public
- a centralized CDC contact
- validated educational materials
- potentially a national media campaign.

California

Peggy Reynolds, Ph.D., Chief, Environmental Epidemiology, Environmental Health Investigation Branch, California Department of Health Services, presented information on California's response to cancer cluster inquiries. Dr. Reynolds explained that their cancer cluster protocol has evolved beyond responding to cluster inquiries, to developing a more comprehensive research program to evaluate the environmental contributions to the patterns of cancer incidence in the State. Their cancer cluster inquiry response consists of two steps:

- the California Cancer Registry (CCR) regional registry epidemiologist initially responds by providing information/education regarding patterns of cancer incidence, evaluates observed vs. expected cases, and consults with the local health department;
- the CCR regional registry epidemiologist refers the inquiry to the Environmental Investigation Branch if there is a significant excess of cancer and environmental concerns.

There are about 120 SIR cancer cluster inquiries annually. Twenty-nine (24%) involve children and eight (6%) have statistically significant excesses. An example of California's surveillance for clusters is included in Chapter 6.

Small Area Health Statistics Unit, U.K.

The Small Area Health Statistics Unit (SAHSU), established in 1987, and relocated in 1996 to the Department of Epidemiology and Public Health, Faculty of Medicine, Imperial College London, serves as a national resource for investigating health concerns in relation to environmental factors in the United Kingdom. SAHSU manages linkable databases on population, cancer incidence, mortality, births, congenital malformations, hospitalization, and environmental factors (Elliott, 1992, Aylin 1999, Jarup 2004). SAHSU has conducted and published studies on cancer risk in relation to residential proximity to landfill sites, incinerators, television and radio transmission sources, and pesticide plants. The Rapid Inquiry Facility (RIF) of SAHSU can rapidly assess relative risk of disease, including cancer, around point sources. In addition, the facility can produce small area maps of disease distributions in user-specified areas. A steering committee composed of the government sponsors of SAHSU as well as independent expert advisors agree on the major research studies to be conducted by SAHSU. The national department of health refers certain cancer cluster inquiries to SAHSU. The RIF usually analyzes such data within a few days and produces a report within a few weeks. The report is given to the local health officials who then interpret and communicate it to the community. SAHSU is currently negotiating with the Centers for Disease Prevention and Control to set up similar data analysis capacity for the U.S., expected to be complete during 2005.

• Summary – Chapter 5: Responding to Suspected Cancer Clusters

In summary, the NJDHSS has had a standard cancer cluster response protocol, the *Interim Cluster Response Protocol (*the *Protocol)*, based on CDC's *Guidelines for Investigating Cluster Health Events*, in place since 1997. Standard operating procedures (SOPs) to ensure appropriate response to all inquiries have also been developed.

Strengths:

- The NJDHSS has a designated central place (i.e. CES) charged with cancer cluster inquiry response.
- An organized system for responding to cancer cluster inquiries and tracking responses has been developed.
- Knowledgeable and experienced professional staff is available to respond to cancer cluster concerns.
- Since 1978, the NJSCR, one of the leading cancer registries in the country, has collected high quality incidence data. These data are accessible to the response staff.
- The NJSCR has established relationships/partnerships with other programs within the NJDHSS and with external agents and agencies such as local health officers.

Weaknesses:

- The *Protocol* has not been modified or updated since 1997.
- Many of the SOPs are not written, meaning that the collective memory of long-serving staff must be relied upon.
- There is lack of standardization regarding cancer cluster response among LHOs, important partners in cancer cluster response.
- New Jersey citizens are not aware of the cancer cluster response protocol and procedures.

Recommendations:

- Update and modify the *Interim Cluster Response Protocol* and SOPs to reflect changes in the *Protocol*, in the statistical tools available for cancer cluster response, and in the NJSCR (e.g.

geocoded residential addresses). Especially consider including qualitative criteria in addition to p-values to trigger further investigation.

- Prepare a cancer cluster response procedures manual to accompany the *Protocol*.

- Offer additional training opportunities to the LHOs and other partners.

- Prepare a *Citizen's Guide to Cancer Clusters in New Jersey*.

- The NJDHSS should develop and implement a written protocol and procedures to address cancer cluster risk communication issues. The protocol and procedures would address risk communication with individuals, the media, elected officials, community representatives and at public meetings.

- Develop a mechanism for the public to request an independent review of NJDHSS response to a cancer cluster inquiry. Public entities such as the New Jersey Public Health Council or ATSDR should be considered as the agency to conduct such a review.

Chapter 6:

Surveillance for Cancer Clusters

• Purpose and Strengths of Cancer Cluster Surveillance

The previous chapter discussed approaches on how to *respond* to concerns about possible aggregation or clustering of cancer expressed by members of a community, workplace or medical practice. In contrast to these approaches, this chapter considers approaches for the detection of cancer clustering through systematic evaluation of public health surveillance data (i.e., cancer cluster surveillance). Specifically, this chapter examines how state cancer incidence data may be systematically evaluated to detect aggregation or clustering of cancer cases in space and/or time, whether or not community concerns have been expressed.

An important reason to consider cancer cluster surveillance is that waiting for communities or others to notice or perceive clustering is an unreliable way to find those clusters in most need of attention. Communities may never become aware of a real spatial or temporal cluster, or may be hesitant to express concerns even if they have suspicions. Furthermore, most community concerns about cancer incidence that are reported and investigated show no actual elevation in cancer incidence in the community.

One striking example of an unreported cluster is Manville, NJ, where community exposure to asbestos from a manufacturing facility led to excess mesothelioma, an extremely rare disease. Both males and females, separately, who did not work at the facility but lived in the town, had greater than 10-fold excesses of disease, 16 and 8 cases, and SIRs of 10.1 and 22.4, respectively. This is the most extreme, statistically significant cluster ever detected in New Jersey, and yet there has never been a request from the community to investigate (Berry 1997). This situation would have triggered most, if not all, of the standard ‘cluster alarms’, had it been evaluated.

Follow-up investigations of increases in local cancer incidence may lead to the identification of risk factors that may be preventable or the identification of environmental conditions that can be remediated. Systematic cancer cluster surveillance may also facilitate response to community concerns by reducing response time and demonstrating a comprehensive evaluation of existing data.

Surveillance is defined as, “the ongoing systematic collection, analysis and interpretation of outcome-specific data for use in the planning, implementation and evaluation of public health practice” (Thacker et al., 1996). Inherent in this definition is that data are not just collected, but are critically examined for the purpose of improving public health. But high quality cancer incidence and mortality data are only one of the elements necessary for a fully functioning and effective system (Hertz-Picciotto, 1996, Rothman chapter). There must also be accurate data on the population at risk, geographic variation in potential risk factors, methods for linkage of disease, population and risk factors, and an appropriate geographic resolution of the data for useful analysis.

• Methods for Cancer Cluster Surveillance

Cancer Incidence and Mortality Mapping Using Geographic Information Systems (GIS)

Mapping of cancer mortality and incidence enables public health researchers to note time trends and spatial patterns in cancer occurrence and death, and develop hypotheses about risk factors potentially responsible for variation. The National Cancer Institute's (NCI's) *Atlas of Cancer Mortality for U.S. Counties: 1950-1969* (Mason et al., 1975) represented the first effort to map cancer mortality rates on the county level throughout the U.S. These early maps showed clear regional and geographic variation in the mortality of certain cancers, and stimulated research into the role of geographic differences in risk factors such as smokeless tobacco use or occupational factors (Hertz-Picciotto chapter in Rothman and Greenland). The publication of the *NCI Atlas* spurred the establishment of the NJSCR, since many cancer mortality rates were elevated in areas of New Jersey. The *NCI Atlas* was recently updated for the years 1950-1994 (Devesa et al., 1999). The NJDHSS has presented municipal level mortality data in one report (Stemhagen et al., 1981), county level incidence data in several reports (NJDHSS, 1989; Roche et al, 1999), and county level mortality data in two reports (Stemhagen et al., 1981, NJDHSS, 1989).

In the past decade there have been significant advances in computerization of geographic elements of public health data. GIS has become an important tool in public health, health care planning, and epidemiologic research. GIS-based mapping of disease rates enables spatial and temporal visualization and analysis of disease occurrence data, and facilitates the use of complementary statistical and environmental modeling and analysis (Diggle in Elliott and Briggs; Clarke et al.). Advances have also been made in smoothing the data for mapping; smoothing is a method to remove some of the variability in a quantitative map so that the underlying pattern is highlighted. The latest smoothing techniques take into account the stability of the rates, i.e. the size of the population. NCI used smoothing in their recent report that predicts county cancer incidence rates, *U.S. Predicted Cancer Incidence, 1999* (Pickle et al., 2003).

The Internet also has become an important means of distributing cancer information. For example, several federal agencies including NCI, CDC, and ACS have developed a universal "portal" website called Cancer Control PLANET (http://cancercontrolplanet.cancer.gov). Cancer incidence data from the NJSCR are included at the state and county levels for the major cancers. Cancer mortality data for New Jersey are also included for the state and each county. New Jersey Cancer data also appear on CINA Deluxe Online, an interactive data tool with statewide mapping functions (www.naaccr.org). The NCI's *Atlas of Cancer Mortality in the United States, 1950-1994* is on their website (http://www.nci.nih.gov/atlas).

Descriptive Statistical Analyses of Geographic and Temporal Aggregation

The occurrence of disease in a geographic area may be evaluated statistically in comparison to a reference population. Because there will nearly always be differences between the comparison and reference population in the distribution of factors important to disease risk (for example, age), these comparisons have to be adjusted or standardized for these confounding factors. A common method is to calculate standardized incidence ratios (SIRs), which are derived by dividing the observed number of cases by an expected number in a specified study population over a defined period of time. The expected number, in this example, is calculated by multiplying the age group-specific incidence rates for the disease in a reference population (often a state or country) by the age group specific population of the study area, and summing the products for all age groups (Kelsey, Thompson and Evans, 1986; Breslow and Day, 1987; Checkoway et al., 1989). The expected number can be interpreted as the number of cases that would have occurred in the study population if it had experienced the cancer rate in the reference population.

If the observed and expected numbers are equal, the SIR is one. If more cases are observed than expected, then the SIR exceeds one, and if fewer cases are observed than expected, the SIR is less than one. Because SIRs may differ from one by chance alone, a confidence interval can be constructed to evaluate the probability that the SIR is greater or less than one due to chance alone (Breslow and Day, 1987).

For cancer cluster surveillance, SIRs can be routinely calculated for appropriate geographical scales and time periods. Hardy et al. (1990) proposed a surveillance system based on this method, with a two-stage decision process. In the first stage, SIRs are evaluated for all areas in a specified time period. Any area with a SIR exceeding a certain threshold would be placed on an “alert” status. The area would enter “action” status if the SIR remains elevated in a subsequent time interval, triggering an in-depth study of possible local causes. An initial SIR may also trigger action status if it exceeds a stricter threshold.

There are limitations, however, to this type of surveillance approach. As noted, clusters will occur by chance. If a population is subdivided into a large number of areas, and many different cancer types are considered at once, the multiple comparisons will result in a large number of excesses occurring by chance alone (Neutra et al., 1992). For example, CES estimated that, if 100 areas are examined for each of the 60 major cancer classification types, for time periods in which 5 cases are expected, and using a standard criterion for statistical significance (less than 5 percent probability of occurring by chance), there is a 95 percent chance that an area would have at least one false positive excess (Weinstein and Klotz, 2000). Even with a stricter criterion for statistical significance (less than 1 percent probability of occurring by chance), 45 percent of areas would have at least one false positive excess. The implication for the system proposed by Hardy et al. (1990) is that most areas would be in alert status most of the time by chance alone. Applying the two-stage Hardy et al. system to this example, 27 excesses would occur in the 100 areas that would reach the action stage after two successive time periods.

In contrast, setting too strict a statistical criteria increases the chance that a cluster due to an exposure condition might be missed, since only the most extreme events would be noticed by the surveillance system. Clearly, decisions about possible clustering of cancer and the need for follow-up investigation should not be based solely on statistical criteria, or low probability of occurrence in one time period. The Hardy et al. (1990) proposal recognizes that the persistence of an elevated risk (in two successive periods) should be considered, as well as the absolute magnitude of the relative risk (SIR) in any given period. In addition, a surveillance system may need to consider the existence in a community of exposures to biologically plausible cancer risk factors, and consistency of elevations across areas that share common exposure characteristics.

The absolute number of cases contributing to a local cancer excess is also an important factor to determine whether follow-up studies should be pursued. Follow-up investigations as proposed by Hardy et al. (1990) need to have sufficient statistical power to detect associations with risk factors. Weinstein and Klotz (2000) show that a case-control study conducted in response to a local excess of cancer requires both a large relative excess of cases (SIR), as well as a large absolute number of cases. For example, the authors conclude that at least 20 cases are needed to have acceptable statistical power to detect a tripling in risk, assuming a situation in which 30 percent of the population is exposed to the risk factor of interest.

Spatial Scan Statistics

Researchers at the NCI developed a software program called SaTScan to analyze spatial and/or temporal variation in cancer data, using a spatial scan statistic (Kulldorff M et al., 1995; Kulldorff M, 1997; Kulldorff M, 2001). SaTScan may be used to perform geographical surveillance of cancer or other diseases to detect clustering. In SaTScan, a large geographic region (such as a state) is partitioned into subdivisions (cells such as Census tracts) for which the population, number of cases, and geographic coordinates of the cell centroid are known. Zones are constructed of aggregations of cells by allowing the radii of circles centered on the centroids to vary continuously from zero up to a maximum defined by the user. The scan statistic tests the null hypothesis of complete spatial randomness against the alternative hypothesis that the probability of being a case in zone z is greater than the probability of being a case outside that zone. A Monte Carlo method is used to estimate a distribution for the test statistic by randomly assigning the cases to individuals in the population and recalculating the test statistic. Based on the Monte Carlo simulation, the most likely cluster is identified along with the number of actual cases, number of expected cases, relative risk (number of actual cases/number of expected cases), p-value, and geographic coordinates of the cluster. Information on the next several most likely clusters is also provided. Important factors related to cancer, such as age or race, can be accounted for in the analysis.

The advantages of SaTScan are that it can identify a cluster at any location of any size up to a maximum size set by the user, it minimizes the problem of multiple comparisons, it can be used with small geographic areas such as census tracts, it provides output in a GIS-compatible data file so the results can be mapped, and it is available at no cost. A disadvantage of this approach is that it assumes a particular circular shape to the cluster. In reality, an area of increased risk may conceivably follow a straight or irregular line (such as a road or waterway) or may be an irregular shape determined by development patterns, wind direction, watershed boundaries, water distribution system boundaries, or groundwater flow. The developers of SaTScan currently are testing methods that overcome this disadvantage.

Studies of Cancer and Geographically Varying Risk Factors

Descriptive statistical or spatial scan analyses may identify areas of higher risk for specific cancers, but do not by themselves provide specific insight into possible causes of the diseases. Additional study is usually needed to investigate the roles and interaction among demographic, genetic, behavioral, environmental or health care system-related factors (for example, the action status stage of the Hardy et al. proposal).

As a complementary strategy, surveillance data can and should be examined based on concerns about the geographic distribution of specific potential risk factors, independent of the identification of any local clustering of disease. Studies may be designed that evaluate SIRs for populations in geographic areas pooled by level of a suspected risk factor. Geographic rates of disease can also be evaluated in statistical models (for example, Poisson regression analysis) that are capable of measuring complex interactions among potential risk factors, and controlling for multiple confounding factors.

Timeliness of Follow-up

Regardless of the methods used, in order for cancer cluster surveillance to be successful, there must be a protocol for follow-up of cancer clusters that are revealed. This protocol should include procedures for investigating why there is a cluster, as well as for informing the public of any findings.

• Practices in New Jersey

Surveillance of Cancer Incidence Patterns and Trends

In 1998, the Cancer Epidemiology Services (CES) developed the *New Jersey Department of Health and Senior Services (NJDHSS) Plans for Statewide Pro-Active Surveillance of Rates and Trends.* The *Plans* outlined a schedule for generating statewide and county level tables, charts, and narratives on incidence rates and trends for major types of cancer (using data from the NJSCR), discussions of known risk factors, emerging prevention and control strategies, and indicated actions. As part of the *Plans*, the CES also began exploring methods for the analysis of rates and trends at smaller geographic scales, including municipality, ZIP code, and census tract levels.

Implementing these plans required geocoding the diagnosis address for the more than one million cases in the NJSCR at the latitude/longitude level, in order to conduct the data analyses at the smaller geographic levels listed above. Considerable technical difficulties have been experienced. Currently, the state Office of Information and Technology (OIT) is providing geocoding services. Nearly one million street addresses of patients diagnosed from 1979 through the present were passed through OIT's geocoding process in September-October 2003. Of these, 95.6 percent were successfully geocoded to the street address or ZIP code centroid. Only 4.4 percent could not be geocoded and are being manually reviewed. These results exclude 38,000 death certificate only records that do not have a street address at diagnosis. Geocoding results for later years were slightly better. Over 97 percent of the addresses were successfully geocoded for cases diagnosed in 2001. A manual review of 5,000 addresses is underway to verify the accuracy of the geocoding process. At this time, about 1,300 addresses have been verified and the error rate is about 1 per 300 records.

At the same time, CES began piloting the use of its GIS with the spatial statistical software, SaTScan. SaTScan has been used with two data sets that could be fairly easily geocoded, breast cancers among women diagnosed in 1995-1997 and men diagnosed with prostate cancer in 1995-1999, to identify geographic areas of the state with significantly high proportions of cancer diagnosed at the distant stage. The projects used data aggregated at the census tract level. Clusters of distant stage disease were identified for each cancer and these clusters were then mapped and compared with the rest of the state on various demographic and other factors related to the use of screening tests.

The first project, *Use of GIS to Identify and Characterize Areas with High Proportions of Distant Stage Breast Cancer* identified two areas in the northeast part of New Jersey with relative risks of 2.4 and 1.7, respectively, for distant stage breast cancer compared to the state as a whole. The project also identified population characteristics of these two areas: high proportions of black or Hispanic women and linguistically isolated households (Roche et al., 2002). The second project currently in progress, *GIS to Assess Late-Stage Prostate Cancer Incidence,* identified three statistically significant clusters of distant stage prostate cancer. Two of the cluster areas had higher proportions of black, Hispanic, and persons with limited English-speaking ability and lower per capita income than the remainder of the state (Abe T et al., 2004). One important purpose of both projects is to identify areas for targeted screening and education programs. In addition, the projects assisted in developing and refining the tools employed for detection of clustering of cancer incidence or mortality.

Studies of Cancer Incidence and Geographically Varying Risk Factors

In the early 1990's, researchers at Rutgers and the University of Medicine and Dentistry of New Jersey (UMDNJ) Graduate Program in Public Health systematically examined the NJSCR 1979-1985 data for childhood and young adult (0-24) clustering at various geographic levels (Schneider et al., 1993). The specific types of cancer studied were brain/cns, bone/soft tissue, leukemia, Hodgkin disease, non-Hodgkin lymphoma, digestive, endocrine/thyroid, and other. The space-time cell occupancy method of Ederer, Myers, and Mantel was used. The results showed that childhood and young adult cancers clustered statewide and that clustering was strongest among Caucasians in specific age groups (0-14, 15-24) for specific cancer types (brain/cns, Hodgkin disease, non-Hodgkin lymphoma). The clustering was driven by very few cases in very few municipalities that were not adjacent to each other. The researchers concluded that these were not enough cancer cases and municipalities to support epidemiologic studies that would yield fruitful results.

Geographic Distribution of Cancer and Measures of Environmental Pollution

For years, the NJDHSS has investigated geographic distributions of cancer and other health effects, particularly in relation to measures of environmental pollution. The more recent work has piloted the incorporation of GIS technology as a tool for developing study-specific exposure assessments. As the amount and completeness of environmental data improve with time, and as the database of geographically coded addresses of cancer cases expands, GIS technology becomes more feasible as a tool for the examination of geographic factors in cancer incidence evaluation. The following are examples of the investigations conducted by the NJDHSS, often in partnership with ATSDR and the New Jersey Department of Environmental Protection (NJDEP).

(1) Drinking Water Contaminants and the Incidence of Leukemias and Lymphomas

In the 1980's, there was growing concern about leukemia incidence and drinking water contamination with volatile organic chemicals (VOCs), prompted primarily by a cluster investigation in Woburn, Massachusetts. However, no systematic evaluation of leukemia incidence in relation to this type of drinking water contamination had been conducted. In 1990, the NJDHSS published an ecologic study using data from the NJSCR considering this hypothesis. The study found that the leukemia incidence rate among females (but not males) was elevated in towns with historic documentation of VOC contamination (Fagliano, Berry, Bove and Burke, 1990). The NJDHSS later expanded the study to encompass more years of observation and a greater geographic area within New Jersey, and to include both leukemias and non-Hodgkin lymphomas (Cohn, Klotz, Bove, Berkowitz and Fagliano, 1994). This study found that rates of both acute lymphocytic leukemias and high-grade non-Hodgkin lymphomas were elevated in females in towns with historic VOC contamination. Rates for non-Hodgkin lymphomas were also elevated among males in these towns.

(2) Mesothelioma Incidence in Manville, New Jersey

For decades, Manville, New Jersey was the location of a major asbestos product manufacturing facility. Workers in the facility were exposed to asbestos; and community members not employed at the facility were potentially exposed through emissions from the plant and dusts carried home by workers. In occupational cohorts, asbestos exposure had been linked to increased incidence of lung cancer and mesothelioma; the latter thought to be nearly exclusively related to asbestos exposure. The NJDHSS evaluated whether the incidence of mesothelioma was elevated among non-occupationally exposed persons in Manville and surrounding Somerset County, using information on cases from the NJSCR (Berry, 1997). After excluding all cases who had worked at the facility (based on union records and other information), the SIRs for mesothelioma in Manville were 22 for females and 10 for males. Similar observations have been made in communities with asbestos exposure in Italy, Sweden, Turkey and South Africa.

(3) Childhood Cancers and Volatile Organic Drinking Water Contaminants

The NJDHSS initiated a statewide study of the incidence of childhood leukemias and brain cancers and drinking water contamination with volatile organic chemicals (Fagliano, 1998). This study piloted the use of a GIS to construct a database of water contaminants tied to maps of the extent of public water supplies (Cohn, Savrin and Fagliano, 1999). GIS is also being used as a tool to identify address locations of study subjects and to assign drinking water contaminant exposures through linkage to the water quality database.

(4) Studies of Radon and Lung Cancer in New Jersey

The NJDHSS conducted a series of case-control studies of radon and lung cancer (Schoenberg, Klotz, Wilcox et al., 1989; Klotz, Schoenberg, and Wilcox, 1993). Exposure data involved short-term and long-term radon monitors in current and previous homes of cases and controls, to assess the geographic and individual variation in exposure to radon. The results were among the first to support the applicability and extrapolation of radon risks from mining studies to the community setting. These studies have been combined with data from analogous studies in other states and nations for meta-analyses of radon risk (Krewski et al., 2004).

(5) Analysis of Osteosarcoma and Radium in Groundwater

The NJDHSS, in cooperation with the NJDEP and the United States Geological Survey (USGS), has completed a collaborative project investigating the association between osteosarcoma incidence and radium levels in community water supplies. Osteosarcoma cases from the NJSCR were geocoded and radium levels in community water supplies were mapped. Populations were aggregated for drinking water regions characterized as high, middle and low potential for high radium exposures through drinking water. The study found that, for males, rates of osteosarcoma were 3 times higher in areas with elevated radium levels. Rates were not similarly elevated among females (Cohen et al., 2002).

• Developing Methodological Strategies

The State of New Jersey has received funding from the CDC National Center for Environmental Health for a cooperative agreement, “Environmental and Health Effects Tracking.” The program is part of CDC’s Environmental Public Health Tracking initiative, which currently includes funding for 21 states, three cities, and three university Centers of Excellence. Under the cooperative agreement, the NJDHSS, in cooperation with the NJDEP, is planning to conduct three demonstration projects. One of the projects involves the examination of patterns of incidence data for selected cancers, and the linkage of these data to data sets on environmental hazards and exposures. Initial phases of the work include the integration of environmental data and development of geographically based exposure potential metrics. Cancer data will be examined using descriptive methods and spatial scan statistics. Analysis of linked environmental and health data will follow based on hypotheses developed in the initial phases.

The National Cancer Institute has funded a series of research studies under a program entitled *Geographic-based Research in Cancer Control and Epidemiology*. The purpose of the program is to stimulate the development and evaluation of tools and applications for the geographic analysis of cancer incidence patterns and trends. One of the research studies funded under the program is *Geographic Tools for Surveillance and Study of Disease* by Daniel Wartenberg of the Cancer Institute of New Jersey. The study is investigating methods to detect spatial and temporal clustering prospectively, accommodate instability of rates in areas with small populations at risk, and impute values for geographic areas with missing data.

Similarly, the ATSDR, CDC, has funded a series of research studies under a program entitled *Linking Chronic Disease and Environmental Data Sources*. The purpose of the program is to stimulate development and evaluation of tools and applications for identifying, describing and validating observed associations between specific chronic diseases and environmental exposures. One of the research studies funded under this program is *Investigating Environmental Causes of Chronic Disease* by Daniel Wartenberg of the Cancer Institute of New Jersey. The study is undertaking a series of specific exposure-disease association investigations using birth, death and cancer registry data in conjunction with routinely collected environmental quality data using a variety of spatially oriented analytic approaches.

New statistical and spatial analysis tools continue to be developed. The SaTScan software continues to be improved and extended, for example, to identify elliptical-shaped or irregularly shaped clusters. Work is ongoing to expand GIS to include the time dimension as well as the space dimension, i.e. space-time information systems (STIS).

• Practices in Other Jurisdictions

New York State

In 2000, as part of the New York State Cancer Surveillance Improvement Initiative (CSII), the New York State Department of Health posted county tables and maps with 1993-1997 breast cancer incidence by ZIP code on their website. The county maps were color-coded to indicate which ZIP code areas had case numbers that were more than 100 percent above expected, 50-100 percent above expected, 15-49 percent above expected, within 15 percent of expected, 15-50 percent below expected, more than 50 percent below expected, and very sparse data. Also indicated on the map were areas of the state with expected case numbers 15-50 percent above the statewide average and areas of elevated incidence identified by the spatial scan statistic. Since 2000, similar tables and maps of lung, prostate, and colorectal cancer, the three other most common cancer types, have been added.

The CSII has developed a stepwise process for follow-up investigation, including selecting priority areas for follow-up, and examining and ruling out demographic, behavioral and health care system-related factors. Consideration will then be given to evaluation of environmental pollution factors, in consultation with communities and scientists. A study protocol may then be developed and implemented if warranted. The focus of the project is now on the follow-up investigations and risk factor mapping.

California

As mentioned in Chapter 5, the Environmental Health Investigations Branch of the California Department of Health Services has evaluated the utility of surveillance for cancer clusters. One example was the Four County Study that was designed to evaluate childhood cancer rates to see if there were more communities with elevated rates than expected in four Central Valley counties with a history of childhood cancer cluster concerns. Of 101 communities (or “areas of residence”), three had very high childhood cancer rates. This was not more than would have been expected by chance, and all three were already known. Based on this experience and others, the Branch does not believe that surveillance for clusters is a particularly useful strategy. They are currently trying another approach, which is to conduct statewide studies of childhood cancer based on environmental concerns. With funding from the National Cancer Institute, the branch is conducting an ecologic study and a case-control study relating socio-demographic and environmental data to childhood cancer.

In October 2001, then Governor Davis signed SB702, a bill that requires the California Department of Health Services, in consultation with the California Environmental Protection Agency and the University of California, to establish an Expert Working Group to recommend approaches and costs to the legislature for developing an Environmental Health Surveillance System. Regarding cluster investigations, the Group’s draft report, *Strategies for Establishing an Environmental Health Surveillance System in California*, states that health-tracking information can be used to identify disease clusters when an association between a specific exposure and health outcome is known, e.g. asbestos and mesothelioma, vinyl chloride and angiosarcoma. The report recommendation is that when there is a known association between a specific hazard and health outcome, cluster investigation could serve to determine if that environmental hazard is present. Conversely, if a known hazard is present, tracking should serve to determine whether the rate of a specific health outcome is elevated among the exposed population. In either case, the overarching public health objective should be to identify efficacious means of exposure prevention. In the absence of an existing specific association between a disease and an exposure, searching for disease clusters is not warranted (SB 702 Expert Working Group, 2004).

• Summary – Chapter 6: Surveillance for Cancer Clusters

Strengths:

- The NJDHSS is developing a GIS with geocoded cancer incidence data, Census data, and geospatial software.
- The NJDHSS has geocoded up to 97 percent of its cancer data to the census tract level.
- The NJDHSS staff is capable of performing spatial scan statistics to detect clusters of cancer incidence in the state.

Weaknesses:

- There is a need for more expert GIS staff.
- A comprehensive strategy for cancer cluster surveillance is needed.

Recommendations:

- NJDHSS should develop a proposal for assessing the feasibility of cancer cluster surveillance based on cancer incidence data, on an appropriate geographic and temporal scale.
- NJDEP should develop integrated, geographically based and time-specific environmental exposure metrics based on permitting, monitoring and modeling. Environmental data should be linkable to cancer surveillance data to facilitate follow-up investigations and epidemiologic research studies.

Chapter 7:

Delineation of Partner Roles

• Role of the Public

Members of the community are instrumental in bringing cancer concerns to the attention of the New Jersey Department of Health and Senior Services (NJDHSS) and their local health department. New Jersey citizens provide valuable information regarding cancer incidence in their neighborhoods and workplaces. The public can provide the NJDHSS with valuable feedback and opportunities for further information sharing. The more information the public brings to the attention of the NJDHSS, the better the NJDHSS can respond.

NJDHSS and Local Health Officers (LHOs) represent an often-untapped resource that the public could take advantage of, for example, educational opportunities and resource material that these departments offer. A great deal of information on cancer, its causes and cancer clusters is available through the state's website and NJDHSS staff, as well as other organizations and government agencies.

• Role of the New Jersey Department of Environmental Protection

For cancer cluster response, Cancer Epidemiology Services (CES) contacts the New Jersey Department of Environmental protection (NJDEP) on an "as needed" basis regarding residents' specific concerns about environmental contaminants. The NJDEP provides information regarding hazardous waste sites and dumps and monitors drinking water, radiological hazards, air pollution, and soil contamination.

Related to cancer cluster surveillance, the NJDEP maintains extensive databases to track facility releases to the air, water and soil, and monitored levels of contaminants in these environmental media. The NJDEP also tracks the quantity of pesticides applied for various uses in the state. These databases will be utilized to develop an integrated, spatially and temporally coded database for the development of environmental exposure metrics. The following table summarizes selected, key environmental data tracked by NJDEP:

Database	Geographic Coverage	Temporal Coverage	Data Type
Air Emission Statement	State-wide: ~500 facilities	Begins 1990	Estimated actual releases
Air Permit Information	State-wide ~ 1,600 sites older than 1987 225 older than 1959	Original equipment installation date as for back as 1930 and grand fathered status back to 1954	Activities, permitted releases
National-Scale Air Toxics Assessment (NATA)	State-wide, with county and census tract level information	1990, 1996, 1999	Air releases, modeled ambient air concentration, exposure
Release and Pollution Prevention Report (RPPR)	State-wide: ~500 facilities	Begins 1987 best from 1993 Original Survey 1979	Release to all media
Community Right-to-Know Inventory	State-wide: ~ 20,000 facilities	1990 in database, but begins 1984?	Storage quantities
Hazsite Database (Equis)	State-wide ~8,000 sites	Electronic reporting began July 1997	Soil and ground water
Known Contaminated Sites List/	State-wide ~13,700 facilities		Location--point X,Y
Ground Water Classification Exception Areas (CEA)	State-wide ~ 1,500 areas		Location--polygon
Ground water Known Extent (CKE) Areas	State-wide ~ 100		Location--polygon
Soil Deed restrictions			Location--polygon
Historic fill			Location--polygon
Community Drinking Water Systems (including DHSS database)	4,249 public water systems DHSS 485 systems	Begins 1978	Delivered drinking water
Private Well Testing	State-wide, individual wells	New since Sept. 2002	Ambient ground water
Discharge Monitoring Reports	State-wide: ~6,700 facilities		Release to surface water
Pesticides	State-wide		Quantity of pesticides applied
Urban Air Toxics Monitoring Program (UATMP)	4 Regional sites	1989	Ambient air
Continuous Air Monitoring Network	State-wide, 28 sites		Ambient air
Photochemical Assessment Monitoring Sites (PAMS)	4 Regional sites		Ambient air
Particulate Sampling Network	23 sites (18 locations)		Ambient air
New Jersey Atmospheric Deposition Network (NJADN)	10 sites		Ambient air, $PM_{2.5}$, wet deposition

The NJDEP will use these data to develop a consolidated, multi-media database. The NJDEP will rely mostly on an existing integrated data management system, the New Jersey Environmental Management System (NJEMS) to house and compile much of the data needed to develop this database. Potentially, this database can be used in conjunction with cancer cluster surveillance. However, specific exposure data collected by the NJDEP cannot be linked to individual cancer cases with routine surveillance methods.

• State/Local Partnership

The NJDHSS and the local health departments work together to respond to cancer cluster inquiries. When cluster inquiries are brought to the attention of LHOs, the NJDHSS and the LHOs coordinate cluster investigation and collaborate in bringing concerns to resolution. To facilitate the process of communication and response to cancer clusters, training seminars have been conducted. The *Interim Cluster Response Protocol* has been distributed to all local health departments along with appropriate documentation and the NJDHSS contact numbers. Additionally, the departments work together to educate the community and individuals on cancer risk factors and to encourage healthier lifestyles and early detection.

Under the Public Health Practice Standards of Performance for Local Boards of Health (N.J.A.C. 8:52 et. seq.), the 114 local health departments have new expanded activities that include increased partnerships and collaborative efforts that could assist the NJDHSS and NJDEP. These requirements, if appropriately funded, could provide a more seamless approach involving state and local partnerships in addressing cancer cluster concerns. A copy of the *Practice Standards* can be found in Appendix I.

• Role of New Jersey’s Universities and Colleges

New Jersey’s academic community also plays an important role in cancer cluster inquiries. The academic community serves as a vital resource to the NJDHSS by providing expertise in a wide variety of subjects including the environment, medicine, working with communities, biostatistics, exposure modeling, epidemiology, geographic information systems (GIS), toxicology, and communications. The academic community often provides valuable input in community meetings on technical issues. They are often effective as a voice of authority that is independent from government. Their rich breadth of knowledge and willingness to become involved with cancer cluster issues has been an asset to the NJDHSS and the citizens of the State.

Many academic institutions have been involved with cluster methods development both in New Jersey and across the country, often with grants from the federal government. Due to the confidential nature of cancer data, the actual application of these methods is the responsibility of health departments. Often, the academic community is consulted to review the analysis formally through a peer review process or a consultative arrangement.

Another essential role of the academic community in New Jersey is the training and development of new scholars in the fields related to cancer cluster inquiries. New Jersey’s colleges and universities have a pivotal role in the future of such research. As science moves ahead in the field by improving methods and achieving greater understanding of the causes of cancer, a new generation of professionals equipped with the most sophisticated tools will be necessary.

• Role of Elected Officials

Often the concerns of citizens regarding cancer clusters are brought to the attention of local, state, or federal elected officials. These officials, in order to respond to their constituents' concerns, turn to the NJDHSS for information and assistance.

It is always helpful when elected officials have knowledge of the issues surrounding cancer clusters. It is important that they understand the known causes of cancer and which cancers are most common in New Jersey. A general understanding of the NJSCR, definitions of a cancer cluster, and the analytic issues involved will help anyone respond to citizen concerns about cancer clusters.

Developing such an understanding will help elected officials to pass citizen concerns to the NJDHSS with realistic expectations as to the analysis and results they may expect. Elected officials should listen to the concerns of the public. In response to these concerns they should choose their words carefully so as not to belittle the publics' concerns and perception of the issue at hand.

• Summary – Chapter 7: Delineation of Partner Roles

Strengths:

- There are many committed partners with expertise necessary to address cancer clusters.

Weaknesses:

- There is no central office within NJDEP for the public to contact about cancer and other health-related concerns.
- Local public health officials may not be aware of the latest research on cancer and cancer cluster methodology.
- There is a lack of consistent communication and collaboration among partners.

Recommendations:

- Designate an office within NJDEP (as in NJDHSS) to be contacted by the public about cancer and other health-related concerns.
- Develop methods to disseminate the latest research on cancer and cancer clusters to the local level.
- Foster communication and collaboration among academic institutions, public health officials, and communities regarding the development of best practices for cancer cluster response and surveillance.

SECTION III: Recommendations

Cancer Incidence Data – the NJSCR:

- Explore the feasibility of collecting complete residence history, especially for children.

- Maintain adequate funding for the NJSCR as a resource for cluster inquiries and analysis in addition to its other public health functions.

- Continue to fund expanded Behavioral Risk Factor Surveillance System data collection.

- Provide additional support to CES to improve GIS capabilities to further spatial and temporal analytic support of cancer registry data.

Responding to Suspected Cancer Clusters:

- Update and modify the *Interim Cluster Response Protocol* and SOPs to reflect changes in the *Protocol*, in the statistical tools available for cancer cluster response, and in the NJSCR (e.g. geocoded residential addresses). Especially consider including qualitative criteria in addition to p-values to trigger further investigation.

- Prepare a cancer cluster response procedures manual to accompany the *Protocol*.

- Offer additional training opportunities to the LHOs and other partners.

- Prepare a *Citizen's Guide to Cancer Clusters in New Jersey.*

- The NJDHSS should develop and implement a written protocol and procedures to address cancer cluster risk communication issues. The protocol and procedures would address risk communication with individuals, the media, elected officials, community representatives, and at public meetings.

- Develop a mechanism for the public to request an independent review of NJDHSS response to a cancer cluster inquiry. Public entities such as the New Jersey Public Health Council or ATSDR should be considered as the agency to conduct such a review.

Surveillance for Cancer Clusters:

- NJDHSS should develop a proposal for assessing the feasibility of cancer cluster surveillance based on cancer incidence data, on an appropriate geographic and temporal scale.

- NJDEP should develop integrated, geographically based and time-specific environmental exposure metrics based on permitting, monitoring and modeling. Environmental data should be linkable to cancer surveillance data to facilitate follow-up investigations and epidemiologic research studies.

Delineation of Partner Roles:

- Designate an office within NJDEP (as in NJDHSS) to be contacted by the public about cancer and other health-related concerns.

- Develop methods to disseminate the latest research on cancer and cancer clusters to the local level.

- Foster communication and collaboration among academic institutions, public health officials, and communities regarding the development of best practices for cancer cluster response and surveillance.

Continued Role of the Task Force:

- The Task Force has addressed the issues of the Commissioner’s charge; therefore, the Task Force activities *per se* are completed. However, it will be useful to reappoint the original members or a smaller committee with some of the original members of the Task Force, to oversee the progress of the implementation of the recommendations of the Task Force. In addition, there should be an annual review of cancer cluster response outcomes.

Listing of Acronyms

ACoS:	The American College of Surgeons
ACS:	The American Cancer Society
ATPM:	Association of Teachers of Preventative Medicine
BRFSS:	Behavioral Risk Factor Surveillance System
BBS:	bulletin board system
CAC:	Community Advisory Committee
CASS:	Center for Applied Social Surveys
CCR:	California Cancer Registry
CDC:	Centers for Disease Control and Prevention
CEHS:	Consumer and Environmental Health Services
CES:	Cancer Epidemiology Services
CI:	Confidence Interval
CMS:	Centers for Medicaid and Medicare Services
CSII:	Cancer Surveillance Improvement Initiative
CTR:	Certified Tumor Registrar
DA:	deliberative analysis
DCO:	death certificate only
EOD:	extent of disease
GIS:	Geographic Information System
IRB:	Institutional Review Board
LHO:	Local Health Officer
NAACCR:	North American Association of Central Cancer Registries
NCI:	National Cancer Institute
NCEH:	National Center for Environmental Health
NCRA:	National Cancer Registrars Association
NIOSH:	National Institute for Occupational Safety and Health
NJCEED:	New Jersey Cancer Education and Early Detection
NJDEP:	New Jersey Department of Environmental Protection
NJEMS:	New Jersey Environmental Management System
NJSCR:	New Jersey State Cancer Registry
NPCR:	National Program of Cancer Registries
ODIS:	Occupational Disease and Inquiry Service
OHS:	Occupational Health Services
OIT:	Office of Information Technology

ORANJ: Oncology Registrars Association of New Jersey
OSHA: Occupational Safety and Health Administration

PEOSH: Public Employees Occupational Safety and Health
PSA: prostate-specific antigen

RMCDS: Rocky Mountain Cancer Data System

SAHSU: Small Area Health Statistics Unit
SEER: Surveillance, Epidemiology and End Results
SOP: Standard Operating Procedure
SIR: standardized incidence ratio
STIS: Space-Time Information Systems

UMDNJ: University of Medicine and Dentistry of New Jersey
USGS: United States Geological Survey

VOC: volatile organic chemical

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Appendices

Appendix A

Executive Order No. 197

January 2003

SUBJECT: Task Force on Cancer Clusters in New Jersey

WHEREAS, cancer is the second leading cause of death in New Jersey, claiming over 18,000 lives each year; and

WHEREAS, over 40,000 new cases of cancer are diagnosed among New Jersey residents each year; and

WHEREAS, lung cancer is the leading cause of cancer among New Jersey men and women, followed by breast and colorectal cancer for women and prostate and colorectal cancer for men; and

WHEREAS, New Jersey residents see cancer as the most important health issue facing the State, according to a survey conducted by the Eagleton Institute; and

WHEREAS, cancer is a group of over 100 distinct diseases with different causes and many of these causes remain unknown;

WHEREAS, The New Jersey State Cancer Registry is the State's most valuable resource to study the occurrence, location and epidemiology of all cancers;

WHEREAS, notwithstanding recent advances, cancer still claims too many lives, and too many people engage in behaviors that increase their risk for cancer;

WHEREAS, it is imperative that the State accelerate its already substantial efforts in the fight against cancer by improving cancer research, prevention and treatment; and

WHEREAS, many state residents are concerned that cancer occurs in "clusters" around the state and that, there is a need to develop a coordinated approach to investigating such "clusters" in order to provide the most responsive service to residents and to educate them about the real dangers related to cancer.

NOW, THEREFORE, I, Clifton R. Lacy, M.D., Commissioner of the New Jersey Department of Health and Senior Services, by virtue of the authority vested in me do hereby ORDER and DIRECT:

A. There is hereby created within the New Jersey Department of Health and Senior Services (DHSS), the "Task Force on Cancer Clusters in New Jersey" ("Task Force").

B. This Task Force shall consist of no more than 15 members appointed by the Commissioner of Health and Senior Services from the following organizations and disciplines:

   1. Public Advocate for Cancer Clusters
   2. Public Health Council
   3. Department of Health and Senior Services
   4. Department of Environmental Protection
   5. New Jersey Local Health Officers Association
   6. Academic medical centers and universities engaged in cancer education, research and treatment
   7. Community-based organizations and coalitions engaged in cancer including risk communication experts and cancer survivors

C. Each member shall serve a term of 1 year and can serve successive terms. The members shall serve without compensation, but shall be reimbursed for necessary expenses incurred in the performance of their duties as members. The term of a member appointed to fill an unexpired vacancy will consist of only the remaining duration of the term.

D. The Commissioner shall appoint a chairperson and vice-chairperson who shall hold office for 1 year until his or her successor is appointed.

E. The Task Force shall meet as soon as practicable after the appointment of a majority of its members and shall be assisted by appropriate NJDHSS staff including, but not limited to:

   1. The State Epidemiologist/Office of the Assistant Commissioner for Epidemiology, Environmental & Occupational Health
   2. Cancer Epidemiology Services Staff
   3. Environmental Health Services Staff
   4. Occupational Health Services Staff
   5. Communications Staff

F. The Task Force shall:

   1. Evaluate current trends in cancer incidence, morbidity and mortality.

   2. Evaluate cancer cluster investigation policies, procedures, guidelines and best practices used in New Jersey and other states.

   3. Develop an integrated set of priority strategies to develop and implement best practices in New Jersey to investigate potential cancer clusters.

   4. Delineate the respective roles and responsibilities for the State and each of its partners in implementing the priority strategies identified pursuant to this Order.

   5. Annually review the findings of cancer cluster investigations to further goals of continuous quality assessment and improvement.

   6. Annually evaluate the continued role and need for the Task Force.

G. The Task Force shall report its findings and recommendations to the Commissioner of Health and Senior Services within 12 months of its organizational meeting and annually thereafter.

H. This order shall take effect immediately.

____
Clifton R. Lacy, M.D.
Commissioner

Appendix B

New Jersey State Cancer Registry Statute and Regulations

26:2-104 Legislative findings and declaration

The Legislature hereby finds and declares:

(a) That New Jersey is currently suffering from the highest overall mortality rates for cancer in the Nation;

(b) That certain forms of cancer are now believed to be attributable to environmental factors which, if controlled, can significantly reduce incidence in this State;

(c) That more complete and more precise statistical data are necessary to determine the correlations between cancer incidence and possible environmental factors and to evaluate cancer treatment and prevention measures that are currently in progress; and,

(d) That a cancer registry would thus provide a vital foundation for a concerted State effort to reduce the incidence of environmentally related cancer in this State.

L.1997, c266, s.1.

26:2-105 Establishment and maintenance; Inclusions

The Department of Health and Senior Services shall establish and maintain an up-to-date registry which shall include a record of cases of cancer and specified cases of tumorous or precancerous disease that occur in New Jersey, and such information concerning these cases as it shall deem necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of cancer and cancer-related diseases in this State and to apply appropriate preventive and control measures.

L.1977, c.266, s.2; amended 2001, c.99, s.1.

26:2-106 Reports and submissions by health care providers; rules and regulations

(a) The Commissioner of Health and Senior Services, in consultation with the Public Health Council, shall require the reporting of cases of cancer and other specified tumorous and precancerous diseases, and the submission of such specified additional information on reported cases or control populations as he deems necessary and appropriate for the recognition, prevention, cure or control of such diseases.

(b) Pursuant to subsection a. of this section, the Commissioner of Health and Senior Services is hereby authorized to adopt and promulgate, in the manner prescribed by the applicable provisions of the Administrative Procedure Act (P.L.1968,C.410;C.52:14B-1 et seq.), rules and regulations specifying the health care providers, individuals, and other organizations obliged to make the report and submissions required by subsection a. of this section, the related information to be included in such reports, and the methods for such reporting.

(c) All abstracting work performed by a health care facility in accordance with this section shall be performed by a certified tumor registrar.

(d) 1.The Department of Health and Senior Services shall contract out its registry services to health care facilities which lack adequate internal capabilities to report cases on a timely basis, as provided in the regulations adopted pursuant to this section. Such health care facilities shall reimburse the department for services rendered.

2.If a health care facility fails to correct deficiencies in its reporting that are discovered on audit by the Department of Health and Senior Services within 30 days, the department will conduct the appropriate registrar activities and charge the facility for all costs related to its services.

(e) Health insurers and other third party health care payers providing health benefits plans to residents of the State shall report to the Department of Health and Senior Services cases of cancer of State residents based upon selection criteria and in a format specified by the department.

(f) 1. A health care facility, health care provider or health insurer that fails to comply with the provisions of this section shall be liable to a penalty of up to $500 per unreported cancer case.

2. A health care facility that fails to report cases of cancer electronically, as required by regulation, within six months of the confirmed diagnosis shall be liable to a penalty not to exceed $1,000 per business day.

3. A penalty sued for under the provisions of this subsection shall be recovered by and in the name of the Department of Health and Senior Services and shall be dedicated to the cancer registry.

(g) All information reported to the Department of Health and Senior Services for inclusion in the cancer registry pursuant to this section shall be verified for accuracy by the department within six months of receiving the information and shall be incorporated in the registry. Aggregate or summary information, to include gender distribution, age groupings of cases, and cancer types, shall be made available to the public no later than six months after verification by the department. The department shall not make public any information reported to the department which discloses the identity of any person to whom the information relates.

L.1997, c.266, s.3; amended 1996, c.74, s.1; 2001, c.99, s.2.

26:2-107 Confidentiality of reports

The reports made pursuant to this act are to be used only by the State Department of Health and Senior Services and such other agencies as may be designated by the Commissioner of Health and Senior Services and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate; and to that end, such reports shall not be included under materials available to public inspection pursuant to P.L.1963,c73 (C.47:1A-1 et seq.).

L.1977, c.266, s.4; amended 2001, c.99, s.3

1/2004

26:2-108 Non-liability for divulging confidential information

No individual or organization providing information to the Department of Health and Senior Services in accordance with this act shall be deemed to be, or be held liable for, divulging confidential information.

26:2-109 Inapplicability of act to compel individuals to submit to medical or health department examination or supervision

Nothing in this act shall be construed to compel any individual to submit to medical or health department examination or supervision.

CHAPTER 57A

CANCER REGISTRY

Authority

N.J.S.A. 26:2-104 et. seq.

Source and Effective Date

R.1995 d.241, effective April 12, 2000,
See: 27 N.J.R. 629(a), 27 N.J.R. 1988(a),

Executive Order No. 66(1978) Expiration Date

Chapter 57A, Cancer Registry, expires on April 12, 2005

Chapter Historical Note

Chapter 57 A, Cancer Registry, became effective June 16, 1986, as R.1986 d2.77, as Subchapter 6 of N.J.A.C. 8:57. See: 17 N.J.R. 2836(b), 18 N.J.R. 1283(a). The text was recodified with amendments to N.J.A.C. 8:57A by R.1990 d.242 effective May 21, 1990. See: 21 N.J.R. 3909(a), 22 N.J.R. 1596(a).

Pursuant to Executive Order No. 66(1978), Chapter 57A was readopted as R.1995 d.241. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. CANCER REGISTRY

8:57A-1.1 Reporting of cancer; general requirements

(a) Cases of cancer and other specified tumorous and precancerous diseases shall be reported to the New Jersey Department of Health and Senior Services. The reportable diseases and conditions shall be specified in a listing promulgated by the Commissioner of the New Jersey Department of Health and Senior Services, at
N.J.A.C. 8:57A-1.8.

(b) All case reports shall be submitted within six months of the date of diagnosis or within three months of the date of discharge from the reporting facility, whichever is sooner.

(c) Follow-up reports shall be submitted on each cancer case at least annually to confirm the patient's vital status. These follow-up reports shall be required until the patient's death.

Amended by R.1990 d.242, effective May 21, 1990.
See: 21 N.J.R. 3909(a), 22 N.J.R. 1596(a).
Third party payers permitted to report cases to the Registry; machine readable submissions permitted.
Amended by R.1995 d.241, effective May 15, 1995.
See: 27 N.J.R. 629(a), 27 N.J.R. 1988(a).
Amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).
Rewrote the section.

8:57A-1.2 Health care facility reporting

(a) The administrative officer of every health care facility shall report to the New Jersey Department of Health and Senior Services every case of cancer or other specified tumors and precancerous disease when it is initially diagnosed or when the patient is first admitted or treated for any reason in that facility. A report shall also be submitted for each subsequent primary cancer diagnosed in that individual.

1. Health care facility means a facility as defined at N.J.S.A. 26:2H-1 et. seq. and amendments thereto.

(b) All abstracting work performed by a health care facility which diagnoses or treats 100 or more cancer cases per year shall be performed by a tumor registrar who is certified by the National Board for the Certification of Registrars, PO Box 15945-302, Lenexa, KA 66285-5945. The certified tumor registrar shall be either employed by the health care facility or employed by an abstract-coding service under contract by the health care facility.

1. The health care facility shall have until August 3, 2000 to comply with the provisions of (b) above.

(c) The information to be reported shall:

1. Be submitted electronically in a standard format which is specified by the New Jersey Department of Health and Senior Services; and

2. Include patient identifying information, medical history, cancer treatment, and an annual report to confirm the patient's vital status until the patient's death.

(d) Health care facilities which lack adequate internal capabilities to report cases in accordance with the requirements of (b) and (c) above shall contract with the New Jersey Department of Health and Senior Services to provide abstracting services.

(e) The New Jersey Department of Health and Senior Services shall charge a fee to health care facilities for the provision of services set forth at (d) above. The fee shall be based upon the fair market value of services.

(f) A health care facility which fails to comply with the provisions of this subchapter shall be liable for a penalty of up to $500.00 per unreported case of cancer or other specified tumorous and precancerous disease.

(g) A health care facility which fails to report cases of cancer or other specified tumorous and precancerous diseases electronically shall be liable to a penalty not to exceed $1,000 per business day.

Recodified from N.J.A.C. 8:57A-1.1(b) and amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903 (b).
Rewrote the section. Former N.J.A.C. 8:57A-1.2, Reportable list, was recodified to N.J.A.C. 8:57A-1.8.

8:57A-1.3 Physician, dentist, and other health care provider reporting

(a) Every physician, dentist, or other health care provider who diagnoses or provides treatment for cancer patients shall report to the New Jersey Department of Health and Senior Services an initial diagnosis of each case of cancer or other specified tumorous and precancerous disease not referred to or previously diagnosed in a health care facility in the State of New Jersey. A report shall also be submitted for each subsequent primary cancer diagnosed in that individual.

(b) The information to be reported shall:

1. Be submitted on forms specified by the New Jersey Department of Health and Senior Services; and

2. Include patient identifying information, medical history, and cancer treatment.

(c) The physician, dentist, or other health care provider may submit the reports electronically in a standard format which is specified by the New Jersey Department of Health and Senior Services.

(d) A physician, dentist or other health care provider who fails to comply with the provisions of this subchapter shall be liable for a penalty of up to $500.00 per unreported case of cancer or other specified tumorous and precancerous disease.

Recodified from N.J.A.C. 8:57A-1.1 (c) and amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759 (a), 30 N.J.R. 2903(b).
Rewrote the section.

8:57A-1.4 Clinical laboratory reporting

(a) The director of every independent clinical laboratory shall report to the New Jersey Department of Health and Senior Services the results of examinations of tissue specimens and/or hematology examinations which are positive for the existence of cancer or other specified tumorous and precancerous disease not previously reported from that laboratory.

(b) The information to be reported shall:

1. Be submitted on forms specified by the New Jersey Department of Health and Senior Services; and

2. Include all available patient identifying information and the name, address, and/or telephone number of the referring physician.

(c) The director of the independent clinical laboratory may submit the reports electronically in a standard format which is specified by the New Jersey Department of Health and Senior Services.

(d) An independent clinical laboratory which fails to comply with the provisions of this subchapter shall be liable for a penalty of up to $500.00 per unreported case of cancer or other specified tumorous and precancerous disease.

Recodified from N.J.A.C. 8:57A-1.1(d) and amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903 (b).
Rewrote the section.

8:57A-1.5 Health care insurer reporting

(a) Health care insurers and other third party health care payers providing benefit plans to residents of the State may report to the New Jersey Department of Health and Senior Services cases of cancer or other specified tumorous and precancerous diseases based upon selection criteria specified by the Cancer Registry.

(b) If reported, the information shall:

1. Be submitted on forms specified by the New Jersey Department of Health and Senior Services; and

2. Include patient identifying information, medical history, cancer treatment, and an annual report to confirm the patient's vital status until the patient's death.

(c) Health care insurers and other third party health care payers providing benefit plans to residents of the State may submit the reports electronically in a standard format which is specified by the New Jersey Department of Health and Senior Services.

Recodified from N.J.A.C. 8:57A-1.1(e) and amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).
Rewrote the section.

8:57A-1.6 Supplemental information

Information necessary to clarify medical or demographic data shall be supplied upon request of the New Jersey Department of Health and Senior Services. This supplemental information shall include, but not be limited to: copies of pathology and/or hematology reports, operative reports, treatment information, history and physical sections of the medical records, and discharge summaries.

Recodified from N.J.A.C. 8:57A-1.1(f) and amended by R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J. R. 2903(b).
Rewrote the section.

8:57A1-7. Access to information and records

(a) Every health care facility, independent clinical laboratory, physician, dentist, or other health care provider who diagnoses or provides treatment for cancer patients and health care insurers and other third party health care payers providing benefit plans to residents of the State shall allow representatives of the New Jersey Department of Health and Senior Services to obtain information from all medical, pathological, and other pertinent records and logs related to cancer cases, as necessary for fulfilling the functions of the cancer registry program.

(b) Every health care facility, independent clinical laboratory, physician, dentist, or other health care provider who diagnoses or provides treatment for cancer patients and health care insurers and other third party health care payers providing benefit plans to residents of the State shall permit representatives of the New Jersey Department of Health and Senior Services access to information or provide necessary information on specified cancer patients and other patients specified by characteristics for research studies related to cancer etiology, prevention, and control which are conducted by the New Jersey Department of Health and Senior Services. These studies, shall have been approved by the Commissioner of the New Jersey Department of Health and Senior Services after appropriate review to assure protection of human subjects. This access or provision of information shall include patients who came under the care of the health care facility, physician, dentist, or other health care provider prior to November 18, 1977.

(c) The reports made pursuant to this subchapter shall be used only by the New Jersey Department of Health and Senior Services and such other agencies as may be designated by the Commissioner of the New Jersey Department of Health and Senior Services. These reports shall not be otherwise divulged or made public. Such reports shall not be subject to public inspection and copying pursuant to the Right-to-Know Act, N.J.S.A. 47:1A-1 et seq.

(d) No individual or organization providing information to the New Jersey Department of Health and Senior Services in accordance with this subchapter shall be deemed to be, or held liable for, divulging confidential information.

(e) Any individual or organization which reveals or discloses any information or data in violation of (c) above shall be the subject of penalties as permitted by law. All violations shall be reported to the appropriate professional licensing authorities and public financing programs.

(f) Failures to permit access to information and records to representatives of the New Jersey Department of Health and Senior Services shall be cause for the imposition of penalties as permitted by law.

Recodified from N.J.A.C. 8:57A-1.1(i) and (j) and amended by R.1998 d.393, effective August 3, 1998.

See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).
Rewrote the section.

8:57A-1.8 List of reportable diseases and conditions

(a) If a diagnosis includes any of the following words, the case shall be reported to the New Jersey Department of Health and Senior Services in accordance with the provisions of this subchapter:

Cancer;
Carcinoma;
Leukemia;
Malignant; and/or
Sarcoma.

(b) Any case having a diagnosis listed at (g) below and which contains any of the following terms in the final diagnosis shall be reported to the New Jersey Department of Health and Senior Services in accordance with the provisions of this subchapter:

Compatible with;
Consistent with;
Most likely;
Probable;
Suspect; and/or
Suspicious.

(c) Basal cell carcinomas of the skin shall not be reported to the New Jersey Department of Health and Senior Services except when they are diagnosed in the labia, clitoris, vulva, prepuce, penis, or scrotum.

(d) Carcinoma *in situ* of the cervix shall not be reported to the New Jersey Department of Health and Senior Services.

(e) Insofar as soft tissue tumors can arise in almost any body site, the primary site of the soft tissue tumor shall also be examined for any questionable neoplasm.

(f) If any uncertainty regarding the reporting of a particular case exists, the New Jersey Department of Health and Senior Services shall be contacted for guidance.

(g) Every New Jersey health care facility, physician, dentist, other health care provider, or independent clinical laboratory shall report the following conditions to the New Jersey Department of Health and Senior Services in accordance with the provisions of this subchapter:

ADRENAL
- Adrenal cortical carcinoma
- Ganglioneuroblastoma
- Neuroblastoma
- Neuroendocrine carcinoma
- Neuroepithelioma
- Paraganglioma (+)
- Pheochromocytoma, malignant only
- Sympathicoblastoma

ANUS (see G-I tract)
APPENDIX (see G-I tract)

BILE DUCTS (see gall bladder and bile ducts)

BLOOD (see Hematopoietic/Lymphoid)

BLOOD VESSELS (see soft tissues)

BONE AND JOINTS
- Adamantinoma
- Ameloblastoma, malignant
- Angioblastoma (+)
- Angiosarcoma
- Chondrosarcoma

- Chordoma
- Ewing's Sarcoma
- Fibrosarcoma (medullary, periosteal, central, endosteal)
- Giant cell tumor of bone (+)
- Giant cell tumor, malignant
- Hemangioendothelioma, malignant
- Mesenchymal chondrosarcoma
- Myeloma
- Osteoclastoma (+)
- Osteogenic Sarcoma
- Osteosarcoma
- Periosteal osteoma
- Plasmacytoma

BONE MARROW (see Hematopoietic/Lymphoid)

BRAIN, SPINAL CORD, CRANIAL NERVES MENINGES, CNS

- Acoustic neuroma (O)
- Angiolipoma (O)
- Angiomatous meningioma (O)
- Astroblastoma
- Astrocytoma (any type)
- Atypical choroid plexus papilloma (+)
- Atypical lipoma (+)
- Atypical meningioma (+)
- Capillary hemangioma (O)
- Cavernous hemangioma (O)
- Central neurocytoma (+)
- Chordoid glioma (+)
- Chordoid plexus papilloma, malignant
- Choroid plexus papilloma (O)
- Clear cell meningioma (+)
- Dermoid cyst (O)
- Desmoplastic infantile astrocytoma (+)
- Diffuse melanocytosis (O)
- Dysembryoplastic neuroepithelial tumor (O)
- Dyplastic gangliocytoma of cerebellum (O) (Lhermitte-Ducios)
- Ependymoblastoma
- Ependymoma
- Fibrolipoma (O)
- Fibroma (O)
- Fibrous meningioma (O)
- Gangliocytoma (O)
- Ganglioglioma (+)
- Ganglioneuroblastoma
- Ganglioneuroma (O)
- Germinoma
- Glioblastoma multiforme
- Gliofibroma (+)
- Glioma, all types
- Gliomatosis cerebri (+)
- Hemangioblastoma (+)
- Hemangioendothelioma, benign (O)
- Hemangioendothelioma (+)
- Hemangioma (O)
- Hemangiopericytoma, benign (O)
- Hemangiopericytoma (+)
- Hemangiopericytoma, malignant
- Leiomyoma (O)
- Leiomyomatosis (+)
- Lipoma (O)
- Medulloblastoma

Medulloepithelioma (O)
Melanotic neurofibroma (O)
Meningeal melanocytoma (+)
Meningioma, malignant
Meningioma (O)
Meningiomatosis (+)
Meningiotheliomatous meningioma (O)
Meningiothelial meningioma (O)
Myxopapillary ependymoma (+)
Neoplasm, benign (O)
Neoplasm, uncertain whether benign or malignant (+)
Neurilemoma (O)
Neurinomatosis (+)
Neuroblastoma
Neurofibroma (O)
Neurofibromatosis (+)
Neuroma (O)
Neurothekeoma (O)
Oligodendrocytoma or
  Oligodendroblastoma
Oligodendroglioma
Papillary meningioma
Paraganglioma (+)
Perineurioma (O)
Pineal teratoma, malignant
Pinealoma
Pineoblastoma
Pineocytoma
Plexiform neurofibroma (O)
Polarespongioblastoma
Psammomatous meningioma (O)
Rhabdomyoma (O)
Schwannoma (any)
Smooth muscle tumor (+)
Soft tissue tumor, benign (O)
Solitary fibrous tumor (O)
Spongioblastoma
Subependymal astrocytoma
Subependymal giant cell astroctyoma (+)
Subependymoma (+)
Teratoma, benign (O)
Teratoma (+)
Transitional meningioma (O)
Tumor cells, benign (O)
Tumor cells, malignant
Venous hemangioma (O)

BREAST

Adenocarcinoma
Apocrine carcinoma
Colloid carcinoma
Comedocarcinoma
Cribriform carcinoma
Cystosarcoma phyllodes, malignant only
Ductal carcinoma, in situ
Fibroadenoma, malignant only
Glycogen rich carcinoma
Infiltrating carcinoma of the breast such as:
    Carcinoma, NOS
    Duct adenocarcinoma
    Duct and lobular
    Duct carcinoma
    Duct and Paget's disease
    Ductular

    - Lobular
    - Lipid-rich carcinoma
    - Lobular carcinoma, in situ
    - Lobular and intraductal, in situ
    - Lobular neoplasia
    - Medullary carcinoma
    - Papillary carcinoma, in situ
    - Paget's disease
    - Phyllodes tumor, malignant
    - Stromal sarcoma of breast
    - Tubular carcinoma

BRONCHUS (see lung)

CERVIX (see uterus)

COLON (see G-I tract)

EAR (see skin, soft tissue)

ENDOMETRIUM (see uterus)

ESOPHAGUS (see G-I tract)

EYE
- Epidermoid carcinoma
- Melanoma, malignant
- Retinoblastoma
- Squamous cell carcinoma
- Squamous cell epithelioma
- (Tumors of the orbit:
See soft tissues and Hematopoietic/Lymphoid)

EXTRA-ADRENAL PARAGANGLIA (see adrenal)

FALLOPIAN TUBE (see uterus)

GALL BLADDER AND BILE DUCTS
- Adenocarcinoma
- Carcinoma (other)

GASTRO-INTESTINAL TRACT
(esophagus, stomach, intestine, appendix, colon, anus)
- Adenoacanthoma
- Adenocarcinoma
- Adenoidcystic carcinoma
- (Adeno) carcinoma in Adenomatous
  polyp with or without invasion of stalk
- Adenosarcoma
- AIN
- Apudoma (+)
- Argentaffinoma (+)
- Bowen's disease of anus
- Carcinoid (except benign - e.g. appendix)
- Carcinosarcoma
- Cloacogenic carcinoma
- Epidermoid carcinoma
- Gastrinoma (+)
- Immunoproliferative disease, small intestinal
- Kaposi's Sarcoma
- Leiomyocarcoma, malignant only
- Lenitis plastica
- Lymphoma
- Mixed tumor or esophagus, malignant only

- Neuroendocrine carcinoma
- Paget's disease of anus
- Polypoid adenoma, malignant only
- Signet ring cell car inoma
- Squamous cell carcinoma
- Squamous cell epithelioma
- Transitional cell carcinoma

HEMATOPOIETIC/LYMPHOID (Including blood, bone marrow, lymph nodes, spleen, and tumors of hematopoietic or lymphoid histogenesis found in other sites.)

- Acute erythremic myelosis
- Acute megakaryocytic myelosis
- Chronic myeloproliferative disease
- DiGuglielmo's syndrome
- Erythroleukemia
- Essential thrombocythemia
- Gamma heavy chain disease (Franklin's Disease)
- Histiocytic medullary reticulosis
- Histiocytosis, malignant
- Histiocytosis-X, malignant only
- Hodgkin's Disease, all such as:
    - Histiocyte predominant
    - Lymphocyte depleted
    - Lymphocyte predominant
    - Mixed cellularity
    - Nodular sclerosing
- Hypereosinophilic syndrome
- Idiopathic thrombocythemia
- Immunoproliferative Disease, NOS
- Letterer-Siwe's Disease
- Leukemia, all
- Leukemic reticuloendotheliosis
- Lymphoma, all
- Lymphosarcoma
- Lymphoreticular process, malignant
- Megakaryocytosis, malignant
- Multiple myeloma
- Mycosis fungoides
- Myelodysplastic syndrome, 5q- syndrome
- Myelofibrosis with myeloid metaplasia, malignant only
- Myeloma
- Myeloproliferative disease (+)
- Myelosclerosis
- Panmyelosis, acute
- Polycythemia Vera
- Refractory anemia
- Reticulosis, malignant
- Reticulum cell sarcoma
- Sezary's disease or syndrome
- Therapy related myelodysplastic syndrome
- Waldenstrom's macroglobulinemia or syndrome

HYPOPHARYNX (See oral cavity)

KIDNEY

- Adenocarcinoma
- Adenomyosarcoma
- Clear cell carcinoma
- Hypernephroma
- Nephroblastoma
- Renal cell carcinoma
- Squamous cell carcinoma
- Transitional cell carcinoma

- Tubular adenoma, borderline or malignant only
- Wilms's Tumor

LARYNX AND TRACHEA

- Adenocarcinoma
- Adenocystic carcinoma
- Cylindroma
- Squamous cell carcinoma

LIP (see oral cavity)

LIVER

- Angiosarcoma
- Bile duct carcinoma
- Cholangiocarcinoma
- Hepatoblastoma
- Hepatocellular carcinoma
- Hepatoma, malignant only

LUNG AND BRONCHUS

- Adenocarcinoma
- Adenoid cystic carcinoma
- Apudoma (+)
- Argentaffinoma (+)
- Bronchial adenoma (+)
- Bronchial adenoma (carcinoid type)
- Cylindroma
- Epidermoid carcinoma
- Intravascular bronchial alveolar tumor
- Large cell (anaplastic) carcinoma
- Neuroendocrine carcinoma
- Oat cell carcinoma
- Pulmonary blastoma
- Small cell (anaplastic) carcinoma
- Squamous cell carcinoma
- Undifferentiated carcinoma

LYMPH NODE (See Hematopoietic/Lymphoid)

MEDIASTINUM
(see Hematopoietic/Lymphoid, soft tissue, or thymus)

MENINGES (see brain)

MUSCLE (see soft tissue)

NERVE (see soft tissue)

NOSE (Nasal cavity, Para-nasal sinus and Nasopharynx)

- Adenocarcinoma
- Epidermoid carcinoma
- Esthesioneuroblastoma
- Lymphoepithelioma
- Mesenchymoma, malignant
- Neuroblastoma
- Rhabdomyosarcoma
- Sarcoma botryoides
- Squamous cell carcinoma

ORAL CAVITY AND SALIVARY GLANDS

- Adenocarcinoma
- Adenoid cystic carcinoma
- Acinic cell carcinoma
- Acinic cell tumor (+)

Cylindroma
Epidermoid carcinoma
Lymphoepithelioma
Melanoma
Mixed tumor, salivary gland type, malignant only
Mucoepidermoid carcinoma
Mucoepidermoid tumor (+)
Pleomorphic adenoma, malignant only
Squamous cell carcinoma
Transitional cell carcinoma
Undifferentiated carcinoma
Verrucous carcinoma

OROPHARYNX (see oral cavity)

OVARY
Adenocarcinoma, NOS
Arrhenoblastoma, malignant
Brenner tumor, malignant only
Choriocarcinoma
Clear cell carcinoma
Dysgerminoma
Embryonal carcinoma
Endodermal sinus tumor
Endometrioid carcinoma
Granulosa cell tumor (+)
Granulosa cell carcinoma
Granulosa cell tumor, malignant
Granulosa-theca cell tumor (+)
Gonadoblastoma (+)
Gynandroblastoma (+)
Leydig cell tumor, malignant
Mesonephroid carcinoma
Mucinous cystadenoma, borderline malignancy (pseudomucinous cystadenoma, borderline malignancy) (+)
Mucinous cystadenocarcinoma
Mucinous cystic tumor of borderline malignancy (+)
Mucinous papillary cystadenoma of borderline malignancy (+)
Mucinous papillary cystadenoma with low malignant potential (+)
Papillary cystadenoma, borderline malignancy (+)
Papillary mucinous cystadenoma, borderline malignancy (+)
Papillary mucinous tumor of low malignant potential (+)
Papillary serous cystadenoma, borderline malignancy (+)
(papillary serous tumor of low malignant potential)
Papillary serous cystadenocarcinoma
Pseudomucinous cystadenocarcinoma
Seminoma
Serous cystadenoma, borderline malignancy (+)
Serous papillary cystadenocarcinoma
Serous papillary cystadenoma of borderline malignancy (+)
Serous papillary cystadenoma with low malignant potential (+)
Serous papillary cystic tumor borderline malignancy (+)
Sertoli-leydig cell carcinoma
Teratoma, malignant
Theca-granulosa cell tumor (+)
Yolk-sac tumor

PANCREAS
Adenocarcinoma
Cystadenocarcinoma
Gastrinoma (+)
Glucagonoma, malignant only
Islet cell adenoma (+)
Islet cell carcinoma

Pancreatoblastoma
Papillary cystic tumor (+)
Squamous cell carcinoma

PARAGANGLIA
Non-chromaffin paraganglioma (+)
(see also adrenal gland)

PARATHYROID
Carcinoma, all

PARANASAL SINUSES (see nose)

PENIS
Basal cell carcinoma of Penis and Prepuce (skin of)
Bowen's disease
Erythroplasia of Queyrat
Squamous cell carcinoma
Verrucous carcinoma

PERICARDIUM (see pleura)

PERITONEUM (see pleura)

PHARYNX (see oral cavity)

PINEAL
Dermoid cyst (O)
Epithelial tumor, benign (O)
Gangliocytoma (O)
Ganglioglioma (+)
Neoplasm, benign (O)
Pinealoma (+)
Pineoblastoma
Pineocytoma (+)
Teratoma, benign (O)
Teratoma (+)

PITUITARY and CRANIOPHARYNGEAL DUCT
Acidophil adenoma (O)
Adamanthinomatous craniopharyngioma (+)
Adenoma (O)
Basophil adenoma (O)
Chromophobe adenoma (O)
Clear cell adenoma (O)
Clear cell tumor (O)
Craniopharyngioma (any type) (+)
Craniopharyngioma, malignant
Epithelial tumor, benign (O)
Granular cell tumor (O)
Lipoma (O)
Mixed acidophil-basophil adenoma (O)
Mixed cell adenoma (O)
Monomorphic adenoma (O)
Neoplasm, uncertain (+)
Neoplasm, benign (O)
Oxyphilic adenoma (O)
Papillary adenoma (O)
Papillary craniopharyngioma (+)
Pituitary adenoma (O)
Prolactinoma (O)
Rathke Pouch tumor (+)
Soft tissue tumor, benign (O)
Teratoma, benign (O)

Teratoma (+)
Tumor cells, benign or uncertain

PLACENTA

Choriocarcinoma
Chorioepithelioma
Hydatiform mole, malignant (+)
Invasive mole (+)

PLEURA, PERITONEUM, PERICARDIUM

Fibrosarcoma
Mesothelioma
Sarcoma

PROSTATE AND SEMINAL VESICLE

Adenocarcinoma
Adenoid cystic carcinoma
Alveolar rhabdomyosarcoma
Carcinosarcoma
Endometrioid carcinoma
Rhabdomyosarcoma

RECTUM (see G-I Tract)

SALIVARY GLANDS (see oral cavity)

SKIN

Amelanotic melanoma
Basal cell carcinoma of labia, clitoris, vulva, prepuce, penis and scrotum
Bowen's disease of anus and penis
Hutchinson's melanotic freckle
Lentigo maligna
Melanocarcinoma
Melanoma
Melanosarcoma
Merkel cell tumor
Mycosis Fungoides
Pilomatrix carcinoma
Squamous cell carcinoma with regional or distant spread only
Superficial spreading melanoma
Sweat gland carcinoma

SOFT TISSUE (Including retroperitoneum, peripheral nerve)

Alveolar rhabdomyosarcoma
Alveolar soft parts sarcoma
Angiofibrosarcoma
Angiosarcoma
Angiomyxoma (+)
Chondrosarcoma
Clear cell sarcoma of tendons
Dermatofibrosarcoma protuberans
Embryonal rhabdomyosarcoma
Fibromyxosarcoma
Fibrosarcoma
Fibrous histiocytoma, malignant
Granular cell tumor, malignant
Hemangioendothelial sarcoma
Hemangioendothelioma, malignant only
Hemangiopericytoma, malignant only
Juvenile rhabdomyosarcoma
Kaposi's sarcoma
Leiomyosarcoma
Liposarcoma
Lymphangioendothelioma, malignant

Lymphangiosarcoma
Mesenchymoma, malignant
Metastasizing leiomyoma (+)
Myosarcoma
Myxosarcoma
Neuroblastoma
Neurogenic sarcoma
Neurilemmoma, malignant
Neurilemmosarcoma
Osteosarcoma
Paraganglioma, malignant
Pigmented dermatofibrosarcoma protuberans Bednar tumor
Reticulum cell sarcoma
Rhabdomyoma, malignant
Rhabdomyosarcoma
Sarcoma botryoides
Schwannoma, malignant
Schwannoma, malignant with rhabdomyoblastomatous differentiation
Synovial sarcoma
Xanthofibroma, malignant

SPINAL CORD (see brain)

SPLEEN (see Hematopoietic/Lymphoid)

STOMACH (see G-I Tract)

TESTIS
Carcinoid tumor (+)
Choriocarcinoma
Chorioepithelioma
Embryoma
Embroyonal carcinoma
Emroyonal teratomaa
Endodermal sinus tumor
Germ cell carcinoma
Gonadal stromal tumor, malignant only
Gonadoblastoma (+)
Interstitial cell carcinoma
Leydig cell carcinoma
Mesonephric adenocarcinoma (infantile, juvenile embryonal carcinoma)
Polyembryoma
Seminoma
Sertoli cell carcinoma
Spermatoblastoma
Spermatocyctic seminoma
Spermatocytoma
Teratoblastoma
Teratocarcinoma
Vitelline tumor
Yolk sac tumor

THYMUS
Epithelioid thymoma, malignant only
Lymphocytic thymoma, malignant only
Seminoma
Spindle cell thymoma, malignant only
Thymic carcinoid
Thymoma, malignant

THYROID
Adenocarcinoma

Anaplastic carcinoma
Follicular carcinoma
Giant cell carcinoma
Hurthle cell adenoma, malignant only
Hurthle cell tumor, malignant only
Medulllary carcinoma
Occult sclerosing carcinoma
Papillary carcinoma = papillary adenocarcinoma
Undifferentiated carcinoma

TRACHEA (see Larynx)

URINARY BLADDER, URETER, URETHRA
Adenocarcinoma
Adenosarcoma
Carcinosarcoma
Chemodectoma, malignant only
Mullerian mixed tumors
Papillary transitional cell carcinoma
Paraganglioma (+)
Pheochromocytoma, malignant only
Rhabdomyosarcoma
Squamous cell carcinoma
Transitional cell carcinoma

UTERUS, UTERINE TUBES, CERVIX
Adenoacanthoma
Adenocarcinoma
Adenosarcoma
Adenosquamous carcinoma
Endolymphatic stromal myosis
Endometrial stromal sarcoma
Endometrioid carcinoma
Leiomyosarcoma
Mesonephric carcinoma
Mixed mesodermal tumor
Squamous cell carcinoma

VULVA AND VAGINA
Basal cell carcinoma of vulva, clitoris, and labia
Clear cell carcinoma
Mesonephroid carcinoma
Paget's disease
Squamous cell carcinoma
VAIN III
VIN III

NOTE: The following superscript indicates the nature of the other than overtly malignant reportable tumors listed:

(+) Borderline, reportable
(O) Benign, reportable

Amended by R.1990 d.242, effective May 21, 1990.
See: 21 N.J.R. 3909(a), 22 N.J.R. 1596(a).
Fourteen conditions added to list.
Repeal and New Rule, R.1995 d.241, effective May 15, 1995.
See: 27 N.J.R. 629(a), 27 N.J.R. 1998(a).
Recodified from N.J.A.C. 8:57A-1.2 and amended by R.1998 d.393, effective August 3. 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).
Rewrote the section.

8:57A-1.9 Audit, notice of violations, and enforcement actions

(a) A health care facility, physician's, dentist's, other health care provider's office, or independent clinical laboratory shall be subject to audit at the discretion of the Commissioner by authorized representatives of the New Jersey Department of Health and Senior Services.

(b) The New Jersey Department of Health and Senior Services shall evaluate completeness and timeliness of reporting as specified by this chapter. Records which shall be reviewed shall include, but not be limited to: medical records, diagnostic indices; such as, radiation, laboratory, cytology, and/or pathology reports, and discharge records.

(c) The audit shall be conducted during normal operating hours.

(d) A deficiency may be cited upon a determination that the health care facility, physician's, dentist's, other health care provider's office, or independent clinical laboratory does not comply with the reporting requirements to this chapter.

(e) At the conclusion of the audit or within 10 business days thereafter, the New Jersey Department of Health and Senior Services shall provide the health care facility, physician's, dentist's, other health care provider's office, or independent clinical laboratory with a written summary of any factual findings used as a basis to determine that reporting has not been complete or timely. This notice shall set forth the proposed assessment of civil monetary penalties, setting forth the specific reasons for the action. Such notice shall be served on a facility, physician, dentist, other health care provider, or independent clinical laboratory or its, his or her registered agent in person or by certified mail.

(f) A health care facility, physician, dentist, other health care provider, or independent clinical laboratory shall have 30 business days in which to correct all deficiencies in its reporting that were discovered during the audit.

1. If a health care facility, physician, dentist, other health care provider, or independent clinical laboratory fails to correct deficiencies in its reporting that were discovered during the audit within 30 days, the New Jersey Department of Health and Senior Services will act as registrar and shall charge the facility, physician, dentist, other health care provider, or independent clinical laboratory for all costs related to these services, including, but not limited to, the retrieval of case information and the cost of the audit. This fee shall be based upon the fair market value of such services.

i. All checks for fees for the Department's audit services shall be made payable to Treasurer, State of New Jersey and forwarded to:

Cancer Epidemiology Services
New Jersey State Cancer Registry
New Jersey Department of Health and Senior Services
PO Box 369
Trenton, New Jersey 08625-0369

New Rule, R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903 (b).

8:57A-1.10 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2-106f(3) and notwithstanding the provisions of N.J.A.C. 8:57A-1.9(f)1 above, the Commissioner may assess a penalty for violation of reporting requirements in accordance with the following standards:

1. For failure of a health care facility, physician, dentist, other health care provider, or independent clinical laboratory to report pursuant to the provisions of this chapter, up to $500.00 per unreported case of cancer or other specified tumorous and precancerous disease; and/or

2. For failure of a health care facility to report electronically, up to $1,000 per business day.

(b) The Department may decrease the penalties in (a) above based upon compliance history, the number and frequency of the deficiencies, the measures taken to mitigate or prevent future deficiencies, the deterrent effect of the penalty, and/or other specific circumstances of the facility or violation.

New Rule, R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a). 30 N.J.R. 2903(b).

8:57A-1.11 Effective date of enforcement action

The assessment of civil monetary penalties shall become effective 30 days after the date of mailing or the date personally served, unless the health care facility, physician, dentist, other health care provider, or independent clinical laboratory files with the Department a written answer to the charges and gives written notice to the Department of its desire for a hearing. In this case, the assessment shall be held in abeyance until the administrative hearing has been conducted and a final decision is rendered by the Commissioner. Hearings shall be conducted in accordance with N.J.A.C. 8:57A-1.13.

New Rule, R.1998 d.393, effective August 3, 1998.

See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).

8:57A-1.12 Failure to pay a penalty; remedies

(a) Upon receipt of a Notice of Proposed Assessment of a Penalty, a health care facility, physician, dentist, other health care provider, or independent clinical laboratory has 30 days in which to notify the Department of its request for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

(b) The penalty becomes due and owing upon the 30th day from receipt of the Notice of Proposed Assessment of Penalties if a notice requesting a hearing has not been received by the Department. If a hearing has been requested, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner, if the Department's assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the Appellate Division pursuant to Rule 2:2-3 of the New Jersey Court Rules.

(c) Failure to pay a penalty within 30 days of the date it is due and owing pursuant to (b) above may result in the institution of a summary civil proceeding by the State pursuant to the Penalty Enforcement Law,
N.J.S.A. 2A:58-1 et seq.

New Rule, R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).

8:57A-1.13 Hearings

(a) Upon request, a hearing shall be afforded to a health care facility, physician, dentist, other health care provider, or independent clinical laboratory pursuant to N.J.A.C. 8:57A-1.9.

(b) A health care facility, physician, dentist, other health care provider, independent clinical laboratory shall notify the Department, in writing, of its request for a hearing within 30 days of receipt of a Notice of Proposed Assessment of Penalties.

(c) The Department shall transmit the hearing request to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et. seq., and the Uniform Administrative Procedure Rules,
N.J.A.C. 1.1.

New Rule, R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).

8:57A-1.14 Settlement of enforcement actions

(a) A health care facility, physician, dentist, other health care provider, or independent clinical laboratory may request that the matter be settled in lieu of conducting an administrative hearing concerning an enforcement action.

(b) If the Department and the health care facility, physician, dentist, other health care provider, or independent clinical laboratory agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) The Department may agree to accept payment of penalties over a schedule not exceeding 18 months where a health care facility, physician, dentist, other health care provider, or independent clinical laboratory demonstrates financial hardship.

(d) All funds received in payment of penalties shall be recovered by and in the name of the Department and shall be dedicated to the New Jersey State Cancer Registry.

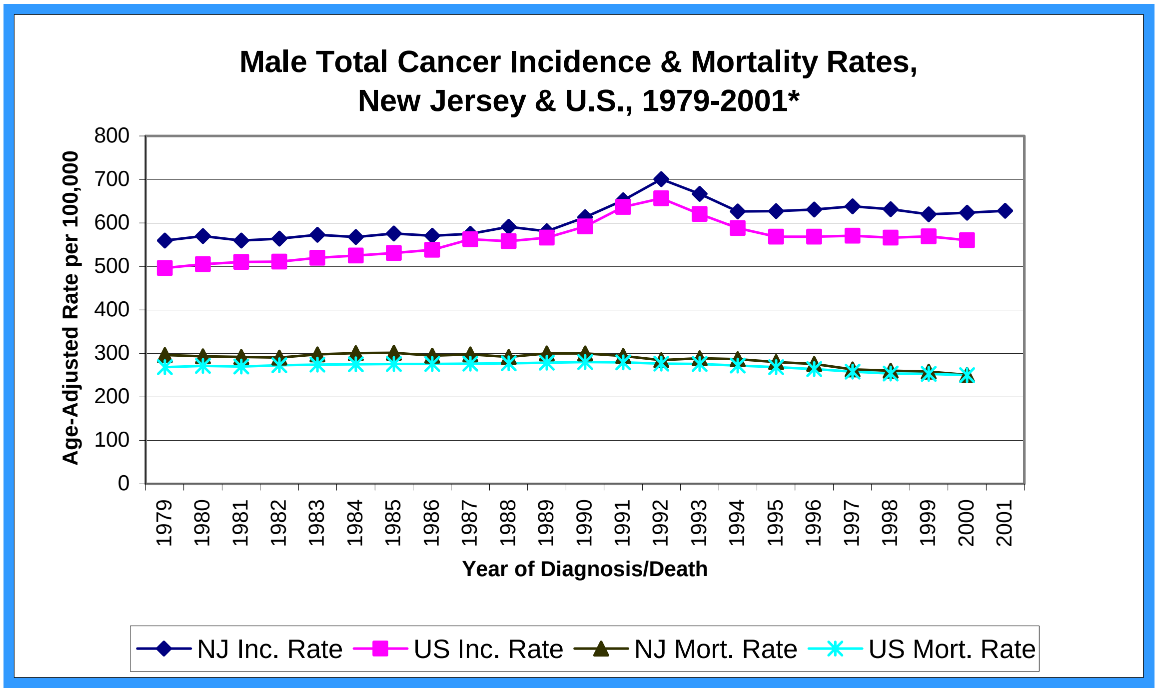
New Rule, R.1998 d.393, effective August 3, 1998.
See: 29 N.J.R. 2759(a), 30 N.J.R. 2903(b).

Appendix C

Trends in Cancer Incidence and Mortality in New Jersey and the U.S.

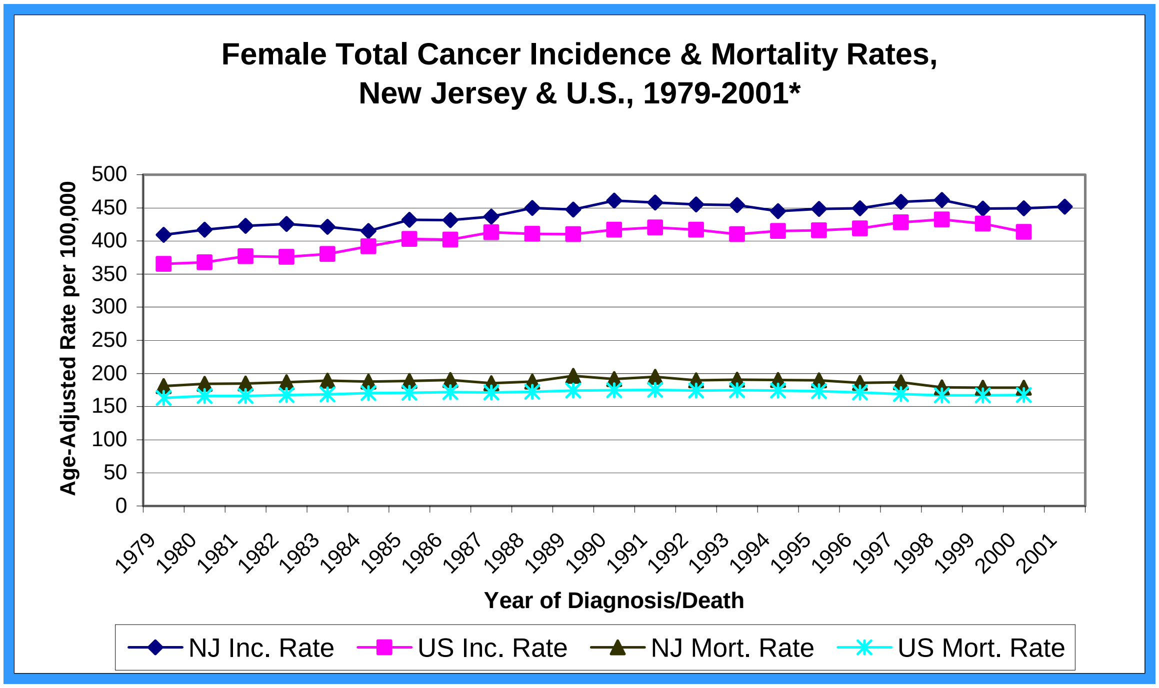
Trends in Cancer Incidence and
Mortality in New Jersey
and the US

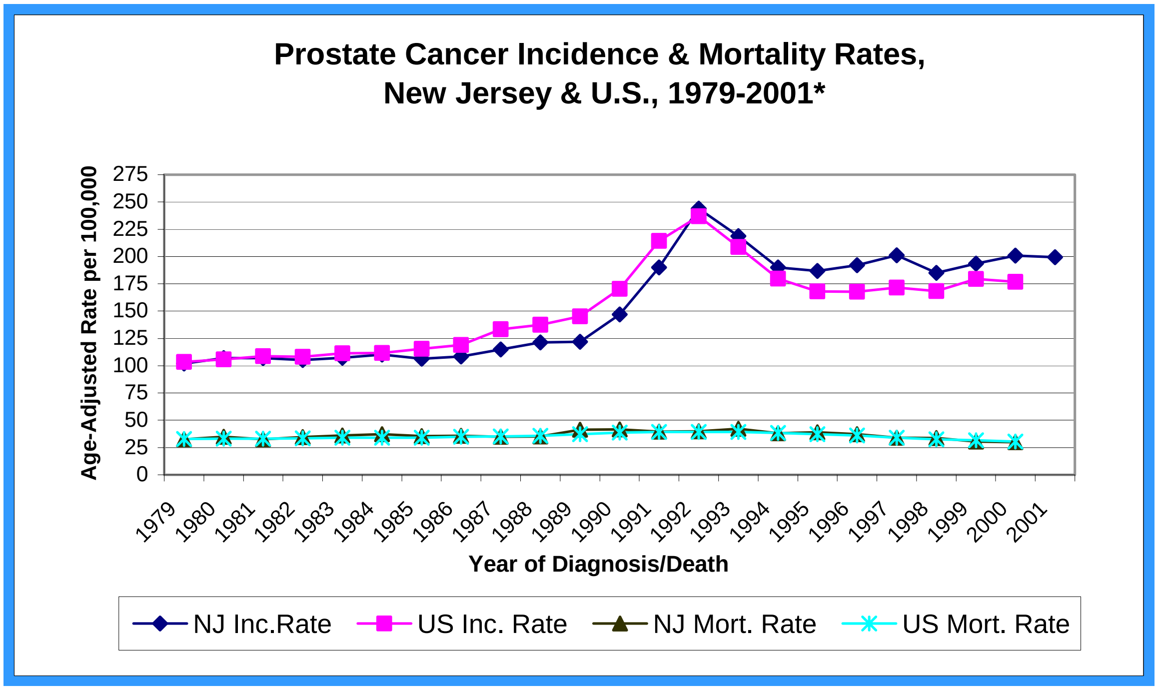
1979 - 2001



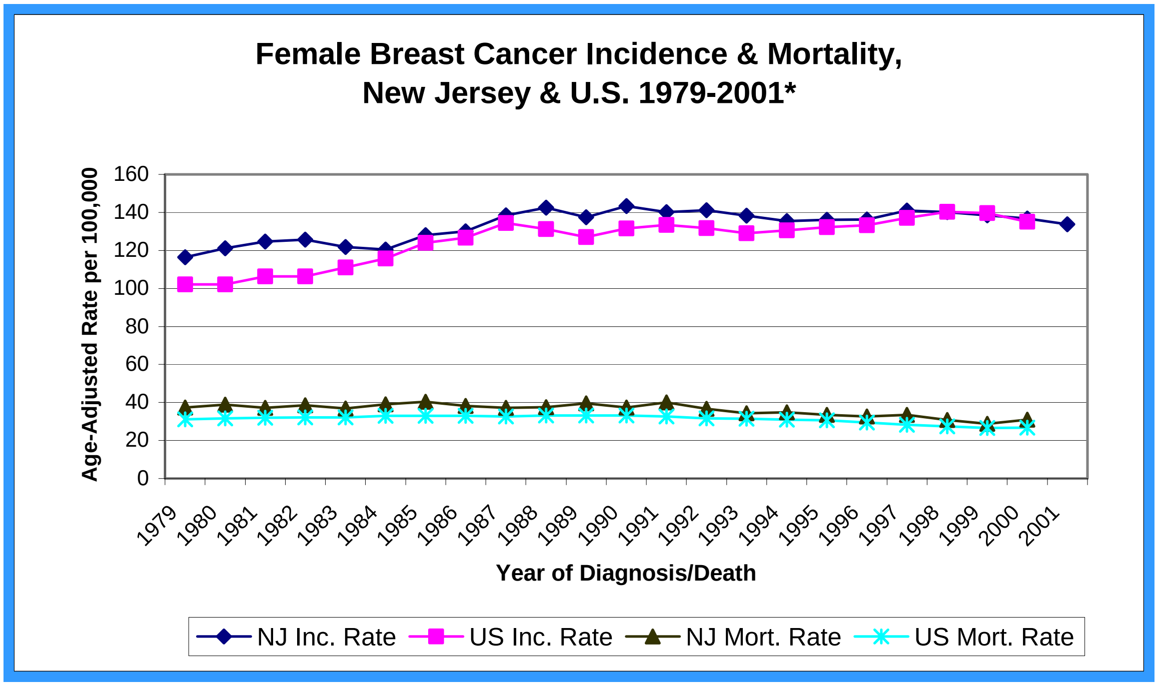
Male Total Cancer Incidence & Mortality Rates, New Jersey & U.S., 1979-2001*

*2001 data are preliminary





*2001 data are preliminary



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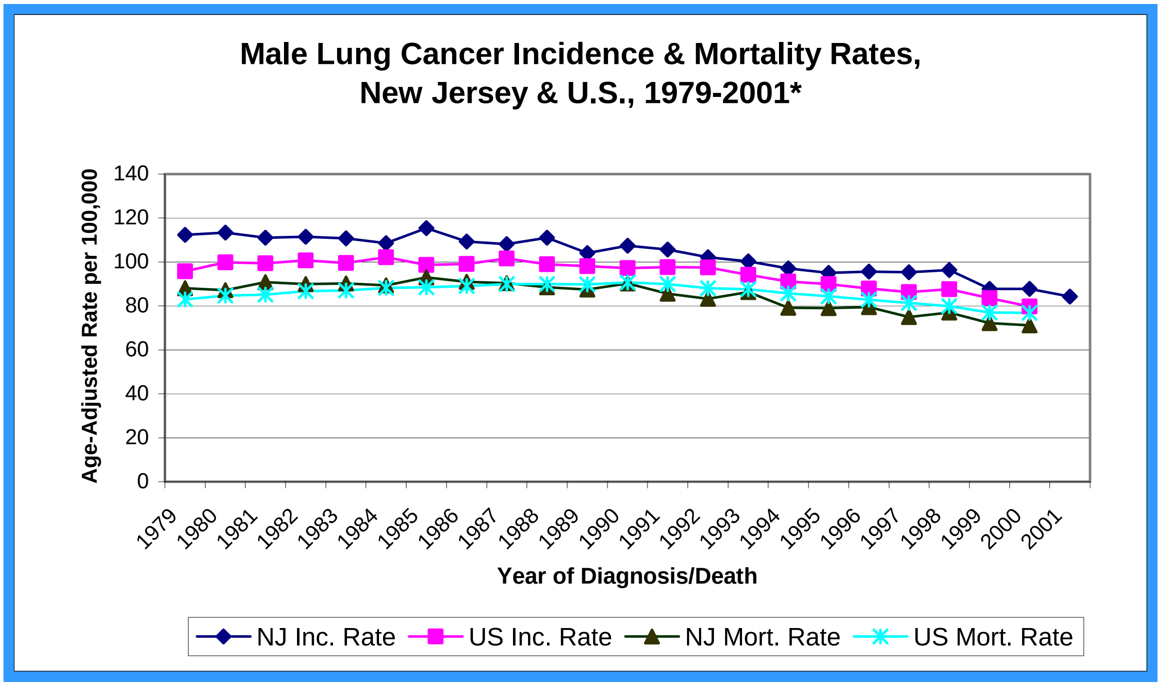
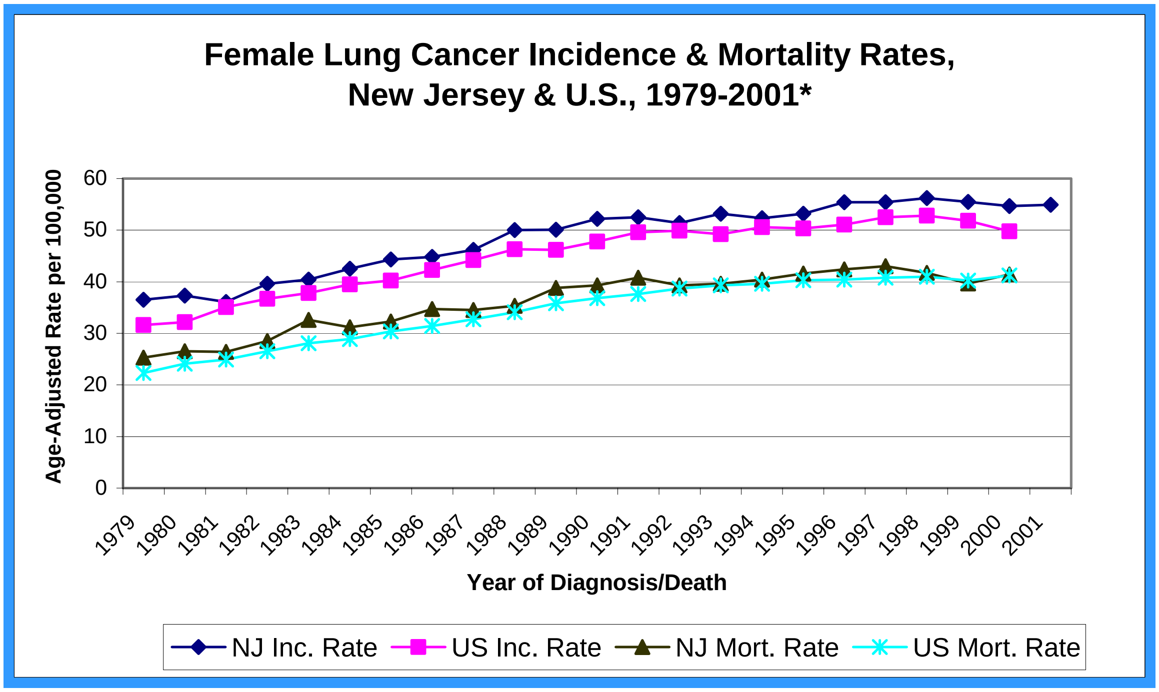
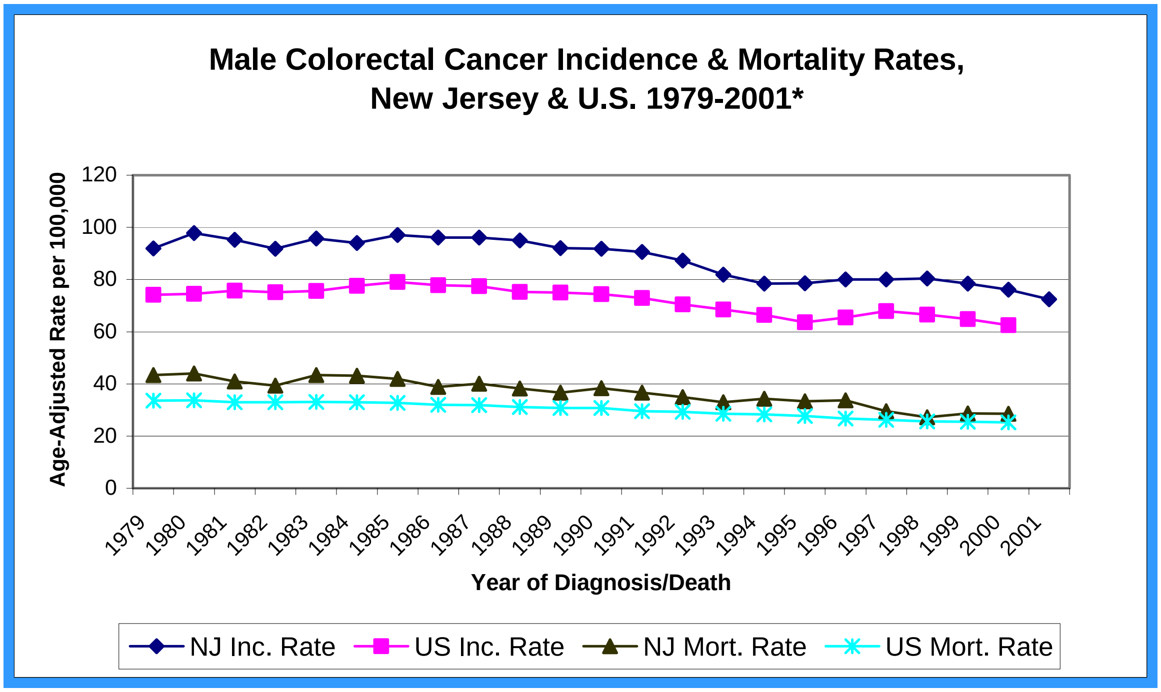
New Jersey & U.S. 1979-2001*



Male Lung Cancer Incidence & Mortality Rates,
New Jersey & U.S., 1979-2001*

*2001 data are preliminary





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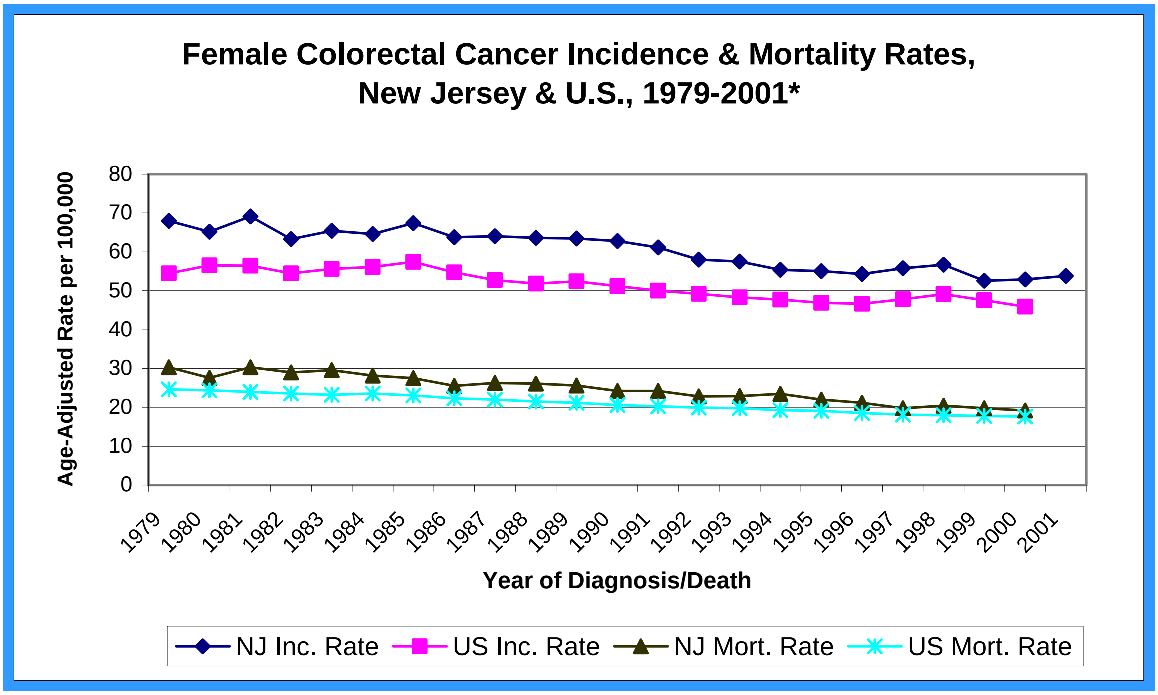

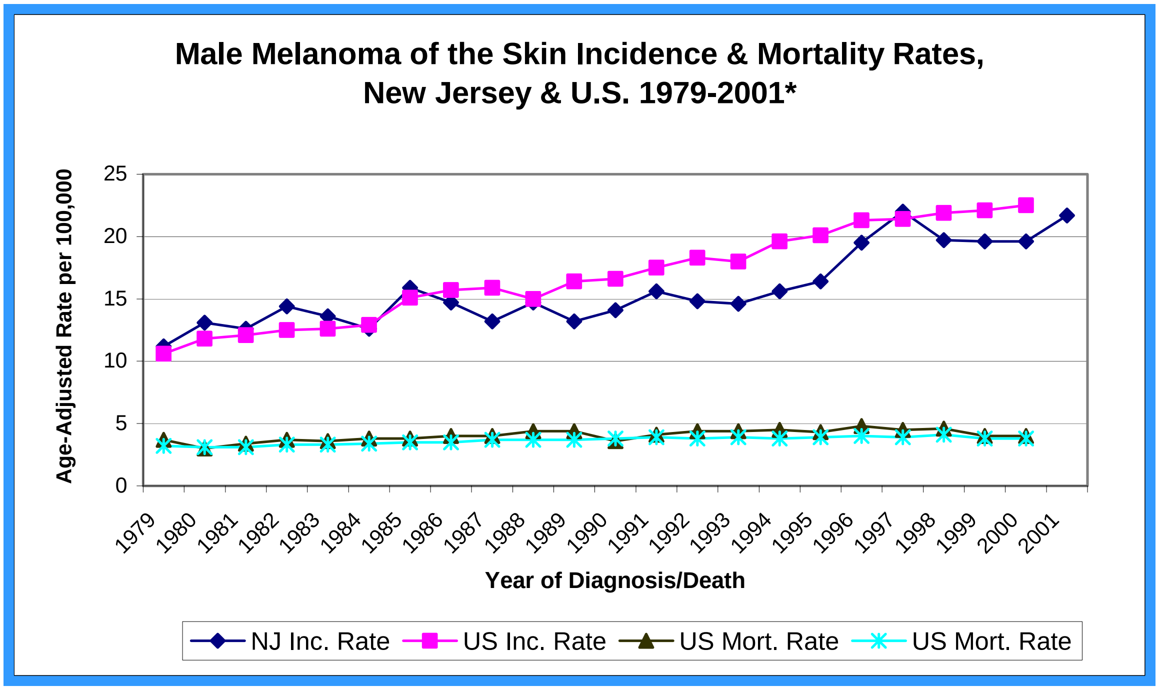

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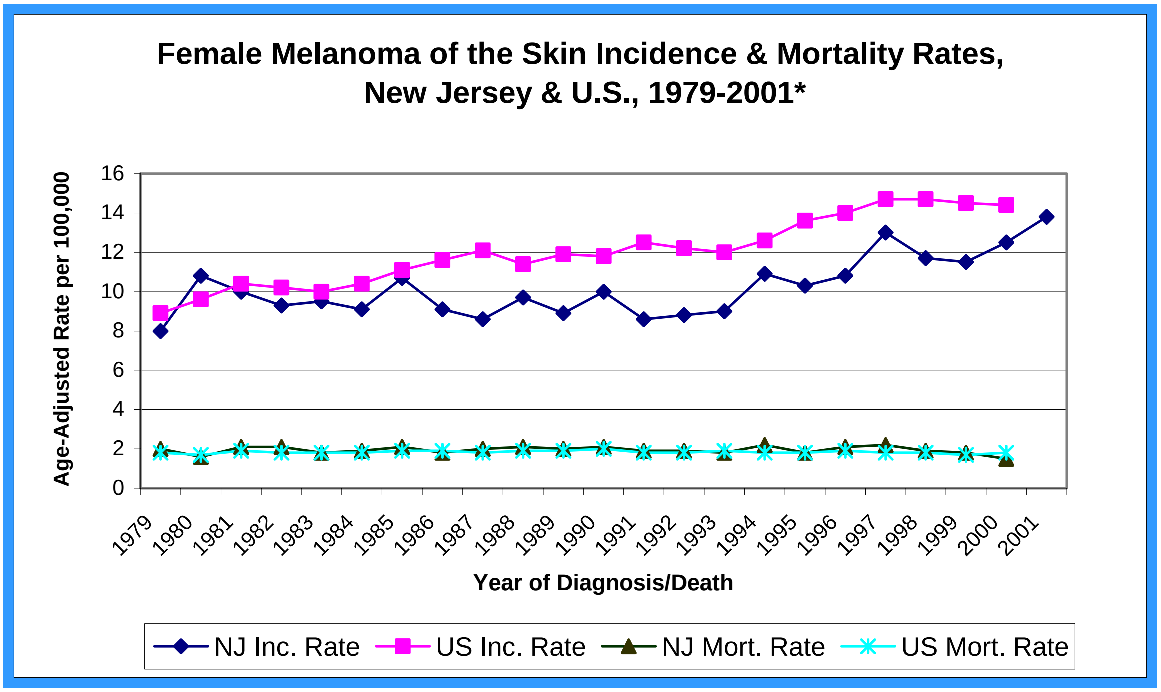

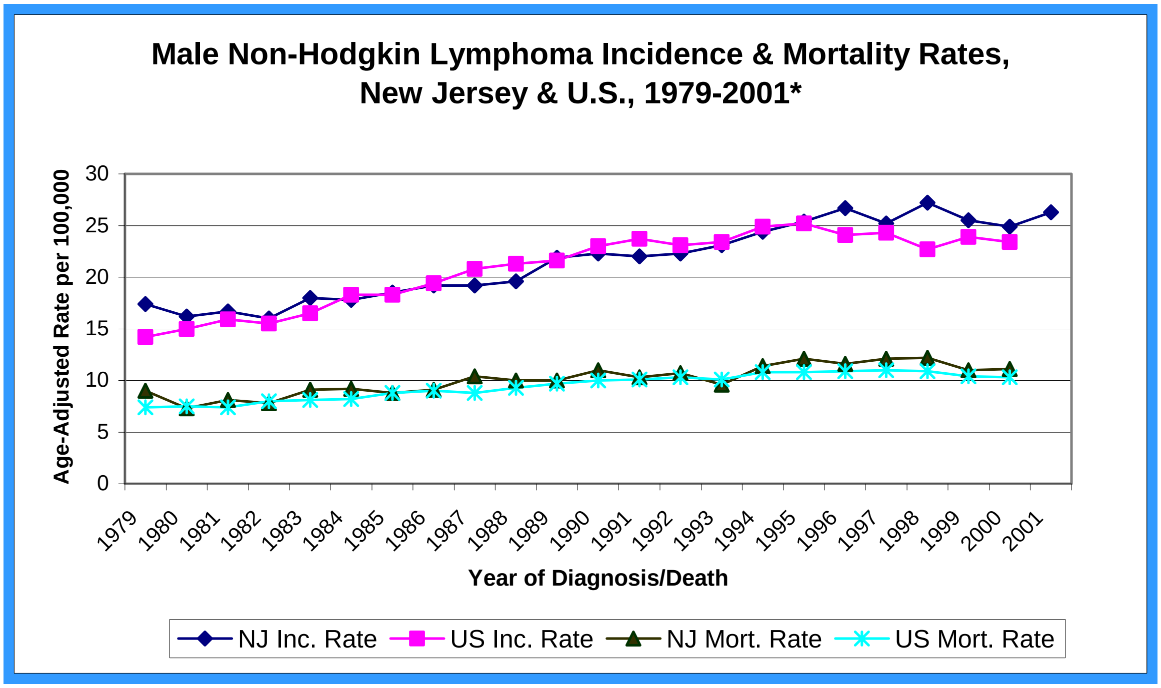

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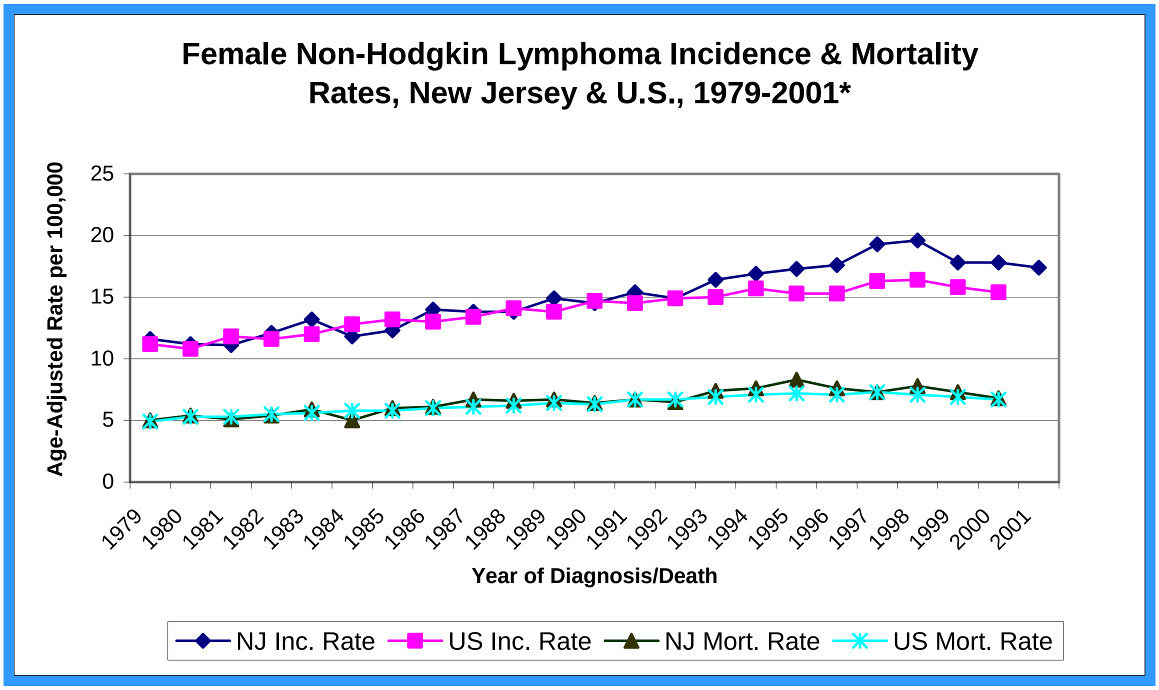

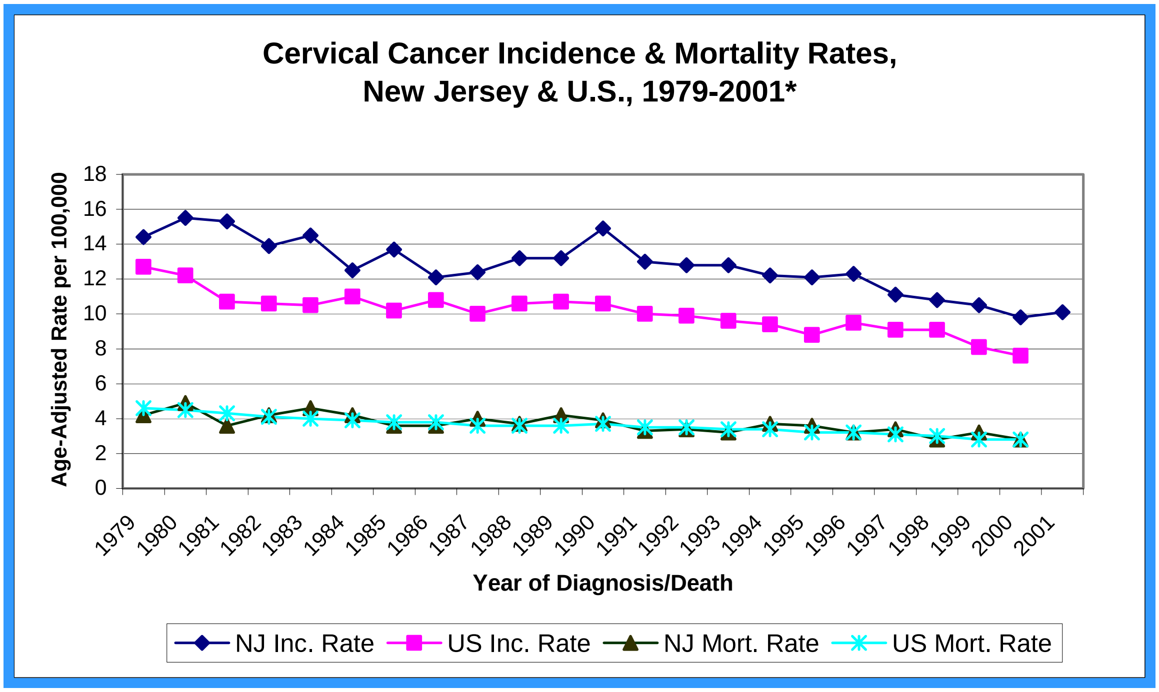

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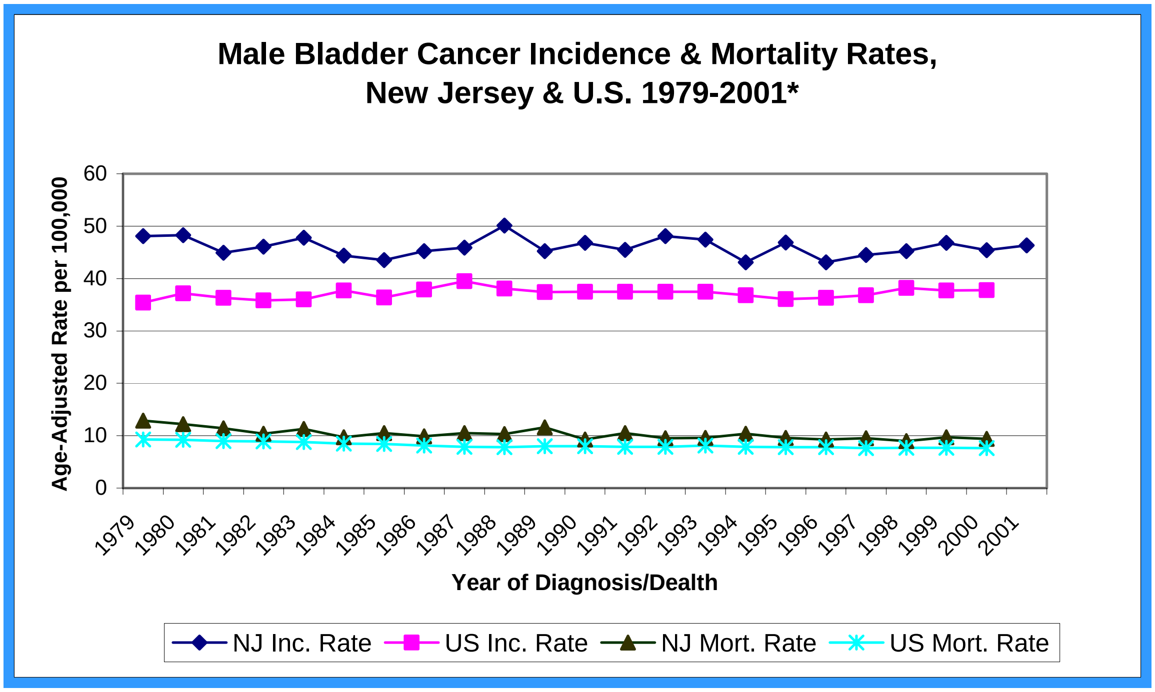

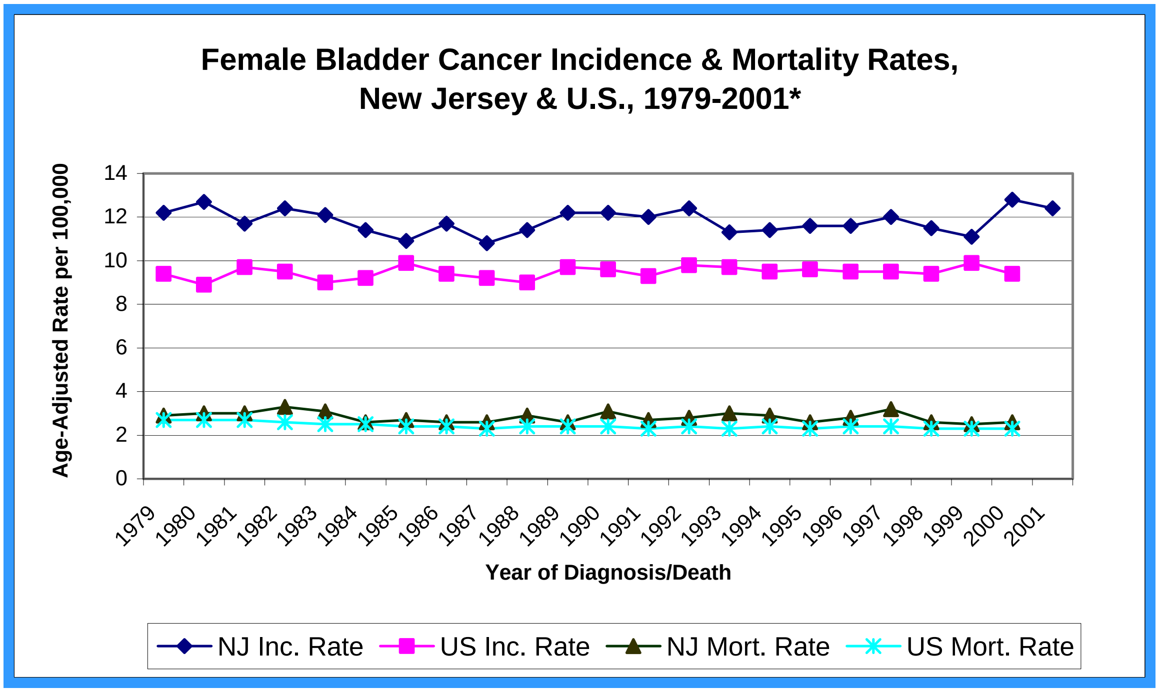

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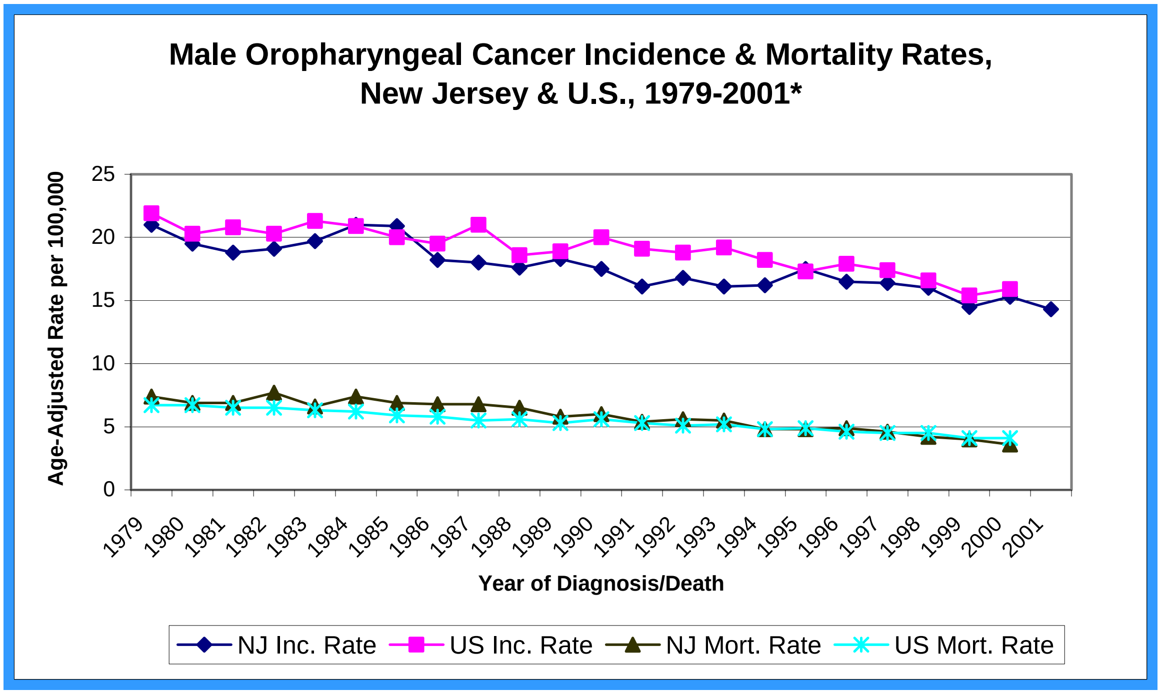
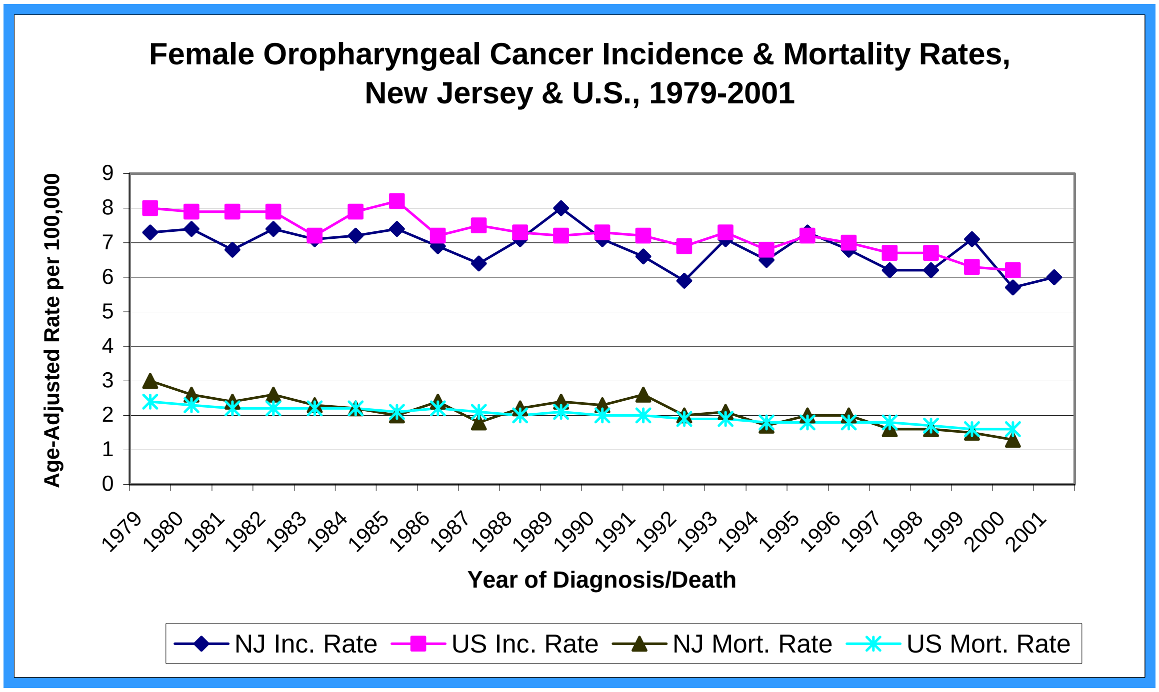

Male Oropharyngeal Cancer Incidence & Mortality Rates, New Jersey & U.S., 1979-2001*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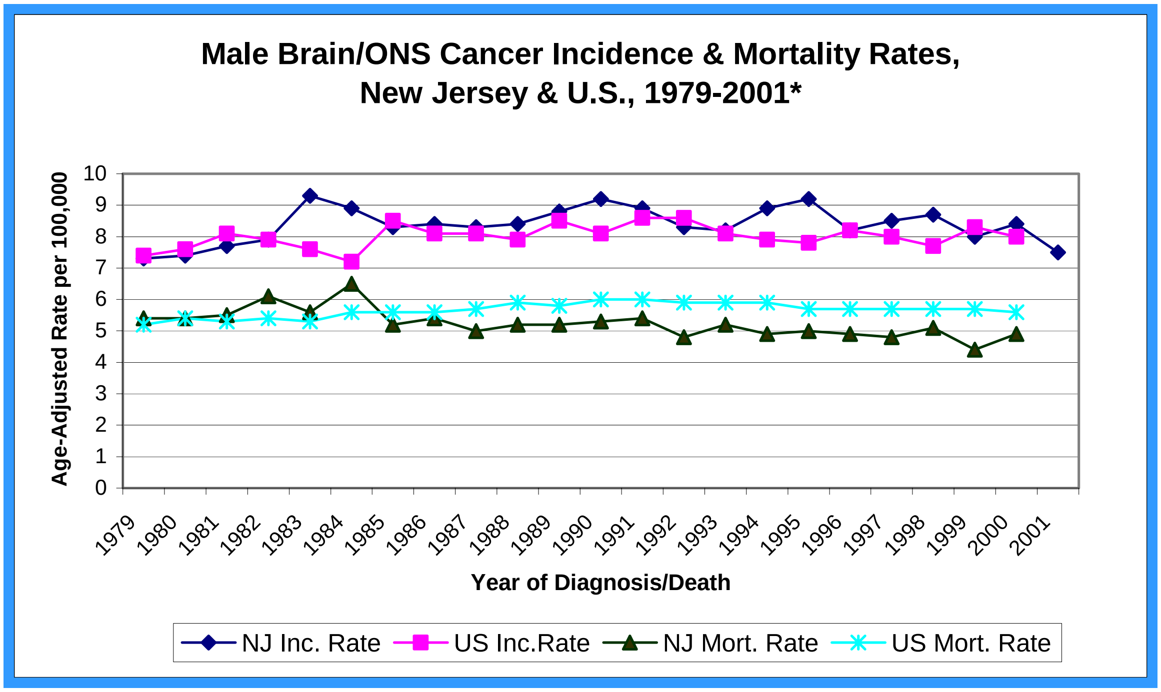
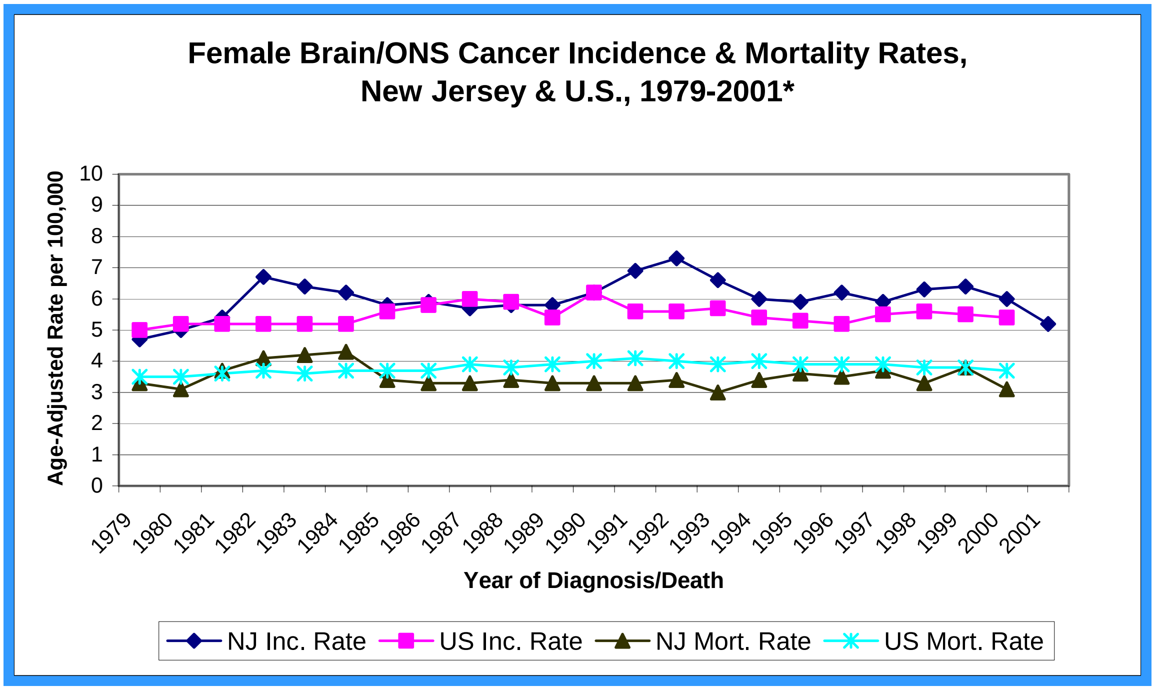
*2001 data are preliminary





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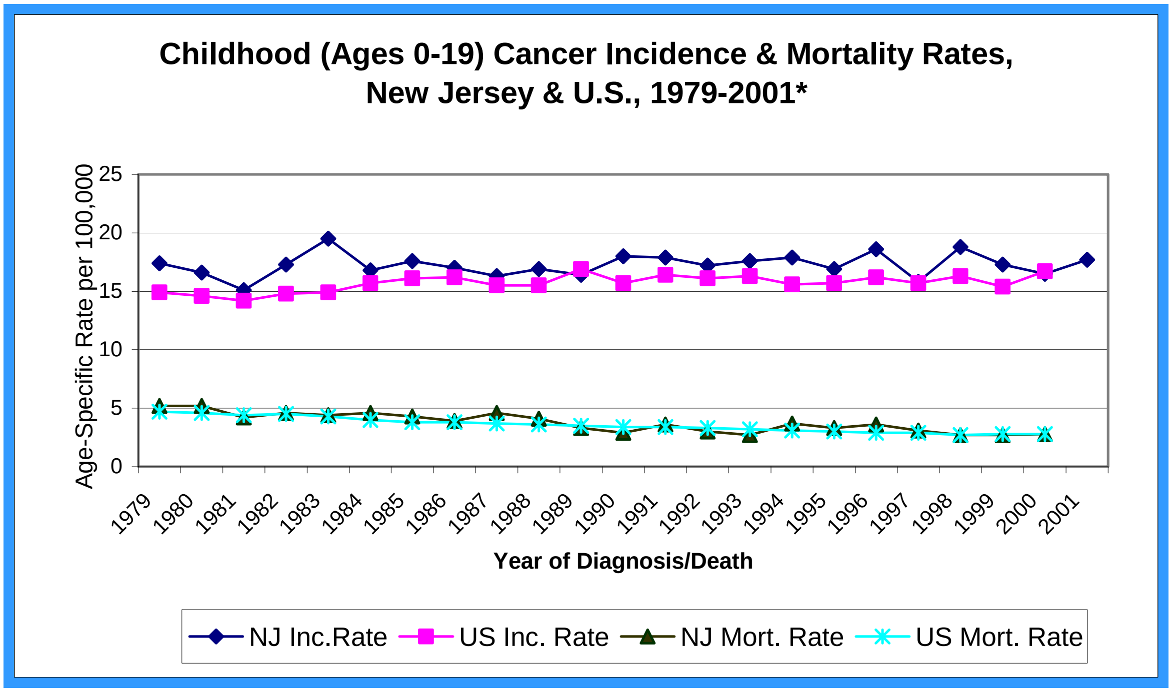
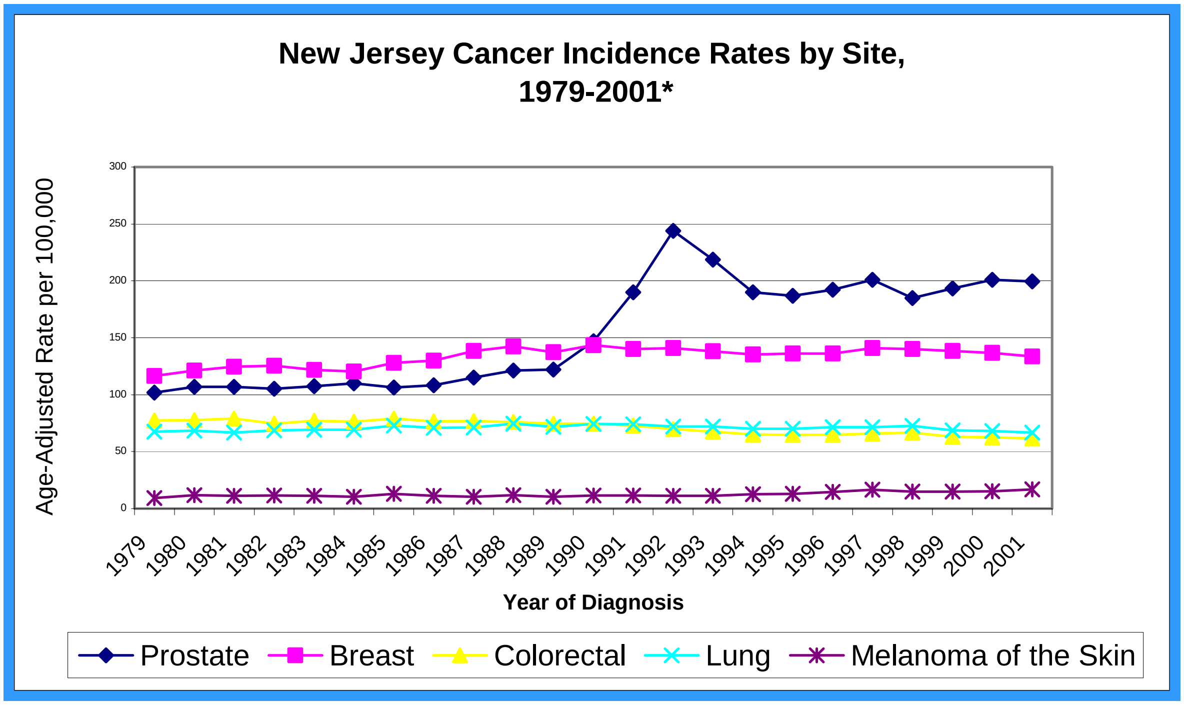

Childhood (Ages 0-19) Cancer Incidence & Mortality Rates, New Jersey & U.S., 1979-2001*


New Jersey Cancer Incidence Rates by Site, 1979-2001*

*2001 data are preliminary

Appendix D

CDC Guidelines for Investigating Clusters of Health Events

Morbidity and Mortality Weekly, Recommendations and Reports, July 26, 1990/39(RR-11);1-16

Summary
Clusters of health events, such as chronic diseases, injuries, and birth defects, are often reported to health agencies. In many instances, the health agency will not be able to demonstrate an excess of the condition in question or establish an etiologic linkage to an exposure. Nevertheless, a systematic, integrated approach is needed for responding to reports of clusters. In addition to having epidemiologic and statistical expertise, health agencies should recognize the social dimensions of a cluster and should develop an approach for investigating clusters that best maintains critical community relationships and that does not excessively deplete resources.

Health agencies should understand the potential legal ramifications of reported clusters, how risks are perceived by the community, and the influence of the media on that perception. Organizationally, each agency should have an internal management system to assure prompt attention to reports of clusters. Such a system requires the establishment of a locus of responsibility and control within the agency and of a process for involving concerned groups and citizens, such as an officially constituted advisory committee. Written operating procedures and dedicated resources may be of particular value. Although a systematic approach is vital, health agencies should be flexible in their method of analysis and tests of statistical significance. The recommended approach is a four-stage process: initial response, assessment, major feasibility study, and etiologic investigation. Each step provides opportunities for collecting data and making decisions. Although this approach may not always be followed sequentially, it provides a systematic plan with points at which the decision may be made to terminate or continue the investigation.

INTRODUCTION

Clusters of health events may be identified by an ongoing surveillance system, but more often they are reported by concerned citizens or groups. Although health agencies must respond to these reports, little guidance has been available to them. These guidelines focus on noninfectious health events such as chronic diseases, injuries, and birth defects. Numerous related issues--such as the epidemiologic workup of infectious disease outbreaks, the assessment of the health effects of environmental exposures, the prospective detection of clusters, and the investigation of interpersonal networks--are not addressed.

Purposes and Assumptions

The purpose of these guidelines is:

- To provide epidemiologic and statistical source material to state and local health agencies to aid in their development of a systematic approach to the evaluation of clusters of health events.
- To provide generic guidelines for assessing clusters of health events (e.g., noninfectious diseases, injuries, birth defects, and previously unrecognized syndromes or illnesses).
- To supplement, rather than supplant, existing state and local plans for evaluating clusters.

Largely on the basis of conference deliberations, the working group (see Preface for list of participants) has used the following operating assumptions:

--In many reports of cluster investigations, a geographic or temporal excess in the number of cases cannot be demonstrated. --When an excess is confirmed, the likelihood of establishing a definitive cause-and-effect relationship between the health event and an exposure is slight. --A cluster may be useful for generating hypotheses but is not likely to be useful for testing hypotheses. Frequently, the issues raised by a cluster cannot be definitively answered by the investigation per se; they require an alternative epidemiologic approach. --From a public health perspective, the perception of a cluster in a community may be as important as, or more important than, an actual cluster. In dealing with cluster reports, the general public is not likely to be satisfied with complex epidemiologic or statistical arguments that deny the existence or importance of a cluster. Achieving rapport with a concerned community is critical to a satisfactory outcome, and this rapport often depends on a mutual understanding of the limitations and strengths of available methods.

Definition, Background, and Characteristics of Clusters

As used in these guidelines, the term "cluster" is an unusual aggregation, real or perceived, of health events that are grouped together in time and space and that are reported to a health agency.

Several breakthroughs and triumphs in infectious disease control have resulted from the epidemiologic evaluation of clusters of cases. Well-known examples include the epidemic of cholera in London in the 1850s (1), the investigation of cases of pneumonia at the Bellevue-Stratford Hotel in Philadelphia in 1976 (2), and the report in 1981 that seven cases of Pneumocystis carinii pneumonia had occurred among young, homosexual men in Los Angeles (3).

Investigations of noninfectious disease clusters have also resulted in notable examples of breakthroughs, such as angiosarcoma among vinyl chloride workers (4), neurotoxicity and infertility in kepone workers (5), dermatitis and skin cancer in persons wearing contaminated gold rings (6), adenocarcinoma of the vagina and maternal consumption of diethylstilbesterol (7), and phocomelia and thalidomide (8).

A review of these landmark events and other material on clusters enables public health personnel to identify characteristics of a cluster from which an investigation might lead to important results. Usually, such a cluster has a definable health outcome, either new or rare; a potential exposure or agent is suspected, along with a connection between the exposure and the health event; the situation is highly unusual, and statistical testing confirms the investigator's impression; and the short-term public health impact is immediate and self-evident.

The reported experience of health agencies confirms, however, that major associations between exposures and outcomes are rare. Minnesota, for example, has reported results from over 500 investigations of clusters (9), six of which were full-scale investigations. In one instance, in an occupational setting, an important public health outcome concerning cancer was documented (10). Missouri (11) and Wisconsin (12) have reported similar experiences: large numbers of requests for investigations have been received, but only an occasional in-depth evaluation is warranted. CDC has been consulted in over 100 such investigations, and again, major associations between exposures and outcomes have been rare (13).

Investigations of clusters reported reflect only a fraction of the activity of health agencies. The unofficial consensus among workers in public health is that most reports of clusters do not lead to a meaningful outcome. Often, a "case" is not clearly defined, and the "cluster" is, in fact, a mixture of different syndromes. Frequently, no exposure or potential cause is obvious, and--to make the investigation even more difficult--there are many possible causes. For example, an inactive toxic waste site may contain hundreds of chemicals. An investigation at the site may indicate no immediate or obvious connection between exposure or disease, and considerable manipulation may be required to demonstrate a statistically significant excess. Finally, the biologic consequences and public health impact often are not clear.

Despite these impediments, reports of clusters cannot be ignored. The health agency must develop an approach that maintains community relations and that manages clusters without excessively depleting resources (14). At times, the health agency must assume a leadership role in recognizing the underlying issues, in understanding the limits of epidemiologic investigation, and in guiding concerns to the appropriate arena.

These guidelines are divided into four sections and an Appendix.

--Section 1 addresses the epidemiologic and management skills required for a systematic public health approach to clusters.
--Section 2 suggests organizational requirements that can facilitate the management of clusters within a health agency.
--Section 3 outlines a systematic, four-stage approach to evaluating clusters.
--Section 4 describes statistical and epidemiologic techniques.
--The Appendix provides a review and critique of available statistical methods.

SECTION 1. MANAGING INVESTIGATIONS OF CLUSTERS: SKILLS AND KNOWLEDGE REQUIRED

The investigation of a perceived cluster of adverse health effects is not simply an isolated epidemiologic or statistical exercise. Appropriate response by public health agencies to requests for such investigations demands that the complexity of this area be recognized and, in addition, requires the possession and application of skills and knowledge that extend well beyond statistical and epidemiologic tools. These additional skills include a sensitivity to the psychology of the situation, an understanding of the principles of risk perception, a recognition of the functions of public media, and an awareness of potential legal ramifications of the investigation.

Scientific Tools

The investigation of clusters may be best viewed as a form of public health surveillance (i.e., the ongoing collection, analysis, and dissemination of information important to public health practice) that responds to community needs. It is not necessarily a primary mechanism for investigating etiologic relationships. Thus, the investigator may be looking more at patterns (spatial, temporal, or both) in data than searching for specific associations between agent and disease (15). As discussed in Sections 3, 4, and the Appendix, various statistical techniques may be used to detect and characterize such patterns--none of which is consistently the technique of choice or the most appropriate. The investigator should select the epidemiologic or statistical approach to be used according to the circumstances under study (e.g., the nature of the condition, the type of data available on the cases, and the availability of comparison divided by denominator data). In addition to knowing how to apply the selected method, the investigator will need to know its limitations, assumptions, and tendency to give false-positive or false-negative results (and under what conditions it is prone to do so). Finally, the investigator should be familiar with the concept of statistical power and be able to determine the power of any planned study to detect an increased number of cases.

Once the presence of a cluster or an excess of disease or injury is confirmed, a comprehensive investigation may require the capacity to conduct environmental sampling, including the knowledge and equipment necessary to design an appropriate sampling scheme and to collect the specimens; access to laboratories with adequate facilities and experienced staff to analyze these specimens quickly and accurately, with appropriate attention to quality control/assurance procedures; and the ability to interpret the results. Similarly, the capacity must exist to collect, analyze, and interpret biological monitoring specimens (whether used as measures of exposure or adverse health effects). What is initially thought to be a cluster of cases may, in fact, represent a cluster of incorrectly performed laboratory tests (16).

Psychological Factors

Investigators of clusters should understand the various ways in which individuals respond to stressful situations and react to uncertainties (17). Investigators also should be able to recognize the source of inevitable community suspicions (e.g., of deliberate delay and cover-ups) and demands (e.g., for the unrealistic allocation of resources and schedules). Investigators should respond to these suspicions and demands without hostility and should be able to diffuse them. Finally, investigators must be aware of and responsive to the fact that a perceived problem must be resolved responsibly and sympathetically, even if no underlying community health problem or cluster of disease truly exists.

Risk Communication

Once the investigator has estimated the degree of risk inherent in the situation under study, this information should be given to the community. Simply presenting the numbers usually will not suffice. The risk must be put in perspective--in a sensitive, non-condescending manner--through comparison with involuntary risks associated with more familiar activities (18).

In addition, the risk perceived by community members does not necessarily parallel the estimates of risk that are produced by mathematical or scientific assessments (19). This divergence is more than a failure to communicate the true risk or a failure of the community to understand. Rather, it represents a factoring of other aspects of the situation into the reactions of community members (e.g., the extent to which the acceptance of the risk is voluntary or imposed, the degree of control the individual or community has over the source of the risk, the degree to which the source of the risk is familiar and easily comprehended, and the potential adverse social and economic ramifications) (19).

Public Media

Public health agencies should be aware of media "imperatives." Investigators must understand the factors that influence the various media in their selection and presentation of stories (e.g., the desire for a pictorial/visual component, the presence of conflict or controversy, the presence of strong emotive content, and the availability of target for blame) (20). Similarly, investigators must recognize that the media tend to simplify complex, technical explanations, thereby losing subtle distinctions or qualifications. Thus, investigators should distill the messages they wish to convey and present them in the way they are most likely to be transmitted without confusion or distortion. Investigators must be prepared to stress key points; provide background necessary for understanding; and be straightforward regarding what is fact, what is speculation, and what is not known. Most of all, investigators must remain cooperative and responsive and must be prepared to provide needed information rapidly, before distortion and discord have been introduced into the public exchanges.

Legal Ramifications

Many situations that prompt requests for investigations ultimately involve litigation (ongoing or contemplated litigation may, in fact, stimulate the request for the investigation) or government intervention. Since the investigation report is likely to be used in that litigation or to justify that intervention, members of public health agencies need a basic understanding of the principles of tort law that relate to legal proof of causality and responsibility--and must understand how these differ from the sometimes stricter requirements of scientific proof. Such principles include the concept of negligence, which entails the breach of duty that caused or substantially contributed to harm or damage; the concept of breach of warranty, the understanding that an action or situation is safe; the concept of strict liability, which focuses on the product rather than on the conduct; and the concept of failure to warn (21). Legally establishing a cause-and-effect relationship requires only that a preponderance of the evidence (i.e., the probability is greater than 0.5) indicates the association (21).

SECTION 2. ORGANIZATIONAL REQUIREMENTS

A citizen who reports an apparent cluster wants assurance that the appropriate persons will be notified and that immediate action will be taken. The health agency should be organized to receive and respond to reports of potential clusters so as to systematize the following: --A reporting process that is quick and traceable--and one in which the appropriate person is reached regardless of the first contact made by the concerned citizen. --A response process that is triage-oriented, that can proceed smoothly from one level of action to the next, and that can terminate effectively when resolution is reached. --A feedback and notification process that educates and enlightens with efficiency and courtesy. --A referral process that assures timely and competent field investigation and public health response.

The following organizational components are recommended to assure smooth and timely public health responses:

- A locus of responsibility and control. The health agency should designate an individual with stature in the agency to serve as the identifiable point of responsibility or Program Director (e.g., Director of Environmental Health, State Epidemiologist, Director of Cancer Control Activities, Chronic Disease Director, or County Health Officer). The designation will depend on local circumstances and priorities.

- A process for involving concerned groups and individuals. The health agency should consider the establishment of an advisory committee (or similar group) to oversee the decision-making process for evaluating clusters. Such a committee might include representatives from the health agency, other government agencies, private and voluntary sectors, concerned citizens' groups, and the media, as well as selected individuals. This committee should provide oversight, guidance, and advice to the Program Director. The duties should be carefully specified a priori and agreed to by the committee members. Since the committee is likely to consist of persons with diverse backgrounds, the main focus should be on overseeing the process rather than on making technical decisions.

- A set of operating procedures. The health agency should establish a written protocol for evaluating clusters. The protocol should include mechanisms for reaching responsible persons and a detailed enumeration of the triage process. (Guidelines for such a protocol are provided in Section 3.) This protocol should be disseminated to appropriate points in the health agency to assure proper handling of the report, whatever the point of entry.

- Dedicated resources. Health agencies that have a recurrent need for evaluating clusters probably will require staff and support resources. The Program Director may not be in a position to perform the required day-to-day tasks and may not be the appropriate primary contact. Frequently, responsibilities may be shared by a number of staff members, but the duties and responsibilities should be clearly designated.

Just as no statistical test is best for evaluating all clusters, no organizational structure is best in all situations. The specifics of organization will depend on local circumstances.

SECTION 3. GUIDELINES FOR A SYSTEMATIC APPROACH

This section outlines a four-stage approach for managing a reported cluster, from original contact to final disposition. The section does not speak directly to the particular outcome of concern (e.g., cancer or birth defects), to the types of data available (mortality, hospital discharge, or disease registries), or to the specific analytic techniques (see Section 4 and the Appendix). Usually, these particulars will be determined by local resources and circumstances. The four stages may be viewed as a series of filters that provide appropriate responses to the reported problem. An assessment of feasibility should be made before the actual study is begun, and the issue of increased frequency of occurrence should be separated from the issue of potential etiologies (Figure 1). These guidelines should be viewed with the following caveats in mind: --The boundaries between the stages are not fixed. Often, the health agency will choose to follow a different order, to combine steps, or to pursue a problem on several fronts. Considerable local judgment and discretion are required. --The investigation can be resolved at a number of points along the path by a report to "the caller" (the individual who initiated the contact) and to other interested parties (Figure 1). This step implies that an internal report will be generated for the health agency and its advisory groups. Such reports are useful communication tools, particularly if they are regularly scheduled and available to an established, but flexible, list of recipients. --Although health agencies may have a number of organizational similarities (e.g., the presence of a public affairs office and a cluster advisory committee), their internal structure and function may vary considerably. The guidelines are meant to be tailored to local circumstances. If health agencies choose to establish an advisory committee, the assumption is that the committee will be consulted at critical decision points.

Stage 1. Initial Contact and Response

Purpose: to collect information from the person(s) or group(s) first reporting a perceived cluster.
The initial contact is critical. The caller should be referred quickly to the responsible unit in the health agency, and the problem should never be dismissed summarily. Most reports of potential clusters can be successfully closed at the time of initial contact, and the first encounter is often the health agency's best opportunity for communication with the caller about the nature of clusters.

Procedures

A. Gather identifying information on the caller, unless anonymity is requested: name, address, telephone number, and organization affiliation, if any. If anonymity is requested, advise the caller that the inability to follow up may hinder further investigation.

B. Gather initial data on the potential cluster: suspected health event(s), suspected exposure(s), number of cases, geographic area of concern, time period of concern, and how the caller learned about the cluster.

C. Obtain identifying information on persons affected: name, sex, age (or birth date, age at diagnosis, age at death), occupation, race, diagnosis, date of diagnosis, date of death, address (or approximate geographic location), telephone number, length of time in residence at site of interest, contact person (family, friend) and method for contact, and physician contact. In some instances, the health official may choose not to collect identifying information during the first contact but instead to gather it during several contacts.

D. Discuss initial impressions with a caller. The following frequently arise: --A variety of diagnoses speak against a common origin. --Cancer is a common illness (with a one in three lifetime probability). The risk increases with age, and cases among older persons are less likely to be true clusters. --Major birth defects are less common than cancer but still occur in 1%-2% of live births. --Length of time in residence must be substantial to implicate a plausible environmental carcinogen because of the long period of latency required for most known carcinogens. --Cases that occurred among persons now deceased may not be helpful in linking exposure to disease because of the lack of information on exposure and because of possible confounding factors. --Rare diseases may occasionally "cluster" in a way that is statistically significant, but such an occurrence may be a statistical phenomenon not related to exposure.

E. Request further information on cases, obtain more complete enumeration, and plan a follow-up telephone contact, as needed.

F. Assure the caller that he or she will receive a written response. (Often, the written response simply confirms what has already been communicated by telephone.)

G. Maintain a log of initial contacts, whether they are made in writing, by telephone, or in person. The log should include the date, time, caller identification, health event, exposure, and geographic area. Follow-up contacts should be logged in as well, with a brief note as to purpose and result. If possible, the log should be cross-referenced and computerized so that all personnel concerned will have the same information.

H. Notify the health agency's public affairs office (or equivalent) about the contact. In many agencies, this action is analogous to notifying the commissioner's office of a press contact.

Early in the investigation of a cluster, the health agency may be asked to collect new environmental data or to use previous measurements, although the latter may not exist. Premature environmental measurements should be avoided, since they may be unfocused and un-interpretable.

Outcome --If the initial contact suggests that further evaluation is needed (e.g., single and rare disease entity, plausible exposure, or plausible clustering), proceed to Stage 2, Assessment. --If the initial contact permits satisfactory closure, prepare a summary report for the caller and for the advisory committee (or other supervisory group).

Stage 2. Assessment

Once the decision has been made to proceed with an assessment, an important step is to separate two concurrent issues: whether an excess has actually occurred and whether the excess can be linked etiologically to some exposure. The first issue usually has precedence, and it may or may not lead to the second. This stage initiates a mechanism for evaluating whether an excess has occurred. Three separate elements are identified: a preliminary evaluation (Stage 2a) to assess quickly from the available data whether an excess may have occurred; case evaluation (Stage 2b) to assure that a biological basis exists for further work; and an occurrence investigation (Stage 2c) for the purpose of obtaining a more detailed description of the cluster through case finding, interaction with the community, and descriptive epidemiology. In addition, the investigators may wish to review the scientific literature and seek consultation with other investigators. These activities are often interrelated and may occur in parallel. The health agency is encouraged to be flexible in conducting this portion of the investigation and to recognize that a linear approach is often not possible.

Stage 2a. Preliminary evaluation

Data from the initial contact, possibly with augmentation from other sources, are used to perform an in-house calculation of observed versus expected occurrence.

Purpose: to provide a quick, rough estimate of the likelihood that an important excess has occurred.

Procedures

A. Determine the appropriate geographic area and the period in which to study the cluster. B. Determine which cases will be included in the analysis. Because this stage does not involve case verification, all cases will be assumed to be real. However, some cases may need to be excluded from the analysis because they occurred outside the geographic area or the period decided on, or because the health event for the case differs from that of other cases. A helpful step may be to tabulate frequencies of health events and to look at related descriptive statistics. C. Determine an appropriate reference population. Occurrence rates (or other statistics) calculated for the cluster should be compared with those for a reference population in order to identify an excess number of cases. D. If the number of cases is D. If the number of cases is sufficient, and if a denominator is available (e.g., population of a community, number of children in school, or number of employees in a workplace), calculate occurrence rates, standardized morbidity/ mortality ratios, or proportional mortality ratios (see Section 4). Compare the calculated statistic with that for the reference population to assess significance. Chi-square tests and Poisson regression are also commonly used techniques for comparing proportions. E. If the number of cases is not large enough to obtain meaningful rates, or if denominator data are unavailable, use one of the statistical tests developed to assess space, time, or space-time clustering (Appendix).

Outcome --If the preliminary evaluation suggests an excess occurrence, proceed to case evaluation. --If the preliminary evaluation suggests no excess, respond to the caller, indicating findings and advising that no further investigation is needed. --If the preliminary evaluation shows no excess but the data suggest an occurrence of biologic and public health importance, decide if further assessment is warranted. A decision to proceed further at this point should not be based solely on an arbitrary criterion for statistical significance.

Stage 2b. Case evaluation

Purpose: to verify the diagnosis. Some health agencies may choose to verify diagnoses before calculating preliminary rates (Stage 2a). Because verification may be costly, however, agencies usually calculate rates first.

Procedures

A. Verify the diagnosis by contacting the responsible physicians or by referring to the appropriate health-event registry. Verification is often a multi-step process, involving initial contact with the patient, family, or friends and subsequent referral to the responsible physicians to obtain permission to examine the records.

B. If possible, obtain copies of relevant pathology reports or medical examiner's report.

C. Obtain histologic reevaluation if needed. (Often, however, confirmation and reevaluation are difficult to obtain.)

Outcome --If cases are verified and an excess is confirmed, proceed to Stage 2c, the occurrence evaluation (which already may be under way). --If some (or all) of the cases are not verified and an excess is not substantiated, respond to the caller, outlining findings and advising that further evaluation is not warranted. --If some of the cases are not verified but biologic plausibility persists and the data are suggestive, consider initiating or continuing the occurrence evaluation.

Stage 2c. Occurrence evaluation

Purpose: to design and perform a thorough investigation to determine if an excess has occurred and to describe the epidemiologic characteristics. The occurrence evaluation is meant to define the characteristics of the cluster, often requiring a field investigation. This evaluation begins with a written protocol that outlines the costs and provides information on data collection, the methods to be used, and the plan of analysis. The main product should be a detailed description of the cluster. Up to and including this stage, the allocation of resources is relatively small.

Procedures

Determine the most appropriate geographic (community) and temporal boundaries.

A. Ascertain all potential cases within the defined space-time boundaries.

B. Identify the appropriate data bases for both numerator and denominator and their availability. Identify statistical and epidemiologic procedures to be used in describing and analyzing the data.

C. Perform an in-depth review of the literature, and consider the epidemiologic and biologic plausibility of the purported association.

D. Assess the likelihood that an event-exposure relationship may be established.

E. Assess community perceptions, reactions, and needs.

F. Complete the proposed descriptive investigation.

Although an advisory committee can be helpful at any point in the process, it may be of particular importance at this point. The occurrence evaluation may vary considerably in size and content; consensus on the appropriate level of effort will facilitate acceptance of the results.

Outcome --If an excess is confirmed and the epidemiologic and biologic plausibility is compelling, proceed to Stage 3, the major feasibility study. --If an excess is confirmed but no relationship to an exposure is apparent, terminate the investigation and inform the persons concerned of the possible risks/no risks involved. --If an excess is not confirmed, terminate the investigation and report findings to the caller.

Stage 3. Major Feasibility Study

Purpose: to determine the feasibility of performing an epidemiologic study linking the health event and a putative exposure. The major feasibility study examines the potential for relating the cluster to some exposure. All of the options for geographic and temporal analysis should be considered, including the use of cases that were not part of the original cluster and are of a different geographic locale or time period. In some instances, the feasibility study may provide answers to the basic issue (14).

Procedures

A. Review the detailed literature search with particular attention to known and putative causes of the outcome(s) of concern.

B. Consider the appropriate study design, with attendant costs and expected outcomes of alternatives (e.g., a consideration of sample size, the appropriateness of using previously identified cases, the geographic area and time period concerned, and the selection of controls).

C. Determine what data should be collected on cases and controls, including physical and laboratory measurements. Determine the nature, extent, and frequency of and the methods used for environmental measurements.

D. Delineate the logistics of data collection and processing.

E. Determine the appropriate plan of analysis, including hypotheses to be tested and power to detect differences; assess the epidemiologic and policy implications of alternative results.

F. Assess the current social and political ambiance, giving consideration to the impact of decisions and outcomes.

G. Assess the resource implications and requirements of both the study and alternative findings.

Outcome --If the feasibility study suggests that an etiologic investigation is warranted, proceed to Stage 4. The investigation may require extensive resources, however, and the decision to proceed will be related to the allocation of resources. --If the feasibility study suggests that little will be gained from an etiologic investigation, summarize the results of this process (by now rather extensive) in a report to the caller and all other concerned parties. In some circumstances the public or media may continue to demand further investigation regardless of cost or biologic merit. The effort devoted to community relationships, media contacts, and advisory committee interaction will be critical for an appropriate public health outcome.

Stage 4. Etiologic Investigation

Purpose: to perform an etiologic investigation of a potential disease- (or injury-) exposure relationship.
The primary purpose of the study is to pursue the epidemiologic and public health issues that the cluster generated--not necessarily to investigate a specific cluster. In that context, this step is a standard epidemiologic study, for which all the preceding effort has been preparatory.

Procedures

Using the major feasibility study as a guide, develop a protocol, and implement the study. The circumstances of most epidemiologic studies tend to be unique; therefore, more specific guidance is not appropriate for inclusion in this publication.

Outcome --The results of an etiologic investigation are expected to contribute to epidemiologic and public health knowledge. This contribution may take a number of forms, including the demonstration that an association does or does not exist between exposure and disease, or the confirmation of previous findings.

SECTION 4. STATISTICAL AND EPIDEMIOLOGIC TECHNIQUES

The approach taken to investigate a suspected cluster of health events depends on the nature of the cluster, the data available, and the questions being asked, including the following: --Do the health events cluster in space or time alone, in space and time simultaneously, or in neither? --What are the spatial and temporal boundaries of the cluster? --What are the characteristics of the health events--e.g., acute or chronic disease, long or short latency period, and known or unknown etiology? --What data are available for the health event--e.g., case counts, disease rates, or data on each event, such as place of residence and time of onset of disease or death? --What data are available to describe the population at risk?

A number of problems are encountered in the study of clusters. The health events being investigated (often morbidity or mortality) are usually rare, and increases of these events tend to be small and may occur over a long period. Another issue that complicates the investigation is that some clusters occur by chance. Information on the population at risk or on the expected rates often is not available. A further complicating factor for methods using aggregated data is that health events occur in space and time continua, thus yielding optional and suboptimal units for displaying a pattern. The choice of a geographic area that is too small or too large, or of a time period that is too short or too long, may result in insufficient statistical power to indicate a cluster. Many of the articles referenced in the Appendix contain informative discussions about issues that can compromise application of statistical methods in investigations of clusters.

Standard statistical and epidemiologic techniques for assessing excess risk can often be used to evaluate reported clusters. Tabulating frequencies of the health event and examining related descriptive statistics is a useful first step in the evaluation. Mapping the data is also helpful. If the number of cases is sufficient and population data are available, examination of rates (possibly age-, race-, and sex-adjusted), standardized mortality/morbidity ratios, or proportional mortality ratios may determine whether there is an excess number of events. If the number of health events is too small to show meaningful rates, pooling across geographic areas or time may be possible. Combinatorial methods are often used for small amounts of data. Other commonly used statistical approaches include chi-square tests of observed versus expected frequencies (based on the Poisson distribution for low-frequency data) and Poisson regression (used for comparison of rates). Confidence intervals may be calculated for point estimates.

Whether the rate for a geographic area or time period is excessive may be determined by comparing it with rates of other areas or times. If a spatial cluster is being assessed, the occurrence in the geographic area can be compared with that in adjacent areas (e.g., a census tract with surrounding census tracts) or with other areas of similar size (e.g., a county with other counties in a state). Alternatively, the rate for an area can be compared with that of a larger area (e.g., the rate for a city with that of the surrounding county). If a temporal cluster is being assessed, the occurrence in that time period can be evaluated in the context of previous or subsequent periods. When such comparisons are made, the referent population must be chosen carefully to ensure its appropriateness. Mortality and morbidity data for referent populations are available from state and national vital statistics systems or registries such as cancer and birth defect registries. Population data are available from the Bureau of the Census. A county-level file with both mortality and population data for 1968-1985 (the Compressed Mortality File) is available for public use from the National Technical Information Service.

If the above standard approaches cannot be used in an investigation of clusters because the number of health events is too small, data on the population at risk are unavailable, or space-time clustering is suspected, numerous statistical tests are available for use in detecting spatial, temporal, and space-time clusters. Although some of these tests may not be familiar to investigators and may require the preparation of more data than required by standard techniques, many of the tests are simple to understand and use. Numerous methods for studying clusters have been reviewed (22,23). Brief descriptions and critiques of some of these techniques are presented in the Appendix.

Most of the tests reviewed in the Appendix use data on individual cases of health events, although a few employ aggregated data such as frequency counts or rates. Information generally required for each case is location of the case (often the geographic coordinates of place of residence) and date of onset of the disease (or injury) or of death. Most of the tests based on aggregated data assume that the number of health events that occur in an area and/or time period follows a Poisson distribution. The tests do not usually require knowledge of the distribution of the population at risk. Instead, they may assume that the population at risk remains constant over time, and they offer special considerations for differing population sizes. The reporting rate for the health event is also assumed to be constant.

The assumption of minimal population shifts over time is frequently violated. More subtly, subgroups of the population with different levels of risk may not remain constant over the time period of interest. Violations of these assumptions can lead to spurious results. An additional problem is encountered when investigators study the occurrence of health events over a long period, i.e., the problem posed by migration. Migration tends to decrease the chance of detecting clustering; however, certain tests account for non-uniformity of or changes in the population (24-26). As an alternative, adjustments for the size of the population at risk (to account for population changes during the study period) can be made before testing.

In addition to the techniques described in the Appendix, other approaches in use or under investigation for the analysis of clusters include the quality control measure known as the cumulative sum, or cusum, technique (27), the sets technique (28), nearest-neighbor procedures (29,30), and nonlinear and Bayesian time series methods. Normal-theory confidence intervals and bootstrap-prediction intervals for detecting frequencies of disease occurrence above those expected have been explored (31).

Because of the diverse and complicated nature of clusters, there is no omnibus test for assessing them. Investigators are advised to perform several related tests and to report the results that are most consistent with validated assumptions. This process will be aided by the use of CLUSTER, an IBM PC-compatible software program that will soon be commercially available and will offer investigators a choice of statistical procedures to use when investigating clusters.

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the official text, figures, and tables. An original paper copy of this issue can be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. Contact GPO for current prices.

Appendix E

New Jersey Interim Cancer Cluster Protocol

INTERIM CLUSTER RESPONSE PROTOCOL (1997)
New Jersey Department of Health and Senior Services
Cancer Epidemiology Services

See CDC Cluster Protocol: (See MMWR 1990 article in manual)

Responses are designed to be:
Timely, courteous, empathetic,
Efficient at triaging and communication,
Informational to citizens and their representatives/health care providers, and
Efficient for maintaining of electronic documentation which can facilitate future responses and coordination.

NJDHSS Cancer Investigation Review Panel reviews inquiries for which an appropriate response may be more than routine and meets monthly or as needed. It includes staff of the Office of Cancer Epidemiology, Consumer and Environmental Health Service, Occupational Disease and Injury Service, and Family Health Services.

I. Initial Response to Inquiries:

1. **Listen** to determine: (a) personal involvement with cases (b) the degree of anxiety, and level of knowledge about cancer and cancer incidence.

2. **Record:** Specific information, including number and types of cases and when diagnosed, population characteristics, and any hypothesized causal factor. A standard intake form is completed and data from it is entered into a database (see attachment for sample form which may be adapted by county and municipal agencies).

3. **Provide information on cancer:** A customized letter is sent to the person inquiring, with a copy to the local health officer. The written response includes a brief summary of current scientific understanding of pertinent cancers and/or exposures, excerpts from or copies of public education materials (e.g. on early detection). Reiteration of the telephone conversation, and an invitation to recontact us with more information or questions.

Among the key educational enclosures used are:

1. Cluster inquiry fact sheet (general and occupational if pertinent)
2. Excerpts of NCI and Cancer Rate Risks
3. American Cancer Society's current *Cancer Facts and Figures* (or excerpts)
4. Other pamphlets or papers on specific type of cancer or exposure, as indicated or available
5. Brochure of the NJ State Cancer Registry.

Response to most inquiries are concluded with these activities, however:

*If indicated, local or other State agencies are contacted in order to evaluate related information such as unusual or possibly hazardous conditions.

*If the initial information suggests an unusual pattern regarding number and types of cancer, ages of diagnoses, etc, a data collection form may be sent with a post-paid envelope under the following circumstances:

(a) Workplace or school attendees
(b) Very recent cases (and therefore not in registry)
(c) Other *non-geographic*-based cases
(d) Other reason that cases would not be in registry
(e) Requestor maintains that Registry data is incomplete
(f) Registry data suggest that occupation, years of residence at current address, and smoking history are needed for evaluation

The information requested on the cases includes: (See attached sample form)

Cancer type (site),
Date of diagnosis,
Sex,
Site of cancer (history, if pertinent)
Age at diagnosis or year born,
Address of residency at diagnosis,
Years of residency at that address: beginning and ending/or current date,
Usual occupation,
Smoker or non-smoker
Name, address and phone of diagnosing physician

*Response to occupational cluster inquiries:

For public employee workplace filing complaints to the Public Employee Occupational Safety and Health Program (PEOSH) of the Occupational Disease and Injury Service (ODIS) of the Department, industrial hygiene assessments may be conducted by PEOSH. Complaints to PEOSH are confidential, and letters are copied to the local health departments. However, health officers can request summaries of PEOSH inspection results.

For private employee workplace, an industrial hygiene inspection or referral to the federal OSHA may be conducted by ODIS.

*On-site educational sessions may occasionally be conducted if there are remaining questions after written material is sent, there are a large number of individuals in the concerned group, and a written request is made by that group. In advance of such a session, major questions to be addressed are elicited. The frequency of such sessions by the Office of Cancer Epidemiology is limited to no more than one per month.

II. **<u>Formal SIR analyses</u>:**

Sir analyses are rarely indicated, and are conducted only if all of the following conditions are met.

1. Written request is transmitted through the local health officer.
2. The Department's Cancer Investigation Review Panel endorses.
3. There are at least five cases of one type or related types of uncommon adult cancer, or at least three cases of one type or related types of childhood cancers.
4. There is a plausible reason to suspect more than normal fluctuation.
5. The latency issues are not inconsistent with a common factor (ages, dates of diagnoses and residency).
6. There is appropriate population data available upon which to calculate numbers of expected cases for comparison with observed cases.

When NJDHSS conducts Standardized Incidence Ratio calculations:

Expected numbers of cases are derived from New Jersey rates,
Observed numbers of cases are those confirmed via NJSCR Registry,
  genders calculated separately and combined where appropriate,
Time trends are observed,
Addresses are checked for accuracy if feasible,
95% confidence intervals are indicated.

Formal SIR Report to the requestor may include:

Tables with observed, expected, and 95% Confidence Intervals (CIs).
Explanation of likelihood of chance outliers for SIRs.
Discussion of verification of originally reported cases.
Reference to Cluster Inquiry Fact Sheet as pertinent.
Comment on observed trend or lack of trend.
Comment on major risk factors for the type of pertinent cancer(s), and
  current major hypotheses being investigated/followed.
Comment on behaviors recommended for primary and/or secondary
  Prevention (e.g. early detection).
Enclosures, where appropriate.
All letters are sent or copied to local health officer (LHO).
Reports/letters with positive outcome in analysis are followed up with a
  Phone call to LHO.

Among the possible outcomes of SIR analysis are:

No further actions are indicated.
Public education and outreach recommended, in coordination with local health department
Periodic surveillance for high outliers not meeting criteria for further investigation: for these
  localities, updates will be sent to the local health department.
Further investigation.

<u>III.</u> **<u>Further investigation</u>**: Evaluation of need and feasibility of in-depth study (see MMWR 1990 Step III) may be conducted in collaboration with Consumer and Environmental Health Services, where appropriate: **Minimum criteria are any of the following**:

-SIR for one observation period: $p<0.001$, or
-SIRs of two consecutive observation periods: $p<0.005$ each, or

-There is an increasing trend of rates over several timeframes of an unusual cancer, or

-There is a plausible hypothesis regarding a particular factor or exposure (e.g. completed exposure pathway or unusual population factor) and an SIR with $p < 0.05$ for any period.

The further investigation activities may involve more detailed case characterization, e.g. definition of the time and space boundaries; closer review of case data, including diagnosis, pathology reports, etc,; ages affected; review of existing documents on environmental exposure data, including evaluation of likelihood of completed exposure pathways; interviews with local health care providers and local government officials regarding hypotheses, and further contact of community leaders.

IV. **In-depth studies based on active surveillance or cluster inquiry response:** Case control or other in-depth studies are undertaken only in the event of all the following: (1) sufficient cases and (2) a biologically plausible hypothesis with documented complete exposure pathways and (3) residency and latency characteristics consistent with the timeframes of exposures and diagnoses of cancers.

THE ROLES OF LOCAL HEALTH DEPARTMENT INCLUDE:

Initial response
Evaluation of environmental and other factors contributing to observations,
    -Including characteristics of population (age, diet, smoking, SES, etc.)
Evaluation of sensitivities, history of local population and key informants
Public education
Coordination of local events (if any)
Communication with the public and media, etc (if necessary)
Communication with NJDHSS and other agencies, as needed

Addressing Cancer Cluster Inquiries: NJ Current Protocol and Role of Local Health Departments

Rationales:

Identify locales and subpopulations with high cancer rates where investigations may lead to prevention and control of cancer.
Respond to citizen concerns
Provide public education on primary and secondary prevention (including early detection screening) of cancer, where applicable

Concern about cancer rates in communities present opportunities to educate communities and individuals on cancer risk factors and encourage healthier lifestyles and early detection.

Pitfalls:

There is widespread public misunderstanding and unrealistic expectations concerning cancer in the community. These misconceptions include: the feasibility of assigning a cause-effect relationship between cancer and specific environmental exposures, the difficulty in ruling out other possible causes, the role of environmental contaminants in cancer etiology, the overall incidence of cancers, the latency of cancer diagnoses after etiological exposures, and distinctions between different types of cancer.

In particular, if the following terms are not clearly defined, misunderstanding may result:

- Excess
- Cluster
- Study, Investigation
- Association, Cause

Data caveats and issues:

- Latency between exposure and diagnoses
- Years of residency and diagnoses
- Mailing vs. residency addresses
- Reporting lag, especially from out-of-state

General data needs:

- Numerator (number of cancers): by site/history, age, diagnosis dates, sex, race
- Denominator: population size, age distribution, migration patterns
- Other data on locale: environmental, historical, demographic
- Other data on cases: occupation, smoking, diet, family history, etc.
- Key community contacts

NJ resources on incidence rates:

- NJ State Cancer Registry
- SEER
- NAACCR
- Other publications

Appendix F

Background Information on Risk Communication

Developing A Risk Communication Strategy

The majority of the following text reflects information printed in ***Communicating in a Crisis: Risk Communication for Public Officials, 2002***. It is a publication developed by the U.S. Department of Health and Human Services, and is meant to serve as a handbook for communicating about health risks. Additional resources are listed throughout.

Definition and Scope

Communicating about risks to public health is an integral part of a cancer cluster investigation. Public health officials must utilize effective risk communication techniques to share necessary and appropriate information with the public and to create a partnership that will foster two-way communication. Over the last two decades, facilitating the exchange of information and opinion among individuals, groups and institutions has become vitally important to public health and the published guidance on risk communication has expanded enormously. The Task Force, recognizing the value of examining the most current theories and practices as they apply to cancer clusters, sponsored a conference entitled *Cancer Clusters: Improving Communication with Communities and Individuals* on October 27, 2003. Risk communication experts presented and discussed their experiences, approaches to risk communication, and research. These presentations are detailed in the Summary of the Conference on Risk Communication in Appendix I. Highlights and key points of that seminar, along with information from basic risk communication practices, are included in the following summary. The intent is to provide a basic understanding of risk communication issues as they relate to the development of a constructive and effective approach to communicating the health risks of cancer clusters. Structuring a formal risk communication strategy is key in the development of priority strategies for the investigation of suspected cancer clusters in New Jersey.

The traditional view of risk embodies some objective function of probability (uncertainty) and adverse consequences. This view, however, does not encompass the complex and socially determined nature of the concept of “risk”. More contemporary concepts of risk take into account the important role of social values in risk perception and risk acceptance. The result is that the public perception of risk may differ widely from that traditionally held by scientists and statisticians. Ultimately, the most effective risk communication approach takes both viewpoints into account, providing the keystone around which a robust risk communication program can be structured.

Risk communication, as defined by the National Research Council is, “an interactive process of exchange of information and opinion among individuals, groups and institutions; often involving multiple messages about the nature of risk or expressing concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management.” (US Public Health Service, 1995.) The complex task of communicating health risks in the community is both a process and a skill. Important assumptions of risk communication are that: both the public and health officials benefit from two-way communication and can learn from each other, that public participation improves the likelihood of successful communication, and that risk communicators must, with a great degree of sensitivity, recognize and consider the perceptions and concerns of community members.

In the event of a perceived cancer cluster, the need for the community and its citizens to be fully informed is paramount. The public must feel that they have choices or some personal measure of control. While NJDHSS epidemiologists, the academic community, and other partner organizations take the lead in investigating potential cancer excess and identifying its cause, the community must be kept in the communication and decision-making loop. This was evidenced in public meetings held in Dover Township as citizens vocally declared their need to know what was happening in their community and what the NJDHSS was doing about it.

Bringing the views and values of both health officials and the community to the table results in a joint endeavor that is both deliberative and analytic. In implementing a joint approach, public officials must recognize that honesty, empathy, and caring build the trust that is needed to inform and reassure the public and to find solutions to problems. This precept forms the foundation upon which a credible and effective risk communication plan is built.

Communicating Health Risks: Dissecting the Before, During and After

There are steps that the NJDHSS can take in advance of a reported cancer cluster to better prepare communities, government spokespersons, LHOs, the news media, physicians and hospital personnel to respond to the challenges of communicating health risks. Achieving communication success requires accomplishing a sequence of planning tasks. These steps include issue identification, goal setting, profiling issues, audiences and constraints, assessing the audience, identifying messages and methods, implementing strategy, and evaluating, debriefing and follow up (Johnson, The Conference on Risk Communication, 2003). The NJDHSS must incorporate these strategies into a plan for communicating potential cancer cluster health risks.

Issue Identification: Initiating an Effective Communication Process

Recognizing the importance of the partnership between health officials and the community is a primary tenet of communicating health risk. Communicating risk around possible cancer clusters is both important and difficult in that it requires understanding of how the public views risk, or the “logic behind what may seems illogical.” The concerns of citizens are always legitimate, even if scientific research eventually rules out the possibility of a cancer cluster. The NJDHSS can better prepare itself to understand community concerns by:

- **Identifying with the people of the community.** It can be very helpful for health officials to mentally picture themselves as members of the community in question.

- **Establishing easy and open lines of communication with concerned citizens who have initially contacted the NJDHSS with cancer cluster concerns**. These individuals provide an invaluable source of information regarding community perspective. The community may have a hypothesis regarding the source of the perceived cluster. Investigators must be ready to listen carefully to their concerns. Doing so will enable NJDHSS to investigate and address these concerns as well as suggest appropriate ways the public can protect themselves by giving them options and choices.

- **Monitoring media reports.** Local newspapers and radio stations will almost certainly report on community cancer cluster concerns. Keeping abreast of these reports can help the NJDHSS to monitor community concerns.

Developing Communications Goals

Developing clear communications goals and the key messages to support them are essential elements in planning a response to a potential cancer cluster. These should include informing the public of any known environmental pollutants, providing guidance on appropriate community responses and easing concerns. Messages in support of these goals must be direct and speak effectively to the community. If health risk is low, health officials should say, “the risk to the public is low”.

Once goals and messages have been established, the challenge for the NJDHSS becomes one of delivery. It will be the responsibility of the NJDHSS to ensure that the people of the community have a clear understanding of the intended message. NJDHSS officials must also assess whether communications goals are being met.

Delivering Accurate and Timely Information

In communicating a risk, there is a constant tension between providing accurate information and providing information quickly. Both demands pose dangers. Waiting for all information to be verified and complete can cause an information vacuum that will, almost certainly, become filled with rumor and speculation. On the other hand, releasing information that has not been double-checked and turns out to be inaccurate, runs the risk of misleading the public and undermining the credibility of the spokesperson.

The NJDHSS can establish regular briefings with the public and the media to best address this challenge. At each consecutive meeting, information can be delivered, explained and updated. Estimations can be presented as such and their preliminary nature stressed. The ongoing exchange between the community and a responsive health department will facilitate the formation of trust. Additionally, the notification that all information will be updated in the near future keeps information in its proper context and prevents it becoming prematurely etched in stone. In addition, it will keep the media attentive to the changing nature of the issue and attuned to the need for maintaining contact to keep accurate and up to date.

Communicating Complex, Scientific and Technical Information

The necessity for health officials to communicate clearly and carefully to the public was stressed by several of the speakers at the Risk Communication Seminar held in October 2003. This includes the dissemination of complex scientific information. Health officials need to be prepared to explain their work and findings to the public in ways that the public can readily understand. The use of clear, non-technical language to discuss risks and other specific information is essential to effectively indicate the nature, form and the magnitude of the perceived risk.

It may be helpful for the NJDHSS to relay complex scientific or technical information and communicate to the public more easily by:

- Using consistent names and terms throughout a crisis situation.
- Avoiding acronyms and jargon. Providing careful definitions in advance (e.g. the public often does not understand “the denominator”).
- Using visuals to help to clarify and support key communication points.
- When appropriate to the audience, using familiar frames of reference to explain how much, how big, or how small. Trying to create a mental picture of such measures as “parts per billion”.
- Indicating the level of certainty of your information.

Acknowledging Uncertainty

As previously mentioned, the complex nature of cancer makes cluster investigation problematic. In prior cluster investigations, the NJSCR has had to face the dilemma of acknowledging and explaining uncertainty to the public or a community. This can create tension between the community and health officials as the community is actively seeking answers, namely a cause for the perceived cancer cluster. The reality is that epidemiological data is not always able to provide answers. As a result, the NJDHSS has had to explain the data’s limitations and uncertainties. Adhering to the following guidelines can aid in this difficult effort.

- If information is not known or available, it is best to admit it.
- Saying “I don’t know” is an acceptable response and may help build credibility.
- The public needs to be provided with as much information as possible to help them understand that uncertainty is part of the process.

Understanding Perceptions of Risk

The perceptions of risk for researchers and the community are often dissimilar. The researcher is viewing the risk through the lens of scientific study, while the public is aggressively seeking solutions to a situation in which they have a significant personal stake. In her presentation, *Breast Cancer in Marin County: A Communication Challenge,* Ms. Ereman pointed out that researchers associated increased screening, high socioeconomic status and reproductive factors with the increased rate of breast cancer, while the public’s perception was that air, water and soil must be contaminated. Additionally, the magnitude of perceived risk was greatly increased when community members had an association with, or were themselves, breast cancer patients. Ms. Ereman observed that “everyone has a bias” and that this complicates both the researcher’s efforts in understanding the public’s perception of risk and the public’s understanding of how researchers are handling the situation.

Cluster investigators and communicators should be knowledgeable about the community's "lay hypothesis" and attempt to correct any misconceptions (Johnson, Cancer Cluster Risk Communication Conference, 2003). The NJDHSS needs to be attuned to this perception of risk.

Factors Which Influence Risk Perception

Perceptions of the magnitude of risk are influenced by factors other than numerical data (Fischhoff, et al., 1981). These are evidenced in the table below.

Risks perceived to…	**Are more accepted than risks perceived to…**
be voluntary	be imposed
be under an individual's control	be controlled by others
have clear benefits	have little or no benefit
be distributed naturally	be manmade
be statistical	be catastrophic
be familiar	be exotic
affect adults	affect children

Understanding these factors can help the NJDHSS gauge the degree of risk perceived by people within the community so that both the public and experts may benefit from the two-way communication and learn from each other.

Earning Trust and Building Credibility

Success in establishing constructive communication will be determined in large part by the public's perception of public health officials. It is essential that these officials be perceived as trustworthy and believable. Trust is a critical factor and is likely to be highest when cancer cluster investigators work with the community, keep promises and demonstrate sincere interest and respect for the community (Lewis, Conference on Cancer Cluster Risk Communication, 2003). It is essential to keep in mind that, while trust is difficult to build, it is easy to lose. "The Seven Cardinal Rules" of risk communication, developed by V.T Covello and F.H. Allen, provide guidelines to facilitate the development of trust between researcher and community. They are:

- Accept and involve the public as a legitimate partner.
- Plan carefully and evaluate your efforts.

- Listen to the public's specific concerns.
- Be honest, frank, and open.
- Coordinate and collaborate with other credible sources.
- Meet the needs of the media.
- Speak clearly and with compassion (Covello and Allen, 1988).

Managing Hostile Situations

Risk + heightened public emotions + limited access to facts + rumor, gossip, speculation, assumption and inference = an unstable information environment

An unstable information environment is the situation that all public health officials must strive to avoid in the event of a suspected cancer cluster. Difficult relations between the community and health officials can be attributed to a lack of trust and severely limit the effectiveness of risk communication efforts. Dealing ineffectively with hostility can erode trust and credibility even further. Anger and hostility can be diffused by:

- Acknowledging the existence of hostility.

- Preparing, e.g. practicing the presentation and anticipate questions and answers.

- Listening and recognizing people's frustrations. Communicating sympathy.

- Assuming a listening posture. Maintaining eye contact.

- Answering questions thoughtfully. Turning negatives into positives, bridging back to your messages.

Understanding and Working With the Media

Communicating with and through the news media is an imprecise endeavor at best. The nature of a cancer cluster investigation is such that there are bound to be conflicting reports and misinterpretations. Experts may have differing opinions. Journalists may end up balancing one set of facts against another and arrive at conflicting conclusions. There are, however, guidelines that the NJDHSS can implement to minimize confusion and maximize lines of communication.

- Be sure of the facts.

- Be able to cite sources and key statistics.

- Have information readily available in the form of fact sheets and other concise informational documents specifically prepared for the media's use. Point out, however, that ***not all*** results are listed in the edited sheet for the press.

- Familiarize oneself with information and opinions that are contrary to “official” positions so that these issues may be directly addressed.

- Understand reporters’ time and space constraints.

Much of the success of effective cancer cluster risk communication depends upon the amount of work that goes into the planning and preparation for a potential cluster. Determining what information needs to be in place, addressing community cancer concerns and specifying procedures designed to carry out response initiatives is essential. The U.S. Department of Health and Human Services proposes the following guidelines for risk communication (U. S. Department of Health and Human Services, 2002). These should be adopted as part of the NJDHSS Risk Communication Protocol.

- Form a risk communications team.

- Designate a team leader and assign responsibilities to team members.

- Develop and maintain lists:
    - Primary contacts/experts
    - Secondary contact/experts
    - Media lists identifying national, regional, and local outlets.

- Consider logistics. Public meetings should be held in locations that will accommodate the community.

- Identify information needs. Develop appropriate fact sheets and background materials.

Evaluation

Outcome evaluation is necessary to assess the success of efforts directed towards communicating with the public regarding cancer clusters and easing their concerns. Effectiveness is a measure of how well the communication objectives were achieved in terms of community outreach, and whether the community processing the message, took the recommended actions and made informed health decisions. Ideally, evaluation should be thought about from the beginning. Is the strategy on course? Have problems been identified? If so, can they be solved or adjustments made? Can the public be better served? Are there additional concerns to be dealt with? Specific evaluation strategies may vary according to the situation. Following the event, other issues must be assessed and recorded. It is important to find out what worked and what did not. Learning from communication, and applying the lessons is vital. Asking stakeholders the following questions can assess the impact of the risk communication process. These can be incorporated into the form of questionnaires designed to collect information.

Health officials, epidemiologists and the academic community:

Did communication efforts reach people in the community? What was changed as a result of the involvement? What is known now that was not known before? Was the public influenced by the views given; if so how and what was their response?

The community:

Was the risk communication team sensitive to community concerns? Did they bring expertise to the problem? Did the team adequately educate the community with regards to the nature of the suspected cancer cluster? Did the team offer solutions or some measure of personal control? Has the problem been solved? Was the entire community provided with equal opportunities to participate?

Follow-up

Follow-up is also integral to successful risk communication about cancer cluster investigation. Community attitudes should be monitoring by maintaining regular contact. Make sure that a mechanism for the public to make an appeal is put into place. The NJDHSS's initial response *may not* be sufficient to address community concerns**.** Closely monitor the media, nationally and regionally, particularly publications and programs likely to be read by the community; use the media as a source of intelligence. Regularly scan websites of those groups representing the community. Monitor the nature of cancer clusters inquiries received by the NJDHSS. What are the concerns? What is the general level of concern? Are patterns discernible?

Each risk communication episode represents an opportunity for organizational learning. To prevent lessons from needing to be re-learned and mistakes repeated, the risk communication protocol can include a written review. The review should include a record of the reasons for decisions, what was actually done, and what the outcomes were. The goal is to identify and share learning points. In this way, collective experience may be put to best use.

Appendix G

Summary of Conference on Cancer Clusters

CURRENT PRACTICES IN THE INVESTIGATION OF DISEASE CLUSTERS: July 7, 2003

Epidemiologists, medical experts, communications experts, health educators, and cancer survivors met in New Brunswick to discuss cancer clusters, hear about the experiences of cancer cluster investigators, exchange ideas, and discuss the future of cancer cluster investigation. This conference, sponsored by the Task Force on Cancer Clusters in New Jersey, featured presentations by seven leading cancer cluster researchers, each bringing their expertise to the complex issues inherent in cancer cluster research. Rich discussions between the audience and presenters followed.

Daniel Wartenberg, Ph.D.
UMDNJ-Robert Wood Johnson Medical School and the Cancer Institute of New Jersey

Dr. Wartenberg reviewed the science behind cluster investigations, challenges to cluster investigations, and promising new approaches and technology. He highlighted how future investigations can best be done from a scientific perspective. Dr. Wartenberg asked challenging questions such as what is a cluster? Why is it important to study clusters? Why are they controversial? And, how can we use new tools such as geocoding and other advanced statistical tools, and be proactive while being responsible?

Overview cluster questions raised by Dr. Wartenberg
What is a cluster?

- An aggregation of several cases of cancer in some identifiable subpopulation, the disease must be defined (e.g. leukemia must be differentiated from acute lymphocytic leukemia, and from the broad diagnosis, "childhood cancer")

How do we study a cluster?

- We need to define our cluster populations and subpopulations and ask where are we seeing this.
- We need to characterize it, talk about the number of cases and relative risk, ask how bad is it and how many cases are there so that we can begin to address whether or not it might be just due to statistical fluctuations, and it might be real in a statistical sense but not meaningful in a public health context.
- We need to ask what are we trying to do.
- We want flexibility and generality.

Why are cluster studies controversial?

- Poor investigation track records.
- Lack of adequate resources.
- Track record does exist, but not as much for community-based clusters as for occupational and pharmaceutical clusters.
- Lack good community surveillance programs.

- Do not have information about demographics, behavior, and risk factors that are often available in occupational cohorts.
- Follow-up is haphazard.
- Data is not as good and we don't have effective ways of going after it.
- Lack working definition of cluster.

Why is it important to study clusters?

- It's good public health practice because it is a big public concern when people identify this as a problem.
- Investigating clusters allows us to clarify misconceptions and explain to the public why it happened, that it's a natural variation of cancer or it is due to some other type of risk factor that is not related to the environment, but to really try to begin to understand it.
- When concerns are well founded, it is time to initiate a study and remediate the problem.

The future of cluster investigations

- We need to figure out how we organize the data it and make sense of it.
- CDC has new initiative for disease tracking to develop surveillance systems. The initiative recognizes deficiency in community/public surveillance.
- GIS allows for geographically indexed information where we know where people live, what exposures are, we map it, and conduct sophisticated analyses.
- If we build on history of occupational and pharmaceutical epidemiology, which highlights when and where problems are, we can be responsive to community concerns, we can monitor over time, respond quickly to meaningful inquiries, and prioritize where we do investigations, this is data-driven public health practice.

Carol Rubin, D.V.M
National Center for Environmental Health
Division of Environmental Hazards and Health Effects
Health Studies Branch, CDC

All states receive inquiry calls from the public about the possibility that a cancer cluster exists in their neighborhood or city. In 2001, Dr. Carol Rubin, Chief of the Health Studies Branch at the National Center for Environmental Health (NCEH) and her staff began to survey states regarding their cancer cluster protocols. They also sponsored two workshops involving 11 states, conducted a review of media coverage in the last decade concerning cancer clusters and visited three states that had recently utilized their protocols to address large scale cancer cluster investigations. Their goal was to examine what states were doing, what was and was not working, determine the states' needs with regards to the federal agency, determine how to better coordinate efforts, and ultimately, to develop better science and methods.

Review of States Protocols

- Requested copies of any documentation related to cancer cluster investigations from all states, not to evaluate or rate, but to identify commonalities and differences.
- Developed a comprehensive tool with over 300 descriptors seen in states protocols. If there were variables that appeared in several protocols, these were added to descriptor list.
- Compared what kind of information and education was provided to callers, and who was responsible for initial stages of investigation.

- Looked at decision trees, what kind of data resources were available within the state, and was there a chain of command.
- Found an incredible difference in the level of detail among states. Some states provided a blueprint for action so one would know what the next step would be.

Communication Review

- Cognizant of the tremendous influence media has on public opinion, a review of all databases not normally used in public health took place. NCEH looked at all reports that talked about cancer clusters, including subsets such as leukemia from 1977 onward.

Visit to States

- Eager to learn about lessons learned from cluster investigations, NCEH visited three states that had conducted investigations. They wanted to hear if results of the investigation led to modifications in their cancer cluster protocol, whether or not their experience might affect decisions to conduct subsequent investigations, and overall, the lessons learned.
- All 3 states used a systematic approach; everything was triaged.
- All had websites addressing the issue; and each state felt it did not have adequate staff, money or quality data.
- States reported that their recent investigations had caused their protocols to evolve.
- Each of the 3 states visited, as well as the 11 states that subsequently attended the NCEH workshops, recognized that education was the most vital missing link. Recent focus on the importance of educating the community regarding a potential cancer cluster event has hopefully increased the effectiveness of individual and community communication efforts.
- The 3 states that were visited said they would be interested in moving towards standardized forms.

Lessons learned from all steps of the review process reaffirmed that we cannot ignore cluster inquires. Although states' response plans were superficially dissimilar, content-wise they were fairly consistent. Additionally, there is a continuing need for state and federal coordination. It is time to consider new approaches and while states do not want a uniform protocol, they have asked for modules so that when data are aggregated all involved will be asking the same question. Finally, effective communication was uniformly identified as an essential element to cluster investigations.

Craig Trumbo, Ph.D.

University of Missouri

Nobody will argue that communication is complicated and involves numerous factors. There is a genre of communications that focuses on public understanding of science and health risk communications in fields such as cancer epidemiology. Dr. Craig Trumbo researches communications and perceptions about clusters, and information processing in communities where they think there is a cluster, in relation to advisory signs. During his presentation he reviewed two prominent models of information processing: systematic information processing and heuristic information processing.

In systematic information processing, the most motivated individuals actively seek information. They are the most concerned about risk and are steadfast in their opinions. This means, if you tell them there is no cancer cluster, it is unlikely that they will change their mind. In the heuristic information processing model, one is less motivated and is more likely to make decisions via quick rule-of-thumb. Additional highlights of Dr.Trumbo's presentation include:

- Credibility of sources of information focuses on the experience that professionals have in public meetings associated with cancer cluster cases. There are five characteristics of a credible source: accurate, balanced, complete, fair, and trustworthy.
- Credibility has a direct effect over the perception of risk and does not strongly influence the way people go about processing the information.
- Future work should assess the effect that credibility of the vehicle or messenger has on the credibility of the actual information source and developing a measurement tool for measuring cancer anxiety. Future communicators need to be trained with principles of interdisciplinary theory and principles of communication.

Peggy Reynolds, Ph.D.
California Department of Health Services

The state of California established their California Cancer Registry (CCR) in 1985. CCR is California's statewide population-based cancer surveillance system. This registry contains information about all cancers diagnosed in California (except basal and squamous cell carcinoma of the skin and carcinoma in situ of the cervix) and is used to further their understanding of cancer and to develop and implement strategies and policies to prevent, treat and control cancer. The CCR is considered to be one of the best cancer registries worldwide. It has enabled California to be informed about cancer amongst its diverse population.

Dr. Peggy Reynolds is the Chief of the Environmental Epidemiology Section in the California Department of Health Services. She shared with the conference background information about California's approach to cancer cluster investigations, the progression of the program, and present activities with childhood cancer. Highlights from her talk include:

- Revising their initial approach to investigating clusters. Initially they went into the field and searched and measured everything for individual community clusters. As they gained experience they learned that such an approach was not useful. The program focus has shifted to listening to what people are worried about in cluster communities and designing statewide studies to address those environmental concerns.

Richard Clapp, Ph.D.
Boston University

Many public health successes are a result of steadfast citizen action groups. These groups may suspect a toxic substance exists in their neighborhood and work from a grassroots level to effect change. Dr. Richard Clapp from Boston University relayed accounts of lessons he has learned from his experience on the Upper Cape Cod cluster investigation. He provided an eloquent example of how successful community activists can be in collaboration with public health professionals. "To work with activists, you engage them, they engage you," he said. He further elaborated that working with activists may require compromises and one may need to find ways to either incorporate or say why they're not incorporating an idea.

Raymond Neutra, Ph.D.
California Department of Health Services

Multiple ethical considerations surround cluster investigations. Dr. Raymond Neutra of the California Department of Health Services discussed how epidemiology contributes to public health policy. For example, there are stakeholders who believe investigations should be pursued regardless of cost and because public health has a "duty" to protect the health of the public. Then there are those stakeholders who hold the belief that we should strive to achieve the best results for the most people at the least cost. Dr. Neutra pointed out that it is critical for scientists to be aware of the multiple perspectives or frameworks that stakeholders come from.

We learned a bit about prescriptive ethics and results cited ethics. Prescriptive ethics looks at what the duties are. People from this framework are unconcerned with costs because they believe public health's duty is to explain as much as it can. In result ethics, people look at their options and what they are trying to achieve in the way of results. They strive for the obtaining the most good for the most people at the least cost.

<u>Additional Key Points and Questions from Dr. Neutra's Presentation</u>

- He highlighted the natural tendency of an epidemiological study to be the beginning of a whole series. Studies often uncover new hypothesis that stimulate further research.
- An example of an ethical dilemma: would it be more fruitful to spend a lot of money on repeatedly doing small cluster examinations or larger examinations?
- With regard to nonscientific criteria results, may ask, did I need to do this study to motivate a cleanup. Often, if it was not for the newspaper stories, no cleanup would have occurred.
- Questions/concerns particularly when funds or people-power is low: what other projects were delayed or not done because of this? Is this a win/win or a no/win for the agency?
- Some of the different people that are involved as decisions are made: activists, media, academic epidemiologists, agency epidemiologists, citizens, industry, politicians.
- Concerning responsible mapping: what happens when we come up with a situation that we cannot respond to or what happens if we generate false positives, how do we decide which "statistically significant" results to follow-up?

Martin Kulldorff, Ph.D.
University of Connecticut

Trying to identify clusters, and to distinguish between a pattern that is a potentially random occurrence versus a true cluster, requires the diligent computing of statistics. Dr. Martin Kulldorff of the University of Connecticut is an expert biostatistician. Dr. Kulldorff discussed spatial scan statistics and their ability to look at, events happening over time and space, so that we can see if there are any clusters. His main points included:

- Important to use proper statistical methods: many clusters investigated may not have achieved results because inappropriate statistical methods were used.

- Spatial scan statistics can also be used for surveillance, preventive systems and detecting outbreaks early. The statistics can be used for chronic or infectious diseases, diseases with known or unknown etiology, and data quality control (e.g.: find errors in data, reporting, census numbers).

Appendix H

CDC Summary of Site Visit to the State of New Jersey

Summary of Site Visit to the State of New Jersey
Department of Health and Senior Services
October 9 and 10, 2002

Participants:
Lorraine Backer, CDC
Amy Funk, CDC
Kristine Rae, RTI

Betsy Kohler, DHSS
Judy Klotz, DHSS
Pam Agovino, DHSS
Stasia Burger, DHSS
Jerry Fagliano, DHSS
Michael Berry, DHHS
Pat Haltmeir, DHHS
Eddie Bresnitz, DHSS

Materials Collected

Folder including the following:

- Use of Proportional Cancer Incidence Ratios for Surveillance of Geographic Cancer Patterns (Klotz, Agovino, Weinstein, Kohler) (2002)
- Sample inquiry and response letters
- NJ State Dept. of Health & Senior Services, Cancer Epidemiology Services, Cancer Surveillance Program: Response to Cancer Cluster Inquiries, 1997-2002
- Overview of Cancer Cluster Response Practices (2002)
- Organizational Charts: Cancer Epidemiology Services, Office of the Director; Cancer Registry; Cancer Surveillance Program; NJ State Department of Health and Senior Services, Public Health Protection and Prevention Programs
- Standardized response forms and materials: Cancer Cluster Inquiry Intake Form; Log of Persons with Cancer; Report of Cancer at a Workplace; Instructions for Completing the "Report of Cancer at a Workplace" Form; Fact Sheet: Inquiries About Cancers in Communities; Cancer Facts (NCI); "A Cluster Conundrum" by Mark Jaffe, The Inquirer; Stat Bite: Lifetime Risk of Being Diagnosed with Cancer (NCI); NJ Department of Health & Senior Services: Cancer Risk Factors; NJ Department of Health & Senior Services: Fact Sheet-Occupational Cancer and Response to Reports of Cancers at Work; Environmental Exposures and Your Health; Breast Cancer: Susceptibility and the Environment (NIEHS); Historic Pesticide Contamination (NJ Department of Environmental Protection); NJ Department of

Environmental Protection Site Information Program (Web page); The New Jersey State Cancer Registry: A Legacy of Survival Through Research; NJ-CEED: Early Detection is Your Best Protection; Standards for Safe Drinking Water in New Jersey; An Introduction to the Public Employees Occupational Safety and Health Program
- Improving Bioterrorism (BT) Preparedness via Linkages with Tuberculosis (TB) Programs: A Primer on How TB Can Help BT- Recommendations from the National Tuberculosis Controllers Association
- Characteristics of Communities Where Excess Cancer Can be Studied
- Expected Random Cancer Excesses in Localities
- Local Cancer Excesses and Follow-up Studies (J Registry and Management 2000)
- Memo from Betsy Kohler, Director, Cancer Epidemiology Services to Christine Grant, Commissioner, New Jersey Department of Health and Senior Services (Feb. 9, 2001)
- Analysis of Burlington County Health Department’s Cancer Survey of the East Riverton Section of Cinnaminson, NJ by the NJ Department of Health and Senior Services
- Addressing Cancer Cluster Inquiries: NJ Current Protocol and Role of LHDs
- Notes on “Guidelines for Investigating Clusters of Health Events”
- Interim Cluster Response Protocol

Objectives

1) Learn about how New Jersey’s Department of Health and Senior Services (NJDHSS) has conducted inquiries of reported increases in cancer incidence in the past.
2) Learn about strengths and weaknesses of New Jersey’s inquiry process, as well as directions for future inquiries.

Background

In 1979, cancer became a reportable disease in New Jersey; at the same time, Cancer Epidemiology Services was formed. In the early 1980s, NJDHSS collected SEER data, however the funding to do so was lost a few years later. Toward the end of the 1980s, New Jersey became a SEER state again. To date, NJDHSS has collected more than one million records.

In the early 1980s, NJDHSS was unable to respond to reports regarding suspected cancer “clusters”. Later, a spot was created within Consumer and Environmental Health Services, allowing NJDHSS to respond to such reports. Around 1997, these capabilities moved to Cancer Epidemiology Services.

The staff at NJDHSS feel very strongly that the phrase “cancer cluster” not be used; this preference is based on the extremely low likelihood of detecting a true cancer cluster.

When NJDHSS Receives a Report of a Suspected Cluster

NJDHSS goes to great lengths to educate citizens about the nature of cancer and about the likelihood that an apparent increase in cancer incidence represents a true cancer cluster. This information is conveyed in multiple ways: on the telephone, in a customized response letter, in fact sheets, etc. The staff are committed to resolving the citizen's concerns, and spend as much time with the individual as necessary to do so.

An extensive packet of information is mailed to citizens inquiring about a suspected cluster. This packet always includes a customized response letter, and may include fact sheets from NCI, ACS, or other groups, as well as any other relevant resources. Each customized response letter conveys that environmental exposures are of the highest importance to NJDHSS, even aside from cancer. Every response letter is reviewed by Betsy Kohler and at least one other individual, to ensure that the tone of the letter and the information contained within are appropriate and responsive to the citizen's concerns.

Conducting an Inquiry

A record of all incoming reports is logged; data are collected using standardized data intake forms. For analyses, NJDHSS examines the entire registry period (1979 to present) and looks for elevations in incidence of specific cancers. If an elevation is found, the data are broken up into individual years and examined more closely. In the event it becomes apparent that specific data should continue to be monitored, NJDHSS will add the data to an electronic "watch" list to be monitored over the coming years. If a particular spike in incidence appears a second time, further investigation is conducted. The value of this procedure was illustrated during the Dover Township Study described below.

Currently, an effort to geocode the entire state is underway. Upon completion, NJDHSS staff will be able to utilize Standardized Incidence Ratios (SIRs) as well as GIS software such as ArcView. Until geocoding is completed, NJDHSS uses Proportional Cancer Incidence Ratios (PCIRs) and the CLUSTER software program (Texas utility).

Past Inquiries

Dover Township (Toms River):
In the mid-1990s, ATSDR requested analysis of cancer incidence data for Dover Township (Ocean County), based on a request by a nurse in Philadelphia. Data up to 1991 were used in the analysis. A significant increase in certain kinds of cancers was found.

In 1996, a panel of individuals was formed to talk to the community about the findings of the analysis. Approximately 1,000 people attended the first meeting, which turned out to be extremely confrontational. Despite the difficulties encountered, the meeting served as an impetus for a new and constructive inquiry process and led directly to the establishment of a Citizens Action Committee (CAC).

As part of this process, NJDHSS developed the Public Health Response Plan. Under this plan, CDC and state funds were used to update and improve the state cancer registry, to conduct new analyses of the Dover Township data, and to investigate potential environmental exposure pathways.

A number of new efforts were undertaken, including a cancer incidence evaluation, public health assessments and consultations, and a toxicological consultation for the area. All towns in Ocean County were examined for increases in cancer incidence; only Dover showed a significant difference between observed and expected numbers. This excess was seen predominantly in leukemias among younger female children.

Community meetings organized by the CAC were held monthly. In the beginning, between 100 and 150 people attended; as time went on, between 30 and 40 would attend. Information was presented concerning environmental exposures from drinking water wells and air from past dumping of contaminants from a Union Carbide facility. The CAC was instrumental in obtaining funding for the conduct of an epidemiologic study of cancer incidence in Dover.

For the epidemiologic study, 40 cases and 159 controls participated in telephone interviews. Subjects were matched on sex, year of birth, and residence in Dover Township during the month of case diagnosis. Historical geologic patterns of environmental exposures were created by month between 1962 and 1996 using an innovative technique developed by ATSDR. NJDHSS analysts computed an average environmental exposure factor for the total period of interest, prenatal, and postnatal. The State Department of Environmental Protection, the EPA, several county health departments, and ATSDR were major contributors to the study, which identified Radium-224 in a few drinking water well fields. It was later determined that the findings were an artifact of the sampling and analytic methods used.

Strengths and Weaknesses

Strengths:

- Active listening by person taking the initial report
- Reiteration of caller's concerns
- Thorough documentation of complaints
- Excellence of cancer registry
- Rotation of staff taking initial reports (to prevent burnout)
- Close relationship with Environmental Health
- Staff's strong background and experience in environmental health and related issues
- NJDHSS enjoys the opportunity to educate their citizens
- Empathy of NJDHSS staff responding to the report
- Governor of New Jersey is very interested in cancer issues

Weaknesses:

- Geocoding of state not yet complete
- Inadequate number of staff
- Political pressure
- Need better integration/availability of environmental data
- Public perception of response (persistence of advocates)

CDC Involvement

NJDHSS feels that education of New Jersey's citizens would help a number of issues associated with conducting inquiries. Staff often struggle with translation of data from science to lay terminology; help from a clinician would be useful (particularly an environmental occupational medicine physician).

NJDHSS is interested in CDC development of standardized data collection forms and public education materials concerning clusters. They also would like to see federal agencies and state governmental representatives receive education regarding suspected cancer clusters, as well as training on how to respond to constituents voicing a concern about a suspected cancer cluster. This training could include case scenarios to which legislators could practice responding. NJDHSS is interested in identifying a disinterested, active voice to validate their methods; this would increase their credibility with the lay public. They would also like to see development and promotion of updated national guidelines for conducting inquiries; staff feel that the 1990 MMWR recommendations are not clear enough regarding decision trees for stopping or continuing an inquiry.

NJDHSS noted the utility of being proactive in searching databases for elevations in cancer incidence. Doing so would allow them to be aware of such elevations before the public becomes aware of them. NJDHSS staff requested guidance from CDC in ways for being proactive in this regard.

As sophisticated GIS software becomes available, NJDHSS would like guidance from CDC in choosing which software would be most helpful. They are also interested in a satisfaction survey of citizens following completion of activities resulting from their report of a suspected cluster.

Staff from NJDHSS indicated that the state report resulting from Task 2 of this contract was very helpful to them in gauging where their methods stand, seeing what other states do, and educating others about the state's current inquiry procedures.

Conclusions

NJDHSS is committed to responding to citizen concerns about cancer clusters and about environmental health. The Department enjoys extensive cancer registry data and has developed sophisticated statistical techniques over the years that allow them to conduct the most useful and reliable analyses with their current resources. NJDHSS is working to geocode the entire state, which will allow them to reliably utilize Standardized Incidence Ratios in analyzing registry data.

NJDHSS has a close relationship with the environmental health group, allowing for efficient coordination of efforts in conducting inquiries. Their staff have strong experience in cancer-related fields and they work to ensure that this experience is utilized in a way which will keep advancing their cluster inquiry capabilities.

Despite these strengths, NJDHSS is currently operating with a significant deficit in staffing. Staff have devised "rotation" strategies to help prevent burnout, however these strategies have no overall effect on staff workload, which is currently problematic.

Agenda- CDC Cluster Site Visit

Day 1: **10/9/02**

12:00PM Lunch

1:00PM Cancer Clusters Response NJSCR (Betsy Kohler)
Overview of the Process

1:30PM Response to Cancer Inquiries

- Triaging calls (SB)
- Listen, Record, and Provide cancer information (SB)
- Review of cancer resource/educational material (SB)
- Review of general cancer inquiry response letters (PA)
- Review of general cancer inquiry response letter with examination of Registry data (SB)
- Review of responses requiring more sophisticated analysis (JK)
- Annual follow-up to cancer cluster inquiries (SB)

3:30PM Proportional Cancer Incidence Ratios (PA)

4:15PM Discussion

Day 2: **10/10/02**

9:00AM Review of a Comprehensive Epidemiologic Study

- Discussion of Dover Township Childhood Cancer Study (JF, MB, PH)

10:00AM Other Cancer Cluster Inquiry Investigations with Known Environmental Risk Factors

11:30AM Storage & Maintenance of Cancer Inquiry files and logs

12:00PM Lunch (out)

1:00PM Dr. Eddy Bresnitz, State Epidemiologist

- Political Implications
- Policies

3:00PM Final Review of Discussion Topics

Appendix I

Practices and Standards for Local Health Officers

CHAPTER 52

PUBLIC HEALTH PRACTICE STANDARDS OF PERFORMANCE FOR LOCAL BOARDS OF HEALTH IN NEW JERSEY

Authority
N.J.S.A. 26:1A-15 and 26:3A2-1 et seq.

Source and Effective Date

R.2003 d.51, effective February 18, 2003.
See: 34 N.J.R. 241(a), 35 N.J.R. 1083(a).

Chapter Expiration Date
Chapter 52, Public Health Practice Standards of Performance for Local Boards of Health in New Jersey, expires on February 18, 2008.

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SUBCHAPTER 14. ENFORCEMENT OF PUBLIC HEALTH LAWS

APPENDIX

SUBCHAPTER 1. GENERAL PROVISIONS

8:52-1.1 Purpose

(a) The purpose of this chapter is to:

1. Establish standards of performance for public health services that meet the legislative intent as set forth in the Local Health Services Act, N.J.S.A. 26:3A2-1 et seq. and Local Boards of Health, N.J.S.A. 26:3-1 et seq.;

2. Assure the provision of a modern and manageable array of public health services to all citizens of New Jersey;

3. Designate activities which are required by all local boards of health which shall build local public health capacity and encourage the development of an integrated systems approach for local public health;

4. Encourage cooperation among community partners to protect and improve the health of New Jersey residents;

5. Align local boards' of health and local health agency's performance standards with National Public Health Performance Standards and National Model Community Standards as described in "National Public Health Performance Standards Program Local Public Health System Performance Assessment Instrument";

6. Build a reliable and cost-effective public health system;

7. Protect and promote physical and mental health and prevent disease, injury, and disability, thereby assuring the health of the citizens of New Jersey; and

8. Support the goals of "Healthy New Jersey 2010: A Health Agenda for the First Decade of the New Millennium" to increase the quality and years of life of New Jersey residents and to eliminate health disparities.

8:52-1.2 Scope

Each local board of health shall establish and maintain the standards of performance as set forth in this chapter. No standard shall be construed to authorize a lesser standard than that prescribed by statute or rule or to empower or require a local health agency to act in matters solely under the jurisdiction of a State, county, or municipal government.

8:52-1.3 Compliance

(a) Each local board of health and local health agency shall be accountable for their adherence to standards of performance to the Public Health Council and to the Department pursuant to the provisions of N.J.S.A. 26:3A-2 et seq.

(b) Each local health agency shall make available to the Office of Local Health, within 10 business days of the request, source data and information used for evaluation and determining adherence to standards of performance as set forth at N.J.A.C. 8:52-1.4.

(c) If a local board of health is found to be deficient in meeting the standards of performance as set forth in this chapter, the local board of health shall be required to submit a corrective action plan within 30 calendar days to the Office of Local Health. Regardless of this corrective action plan, the Department may take action at the expense of the non-compliant municipality in accordance with the provisions set forth at N.J.S.A. 26:3A2-11 and 26:2F-13.

8:52-1.4 Performance monitoring and evaluation

A method for evaluation and determining adherence to standards of performance shall be developed by the Office of Local Health as set forth at N.J.A.C. 8:52-16. The information and data may be used by the Office of Local Health for compliance purposes, publication, and research.

8:52-1.5 Registration

(a) Each board of health shall register annually with the Office of Local Health.

(b) Registration information shall be made in a format determined by the Office of Local Health and shall include:

1. Identification of membership of the local board of health;

2. Experience, education and training relevant to public policy development;

3. The type of local governance;

4. The type of authority exercised (governing body, autonomous or advisory);

5. Jurisdictional areas by municipal code;

6. The annual public health budget;

7. A schedule of meetings of the local board of health;

8. Identification of the local health agency and any other providers contracted to deliver public health services; and

9. The names, addresses, telephone numbers, fax numbers, and e-mail addresses of the leadership personnel of the local board of health.

8:52-1.6 Contractual services

A recognized public health activity which meets the standards of performance prescribed in this chapter may be planned and offered directly by the local board of health or by any person or agency under contract to the board, provided that the contract specifies that the services to be provided shall be consistent with the provisions set forth in this chapter and shall not violate any State statute or rule.

8:52-1.7 County environmental health activities

Each local health agency may comply with all applicable provisions of the County Environmental Health Act, N.J.S.A. 26:3A2-21 et seq. and the standards promulgated thereunder by the Department of Environmental Protection, N.J.A.C. 7.1H.

8:52-1.8 Standards and publications referred to in this chapter

(a) The full title, edition, and availability of each of the standards and publications referred to in this chapter are as follows:

1. "National Public Health Performance Standards Program Local Public Health System Performance Assessment Instrument," as amended and supplemented. This document is available through the Public Health Practice Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA, 30333 or at www.phppo.cdc.gov.

2. "Public Health Practice Standards of Performance for Local Boards of Health, N.J.A.C. 8:52-1 et seq., Programmatic Guidelines for Best Practices," incorporated herein by reference as the chapter Appendix, and the "Companion Document to Public Health Practice Standards of Performance for Local Boards of Health, N.J.A.C. 8:52-1 et seq." These documents are available from the Office of Local Health, PO Box 360, Trenton, NJ 08625-0360, 1-609-292-4993 or at www.state.nj.us/health/lh/olh.htm.

3. "The Public Health Workforce: An Agenda for the 21st Century," as amended and supplemented. This document is available from the US Department of Health and Human Services, Public Health Service, Office of Disease Prevention and Health Promotion, 200 Independence Avenue, SW, Room 738G, Washington, DC 20201 or at www.health.gov/phfunctions.

4. The "Core Competencies for Public Health Professionals" Council on Linkages Between Academia and Public Health Practice, as amended and supplemented. This document is available from the Public Health Foundation, 1220 L Street, NW, Suite 350, Washington, D.C. 20005 or at www.trainingfinder.org/competencies.

5. "Assessment Protocol for Excellence in Public Health (APEX-PH) Part 1: Organizational Capacity Assessment," as amended and supplemented: "Mobilizing for Action through Planning and Partnerships" (MAPP) and "Protocol for Assessing Community Excellence in Environmental Health" (PACE EH), as amended and supplemented. These documents are available from National Association of County and City Health Officials, 440 First Street, NW, Suite 500, Washington, DC 20001 or at www.naccho.org.

6. "Healthy New Jersey 2010," as amended and supplemented. This document is available from the Department's Office of Policy and Research, PO Box 360, Trenton, NJ 08625-0360, 1-609-984-6702 or at www.state.nj.us/health/healthy/2010.

7. "Health People 2010," as amended and supplemented. This document is available from the U.S. Department of Human Services, 200 Independence Avenue, SW, Washington, DC 20201 or at www.health.gov/healthypeople.

SUBCHAPTER 2. DEFINITIONS

8:52-2.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Actively participate" means that the local health officer or his or her designees do not miss more than one regularly scheduled meeting in a 12-month period for meetings which are scheduled monthly, or attend 75 percent of all meetings for meetings held more frequently than one time per month, and provide input and take necessary action as required.

"Advocacy" means to act and speak out in support of a specific public health issue or cause.

"Assure" means to achieve agreed Upon goals by encouraging the actions of public or private entities, by requiring such actions through ordinance, or by providing direct service.

"Capacity" means the ability to perform services through available resources, staffing, and/or contractual agreements.

"Clinical preventive health services" means those primary care services that assure timely epidemiological investigation and specific disease prevention and containment and are those services which are an integral component of the public health protection and prevention process.

"Community health assessment" means a formal countywide or multi-countywide process which determines the health status and quality of life. The assessment identifies problems, assesses the community's capacity to address health and social service needs, and allows for Statewide comparability. The assessment also identifies those populations; if any, that are under served by providers in that community and provides information about resource distribution and costs.

"Community Health Improvement Plan" means a formal written plan which includes the roles and responsibilities of all participants as well as a mechanism for accountability for agreed upon goals, objectives and services. The plan is developed though a series of timely and meaningful action steps that define and direct the distribution of essential public health services of community public health providers in a specific countywide or multi-countywide area according to partnerships and processes set forth in this chapter. All plans need to be approved by the Office of Local Health.

“Community public health providers” means governmental local health agencies and other public and private entities in the community that provide public health services.

“Competent leadership” means a public health professional who is trained in supervisory and leadership techniques and who has demonstrated an ability to plan, organize, and direct the work of others in order to attain public health objectives.

“Continuous quality improvement” means a process whereby performance is measured on a regular basis, strategies for improving performance are developed and implemented, and feedback monitoring is performed to assure high quality services.

“Data analysis” or “analysis of data” means the collection, compilation, statistical analysis, and interpretation of data.

“Department” means the Department of Health and Senior Services.

“Designee” means one or more licensed pubic health professional(s) employed by the local health agency who act on behalf of the health office of that local health agency; or one or more licensed health officer(s) employed by one local health agency who agree to act on behalf of a licensed health officer employed by another local health agency.

“Director of health education” means an individual who is responsible for public health education leadership and for the management of the major responsibilities of health education.

“Director of public health nursing” means an individual who is responsible for public health nursing leadership, policy development, planning and quality assurance of public health nursing practice and for the supervision and management of the major responsibilities of public health nursing.

“Distance Learning Network” means a Statewide system of educational facilities which are available and capable of receiving and downlinking satellite transmissions. These facilities also make maximum use of other evolving technologies for the purpose of training public health and other professionals.

"Enforcement" means any action taken by a local board of health or its local health agency to ensure compliance with provisions of N.J.S.A. 26:3-1 et seq., N.J.S.A. 26:3A2-1 et seq., or any other applicable rules promulgated thereunder.

“Epidemiologist” means an individual who is responsible for data instrument design; data analysis; problem solving, development and evaluation of surveillance activities; the design, conduct, and reporting of research projects with the capacity to investigate and describe the determinants and distribution of disease, disability, and other health outcomes; and developing the means for disease prevention and control.

“Field representative, health education” means an individual who performs health education and health promotion activities under the supervision of a health educator.

“Graduate nurse, public health” means an individual who performs direct clinical services under the supervision of a public health nurse.

“Health Alert Network” or “HAN” means the term used by the Federal Centers for Disease Control and Prevention (CDC) to describe the public health infrastructure: the communications system, workforce training and organizational capacity needed to respond to public health emergencies. In New Jersey, the Local Information Network and Communications System (LINCS) and Distance Learning Network form the foundations for the HAN.

“Health education” means any educational, organizational, policy, economic, and environmental intervention designed to stimulate health behaviors in individuals, groups, and communities.

"Health educator" means an individual who is responsible for assessing individual and community health education needs; planning, implementing, and evaluating effective health education programs; coordinating health education services; serving as a resource person in health education; and communicating health and health education needs, concerns, and resources.

"Health officer" means an individual who is licensed pursuant to N.J.A.C. 8:7 and is employed full-time as the chief executive officer of a municipal, regional, county or contractual health agency. This individual is responsible for evaluating health problems, planning appropriate activities to address these health problems, developing necessary budget procedures to finance these activities, and directing staff to carry out these activities efficiently and economically.

"Information technologist(s)/computer specialist(s)” means an individual who evaluates information technology hardware and/or software, provides technical planning, prepares specifications, evaluates information technology vendors and/or contracts, prepares cost benefit analyses of various information technology solutions.

"Linkages" means a set of formal or informal relationships among organizations and agencies which constitute a community public health system.

“Local Information Network and Communications System” or “LINCS” means a network of public health agencies which are inter-connected with the Department through an electronic public health information system that is built on personal computer and Internet technologies.

“Local board of health” means a county or municipal board of health, or a board of health of any regional, local, or special health district having the authority to regulate public health or sanitation by ordinance.

“Local Health agency” means any municipal local health agency, contracting local health agency, regional health commission, or county health department that is administered by a full-time health officer and conducts a public heath program pursuant to law. “Local public health system” means the informational, financial, organizational and human resources that contribute to the public's health. These include, but are not limited to, local health agencies, hospitals, emergency medical services, managed care organizations, primary care centers, social services agencies, schools, health care practitioners, church groups, volunteer agencies, and community-based organizations.

"Monitor" means to systematically measure a process or task or to track compliance with standards, guidelines, laws, rules or regulations.

"Office of Local Health" means the Office of Local Health within the Department of Health and Senior Services.

"Policy" means a set of comprehensive public health laws, methods, and guidelines which are based on scientific knowledge.

"Preventive health services" means those population-based activities such as clinical, health education and/or health promotion, screening, treatment, and follow-up which provide primary or secondary disease prevention.

"Public health" means organized societal efforts to protect, promote, and restore the people's heath, and societal activities undertaken to assure the conditions in which people can be healthy. This includes organized community efforts to prevent, identify, and counter threats to the heath of the public.

"Public health emergencies" means urgent, severe threats to the health of the population which are of an acute nature and require immediate response. Response may include mitigation and enforcement by the local governmental public health system.

"Public health medial director" means an individual under the administrative direction of a health officer of a local health agency who is responsible for developing and evaluating medical policies related to the public's health. These policies include, but are not limited to, evaluation of screening recommendations, treatment recommendations, and the use of medical devices through the performance of core public health functions and the delivery of the "10 essential public health services" at N.J.A.C. 8:52-3.2(a)1 through 10.

"Public health nurse" means an individual who uses knowledge from nursing, social, and public health sciences to promote and protect the health of populations through the performance of core public health services" at N.J.A.C. 8:52-3.2(a)1 through 10.

"Public health nursing supervisor" means an individual who is responsible for managing the daily public health nursing activities for the performance of core public health functions and the delivery of the "10 essential public health services" at N.J.A.C. 8:52-3.2(a)1 through 10.

"Public health planner" means an individual who is responsible for the collection and summary of relevant health information through the use of modern health planning tools; the use of current techniques in decision analysis; the identification and integration of public health laws, regulations and policies into specific local health agency programs and activities; the preparation of policy options with expected outcomes and recommendations for the appropriate course of action; and the development of mechanisms to evaluate the effectiveness and quality of public health programs.

"Registered environmental health specialist" means an individual who is licensed pursuant to N.J.A.C 8:7 and is responsible for the performance of inspections, the compilation of proper records of inspections, the collection of evidence of violations, and the issuance of notice of violation to responsible parties.

"Surveillance" means the continuous systematic collection, analysis, and interpretation of health data that is essential to planning, implementation, evaluation of public health practice, and dissemination of these data.

"Surveillance system" means a functional capacity for data collection, analysis, and dissemination linked to public health programs, and the application of these data to prevention and control.

SUBCHAPTER 3. PUBLIC HEALTH PRACTICE

8:52-3.1 Practice of public health

(a) The practice of public health in New Jersey is defined by the programs and capacities to provide services as set forth at N.J.A.C. 8:52-3.2(a) below, and shall be ensured by each local board of health for each of its residents in accordance with this chapter.

(b) Local health agencies shall be responsible for delivering and ensuring population-based public health services as set for in this chapter.

(c) Local boards of health and local health agencies developing a countywide or multi-countywide systems approach to build the capacity and expertise required pursuant to this chapter may do so in accordance with the guidelines found in the "Companion Document to Public Health Practice Standards of Performance for Local Boards of Health, N.J.A.C. 8:52-1 et seq."

8:53-3.2 Services and capacities

(a) Public health services shall include administrative services as set forth at N.J.A.C. 8:52-5, health education services as set forth at N.J.A.C. 8:52-6, public health nursing services as set forth at N.J.A.C. 8:52-7, and the three core functions of public health which have been expanded to become the "10 essential public health services" in (a)1 through 10 below. Public health services shall:

1. Monitor health status to identify community health problems as set forth at N.J.A.C. 8:52-10. This service includes:

i. Collecting, compiling, interpreting, reporting, and communicating vital statistics and health status measures of populations or sub-populations, as available, within one or more counties. Reporting shall be contingent upon the development of electronic reporting systems;

ii. Assessing health service needs; and

iii. Timely analyzing, communicating, and publishing information on access to, utilization of, quality of, and outcomes of personal health services;

2. Diagnose and investigate health problems in the community as set forth at N.J.A.C. 8:52-12. This service includes:

i. Identifying emerging epidemiological health threats;

ii. Supporting prevention efforts with public health laboratory capabilities.

iii. Supporting active infectious disease prevention and control efforts; and

iv. Acquiring and sustaining technical capacity for epidemiological investigation of disease outbreaks and patterns of chronic disease and injury;

3. Inform, educate, and empower people regarding health issues as set forth at N.J.A.C. 8:52-6. This service includes:

i. Social marketing and targeted public medial communications regarding public health issues;

ii. Providing accessible health information resources at the community level;

iii. Collaborating with personal health care providers to reinforce health promotion messages and programs; and

iv. Initiating health education with schools, community groups, special populations, and occupational sites;

4. Mobilize community partnerships to identify and solve health problems as set forth at N.J.A.C. 8:52-9. This service includes:

i. Convening community groups and associations that have access to populations and resources to facilitate prevention, screening, rehabilitation, and support activities; and

ii. Identifying and organizing community resources through skilled coalition building to support the goals and activities of a countywide public health system;

5. Develop policies and plans which support individual and community health efforts as set forth at N.J.A.C. 8:52-11. This service includes:

i. Systematic countywide and State level planning for health improvement;

ii. Development and tracking of measurable health objectives as a part of a continuous quality improvement strategy;

iii. Development of consistent policies regarding prevention and treatment services; and

iv. Development of codes, regulations, and legislation to authorize and guide the practice of public health;

6. Enforce the laws and regulations that protect health and ensure safety as set forth at N.J.A.C. 8:52-14. This service includes:

i. Enforcement of the State Sanitary Code;

ii. Protection of food and drinking water supplies;

iii. Compliance with environmental health activities regarding air, water, noise, and nuisances; and

iv. Investigation of health hazards, preventable injuries, and exposure-related diseases in both the work and community settings;

7. Link people to needed personal health services and assure health care when it is otherwise unavailable as set forth at N.J.A.C. 8:52-13. This service includes providing:

i. Access to the personal health care by socially disadvantaged individuals;

ii. Culturally and linguistically appropriate materials and staff to assure linkage to services for special populations;

iii. Continuous care management;

iv. Transportation services;

v. Technical assistance and health information for high risk groups; and

vi. Occupational health programs;

8. Ensure a competent local public heath system and assure a competent personal heath care workforce as set forth at N.J.A.C. 8:52-8. This service includes:

i. Assessing existing and needed competencies at the community and organizational levels pursuant to N.J.A.C. 8:52-4.2;

ii. Establishing standards for public health professionals;

iii. Evaluating job performance;

iv. Requiring continuing education; and

v. Training management and leadership;

9. Evaluate the effectiveness, accessibility, and quality of personal and population-based health services as set forth at N.J.A.C. 8:52-16. This service includes:

i. Evaluating the effectiveness, accessibility, and quality of personal and population-based health services;

ii. Developing objectives and measurements and collecting and analyzing data and information which are used to compare performance with agreed upon standards;

iii. Determining the success or failure of a program or activity; and

iv. Recommending for improvement, expansion or termination a program or activity; and

10. Research for innovative solutions to health problems as set forth at N.J.A.C. 8:52-15. This service includes:

i. The continuous linkage between the practice of public health and academic and research institutions;

ii. The capacity to perform timely epidemiological and economic analyses;

iii. The ability to conduct health services and health practice research; and

iv. The appropriate utilization of research findings.

(b) Competencies for delivering the above referenced "10 essential public health services" shall be those set forth in "The Public Health Workforce: An Agenda for the 21st Century" and the "Core Competencies for Public Health Professionals," incorporated herein by reference, as amended and supplemented. See N.J.A.C. 8:52-1.8(a)3 and 4.

8:52-3.3 Local health agency's minimum capacity

(a) Each local health agency shall, at a minimum, have the capacity to deliver:

1. Basic public health services set forth in "Public Health Practice Standards of Performance for Local Boards of Health, N.J.A.C. 8:52-1 et seq., Programmatic Guidelines for Best Practices," which is attached here as Appendix incorporated herein by reference. Upon completion of the community health assessment and the Community Health Improvement Plan set forth at N.J.A.C. 8:52-10 and 11, services provided shall reflect the priorities identified;

2. Administrative services consistent with N.J.A.C. 8:52-5;

3. Environmental health services that integrate Registered Environmental Health Specialist practice as set forth in the State Sanitary Code (N.J.A.C. 8:21, 8:22, 8:23, 8:23A, 8:24, 8:25, 8:26, 8:27, 8:51, 10:122, 5:17 and 7:9A, and N.J.S.A. 24:14A-1 et seq., 26:3-69.1 and 58:11-33);

4. Health education and health promotion services consistent with N.J.A.C. 8:52-6;

i. This service shall be developed by February 18, 2004;

5. Preventive health services, that integrate public health nursing practice and health education and/or health promotion programs, and shall be consistent with N.J.A.C. 8:52-13;

i. This service shall be developed by February 18, 2006;

6. Public health nursing services consistent with N.J.A.C. 8:52-7;

i. This service shall be developed by February 18, 2004;

7. All other public health services required by the State Sanitary Code (N.J.A.C. 8:21, 8:22, 8:23, 8:23A, 8:24, 8:25, 8:26, 8:27, 8:51, 8:57-1 through 4, 10:122, 5:17 and 7:9A, and N.J.S.A. 24:14A-1 et seq., 26:3-69.1 and 58:11-23); unless the population or entity requiring the services does not exist within the local health agency's jurisdiction or the services are otherwise assured through formal written linkages with another local health agency;

8. Emergency response services consistent with N.J.A.C. 8:52-12;

9. Enforcement services consistent with N.J.A.C. 8:52-14; and

10. Specialized services consistent with N.J.A.C. 8:52-3.4.

i. This service shall be developed by February 18, 2005.

8:52-3.4 Specialized regional expertise and capacity

(a) Each local health agency, by February 18, 2005, shall have access to the following regional expertise and capacities to meet standards of performance:

1. Administrative leadership and planning and coordination to implement all "10 essential public health services" set forth at N.J.A.C. 8:52-3.3(a)1 through 10;
2. Public health community planning and coordination of population-based preventive health services;

3. Coordinated public health nursing services and the administration thereof;

4. Coordinated public health education and health promotion services and the administration thereof;

5. Epidemiological investigations and data analysis;

6. Public health laboratory analyses;

7. Coordinated information technology management;

8. Training and staff development;

9. Coordinated environmental health services;

10. Collection, analysis, and dissemination of health data and information;

11. Application skills for health-related grants;

12. Development of medical policy;

13. Coordinated prevention and control of communicable disease;

14. The conduct of public health and health services research and evaluation studies;

15. Development of public health applications that use the geographical index system (GIS);

16. A technical library consisting of current public health information; and

17. Public health emergency preparedness planning.

SUBCHAPTER 4. PUBLIC HEALTH STAFFING

8:52-4.1 Public health staffing requirements

(a) Each local health agency shall employ a full-time health officer who holds an active license and employ or contract for the services of the following professional staff:

1. Public health nurse(s) as defined at N.J.A.C. 8:52-2;

2. Registered environmental health specialist(s) who holds an active license; and,

3. Health educator(s) as defined at N.J.A.C. 8:52-2.

(b) Each local health agency providing specialized regional expertise and capacity pursuant to the provisions set forth at N.J.A.C. 8:52-3.4 shall provide the services of the following professional staff:

1. Epidemiologist(s);

2. Information technologist(s)/computer specialist(s);

3. Public health planner(s);

4. Public health nursing director(s);

5. Director(s) of health education; and

6. Medical director(s) by August 18, 2003.

8:52-4.2 Public health staffing qualifications

(a) Each health officer shall be licensed by the Department pursuant to the provisions of Licensure of Persons for Public Health Positions, N.J.A.C. 8:7.

(b) Each public health nurse shall have the following qualifications:

1. Hold a baccalaureate degree in nursing from an accredited college or university;

2. Hold a current license to practice as a registered professional nurse by the New Jersey State Board of Nursing;

3. Have a minimum of one year experience in public health or working with a preceptor or local resource person; and

4. Complete a course in population-based public health nursing within one year of employment.

(c) Each registered environmental health specialist shall be licensed by the Department in accordance with the provisions of N.J.A.C. 8:7.

(d) Each health educator shall have the following qualifications:

1. Hold a baccalaureate degree in a related field, including, but not limited to, health education, community health, nursing and/or public health from an accredited college or university;

2. Meet national credentialing standards of the profession as a Certified Health Education Specialist (CHES). Specifically exempted from this requirement is any individual who holds this position prior to February 18, 2003; and

3. Have a minimum of two years of relevant experience in health education.

(e) Each epidemiologist shall have the following qualifications:

1. Hold either a Master of Science degree from an accredited college or university or a Master of Public Health from an accredited college or university in epidemiology or biostatistics; and

2. Have a minimum of two years experience working as an epidemiologist in a health-related field.

(f) Each information technologist/computer specialist shall have the following qualifications:

1. Hold a baccalaureate degree from an accredited college or university; and

2. Have a minimum of three years experience in computer programming, information systems design, and systems analysis. The experience shall have included responsibility for the development and implementation of a moderate sized server-based area network of about 20 end users.

(g) Each public health planner shall have the following qualifications:

1. Hold a masters degree from an accredited college or university in public health, business administration, or public administration; and

2. Have a minimum of two years of professional experience in health planning.

(h) Each public health nursing director shall have the following qualifications:

1. Hold a masters degree from an accredited college or university in public health, or a masters degree in nursing from an accredited school of nursing;

2. Hold a current license to practice as a registered professional nurse and who is certified by the New Jersey State Board of Nursing; and

3. Have a minimum of five years of supervisory experience in public health.

(i) Each director of health education shall have the following qualification:

1. Hold a master or baccalaureate degree in a related field, including, but not limited to, health education, community health, nursing and/or public health from an accredited college or university;

2. Meet national credentialing standards as a Certified Health Education Specialist (CHES). Specifically exempted from the requirement is any individual who holds this position prior to February 18, 2003; and

3. Have a minimum of two years of relevant experience if master degree trained for five years of relevant experience if baccalaureate degree trained.

(j) Each public health medical director shall have the following qualifications:

1. Hold a Doctor of Medicine or Doctor of Osteopathy from an accredited medical school or school of osteopathy supplement4ed by at least the first year of post-graduate training (PGY-1);

2. Have a minimum of two years of comprehensive medical experience in private or public health practice or be Board-eligible for one of the certifying boards approved by the American Board of Medical Specialties or one of the certifying boards of the American Osteopathic Association. A Master of Public Health from an accredited school or program in public health may be substituted for one year of experience; and

3. Be licensed by the New Jersey Board of Medical Examiners.

(k) Each field representative health education shall hold a baccalaureate degree from an accredited college or university in health education, community health, or a related field.

(l) Each graduate nurse, public health shall have the following qualifications:

1. Hold an associate degree in nursing from an accredited college or hold a diploma in nursing;

2. Hold a current license to practice as a registered professional nurse by the New Jersey State Board of Nursing;

3. Have a minimum of one year experience in public health or working with a preceptor or local resource person; and

4. Have successfully completed a course in population-based public health nursing within one year of employment.

(m) Each public health nursing supervisor shall have the following qualifications:

1. Hold a baccalaureate degree in nursing from an accredited college or university;

2. Hold a current license to practice as a registered professional nurse by the New Jersey State Board of Nursing; and

3. Have a minimum of three years of experience as a public health nurse.

SUBCHAPTER 5. ADMINISTRATIVE SERVICES

8:52-5.1 Scope and purpose

This subchapter addresses all of the administrative and organizational management services which are necessary to effectively lead a modern local health agency. The functions of management and leadership include, but are not limited to, planning, organization, public health staffing, coordination and response, budgeting, and evaluation and reporting.

8:52-5.2 Management and leadership

(a) Planning is one of the fundamental responsibilities of a licensed health officer who functions as the chief executive officer of a local health agency. Planning relies on the ability to collect and analyze information, to communicate with supervisors, peers and subordinates and to make decisions and take action. The "Assessment Protocol for Excellence in Public Health" (see N.J.A.C. 8:52-1.8(a)5) is a management tool developed to assist the public health manager in evaluating his or her own agency's strengths and weaknesses. Using this information, the manager is equipped to accurately portray the capabilities his or her agency brings to a countywide public health system and to take actions that will improve the agency's performance.

1. Each health officer shall actively participate in and be responsible for the joint development of a countywide or multi-countywide Community Health Profile, Community Health Assessment and Community Health Improvement.
2. Each health officer shall notify the Office of Local Health of the name, title, telephone number, and e-mail address of his or her designees.

3. Each health officer shall be responsible for the completion of an evaluation of the capacity of his or her local health agency in accordance with the process set forth in "Assessment Protocol for Excellence in Public Health." The evaluation shall be used to identify the capacity of the local health agency to deliver the services set forth in this chapter and to provide the information necessary to develop the Community Health Improvement Plan. An evaluation shall be conducted at least once every three years.

4. Each health officer shall be responsible for the development of goals and objectives for each program conducted by the local health agency and the development of a continuous quality improvement process to ensure progress in achieving the local health agency's goals.

    i. Each goal and objective shall include a timeline and be realistic, measurable, and consistent with current public health practice and/or Department program policies and guidelines.

    ii. Each goal and objective shall be consistent with priority public health problems identified through the countywide Community Health Improvement Plan and any other Statewide public health priorities as determined by the Department.

    iii. Each goal and objective shall be consistent with the "10 essential public health services," at N.J.A.C. 8:52-3.2(a)1 through 10.

5. Each health officer shall develop an internal monitoring plan that measures progress in achieving each of the local health agency's goals and objectives.

    i. Monitoring shall be performed, at a minimum, on a semi-annual basis; and

    ii. Monitoring data shall be used to document whether expected objectives are achieved to provide information regarding the implementation of objectives, and to modify activities to improve the achievement of objectives.

6. Each health officer shall develop an improvement plan to address performance deficiencies which are revealed during the Continuous Quality Improvement process.

(b) The ability to organize information and resources is also a fundamental responsibility of an administrative manager. The ability to assess staff competencies and to match those competencies with the appropriate tasks and activities is key to agency performance and goal attainment. A competent manager must be able to determine lines of authority within his or her agency and set forth business practices that are appropriate to the capabilities of the organization.

1. Each health officer shall ensure that the local health agency's resources are organized to promote the health outcomes identified through the countywide or multi-countywide Community Health Improvement Plan.

2. Each health officer shall ensure that competent leadership is assigned responsibility for each major activity and core responsibility.

3. Each health officer shall ensure that the local health agency prepares and has on file a current table of organization which depicts reporting relationships within the local health agency.

(c) The practice of public health, like the practice of medicine from which it derives, relies heavily upon licensure and certification to assure quality services and to protect the public against the services of untrained or incompetent individuals. The practice of medicine literally puts individual people's lives in the hands of the physician. The practice of public health puts the lives and quality of live of populations and communities in the hand of public health professionals. Therefore, it is important that these professionals are also trained and licensed in the disciplines of health science and public health. In addition, it is important for a manager to recruit, retain and develop his or her staff. The publications referenced below provide an organized approach to building staff competencies and developing staff.

1. Each health officer shall ensure that all professional public health staff who require licensure,

certification, or authorization to perform their activities shall be currently licensed, certified, or authorized under the appropriate laws or rules of the State of New Jersey or under the applicable standards of the appropriate body.

2. Each health officer shall ensure that all public health staff receive adequate training for the activities they are expected to perform. Training shall be in accordance with the professional licensing requirements and/or state and/or national standards for each public health program. Each health officer shall determine that professional health staff have obtained continuing education in accordance with the provisions set forth at N.J.A.C. 8:52-8.

i. A plan for staff knowledge and competency development shall be developed and shall meet the standards described in "Assessment Protocol for Excellence in Public Health," incorporated herein by reference, as amended and supplemented. See N.J.A.C. 8:52-1.8(a)5.

ii. Staff competencies shall meet the standards described in "The Public Health Workforce: An Agenda for the 21st Century" and the "Core Competencies for Public health Professionals." See N.J.A.C. 8:52-1.8(a)3 and 4.

3. Each health officer shall ensure that all professional public heath staff who require licensure, certifications, or authorization to perform their activities shall perform within the scope of their license, certificate, or authority as set forth under the appropriate laws or rules of the State of New Jersey or under the applicable standards of the appropriate body.

4. Each local board of health shall ensure that its local health agency and health officer meet all of the requirements of this chapter.

(d) Each health officer shall ensure appropriate coordination and response to public health problems that follow established scientific guidelines within his or her area of jurisdiction as directed and/or coordinated by the Department.

(e) Each health officer shall have access to a financial officer for assistance in managing and overseeing all public health budgets. The financial officer shall assist in ensuring the fiscal integrity of public health finances and that such procedures are in accordance with professionally accepted standards of accounting and auditing.

(f) The ability for a manager to evaluate his or her staff and agency performance is essential to assuring success in meeting the agency's mission and goals. Evaluation is also essential for assuring the prudent use of precious resources and for maximizing cost benefits. Reporting the results of evaluation processes and other important information is a key communication responsibility. Communication is a critical ingredient for success and public health administrative manager must have to the skills to communicate effectively o superiors, subordinates, professional peers and the public.

1. Each health officer shall report local board of health performance data as required in the Local Health Evaluation Report.

2. The Local Health Evaluation Report shall be completed annually and in accordance with the format developed and promulgated by the Office of Local Health. It shall be filed with the Office of Local Health no later than February 15 of the year succeeding the year for which the performance is being reported.

3. The following information shall be reported and shall conform to the reporting schedule set forth herein and shall include:

i. Registration of the local board of health pursuant to N.J.A.C. 8:52-1.5;
ii. Information and data regarding a local health agency's capacity as set forth at N.J.A.C. 8:52-3.3 and 5.2(a), above;

iii. Information and data regarding specialized regional expertise and capacity as set forth at N.J.A.C. 8:52-3.4;

iv. Information regarding workforce assessment as set fort at N.J.A.C. 8:52-8.2(a);

v. Training of each local board of health member as set forth at N.J.A.C. 8:52-8.2(b);

vi. Evaluation of each community's public health partnerships effectiveness as set forth at N.J.A.C. 8:52-9.2(d);

vii. County Health Status Indicators Report as set forth at N.J.A.C. 8:52-10.2(c) and (e);

viii. Community health planning information as set forth at N.J.A.C. 8:52-11;

ix. Epidemiological economic, and health services research findings as set forth at N.J.A.C. 8:52-15.

4. Each local health agency shall report all diseases, threats, and emergencies in accordance with all applicable State and Federal laws as set forth at N.J.A.C. 8:52(f)3.

(g) Rapid advances in communication technologies are making it possible to be more knowledgeable and current in the practice of public health. The practice of public health relies on scientific capabilities to study, investigate and understand the determinants of health. Based upon organized scientific collection and analysis of data and information, preventive strategies are developed and communicated to the populations at risk. Modern public health practitioners must be able to use electronic tools and become integrated in an evolving state health information network that will allow them access to real time information upon which to take appropriate actions.

1. Each local health agency shall be part of a Statewide public health information and communication system. This shall include maintaining a link via the Internet with the New Jersey Local Information Network and Communications System (LINCS).

2. Each local health agency shall participate in information sharing and data interchange with the Department.

3. Each local health agency shall use LINCS to:

i. Report all disease and threats to the public health to the Department in accordance with applicable State and Federal laws, rules, and regulations. Electronic reporting shall be contingent upon the development of electronic reporting systems;

ii. Immediately report to the Department all emergencies that threaten the health or safety of the citizens in its jurisdiction; and

iii. Monitor LINCS e-mail twice per day, at the beginning and at the end of the workday.

(h) Each local health agency shall have access to an attorney licensed to practice in New Jersey for assistance in interpreting, developing, and/or guiding the enforcement of public health laws, rules, regulations, and ordinances.

(j) Records which are required by this chapter shall be maintained in accordance with State record retention standards as promulgated by the New Jersey Department of Education, Bureau of Archives and History, at N.J.A.C. 15:3-3.8.

8:52-5.3 Community public health activities

(a) Each local board of health shall ensure that there is a mechanism that provides leadership to develop partnerships with community organizations and/or agencies which have a demonstrable affect on, or compelling interest in, the health status of the population in accordance with N.J.A.C. 8:52-9.2.

(b) Each health officer shall conduct an annual public meeting to report the status of the community's health and how it compares with corresponding objectives set forth in “Healthy New Jersey 2010,” or its Federal equivalent, and with objectives from the Community Health Improvement Plan. The meeting shall also include a discussion of the local health agency's progress and performance in accomplishing its mission and achieving its objectives.

8:52-5.4 Public health system assurance

(a) Each health officer shall actively participate in countywide or multi-countywide meetings to assess the health status of the population, to develop a Plan as set forth at N.J.A.C. 8:52-11.2. Community Health Improvement Plan and to determine his or her local health agency's roles and responsibilities within the Plan in accordance with N.J.A.C. 8:52-9, 10 and 11.

(b) Each local board of health shall ensure representation in the planning process to develop the Community Health Improvement Plan as set forth at N.J.A.C. 8:52-9.2.

(c) Each local board of health shall ensure the development of local policies and programs t hat are consistent with the Community Health Improvement

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SUBCHAPTER 6. HEALTH EDUCATION AND HEALTH PROMOTION

8:52-6.1 Scope and purpose

This subchapter addresses the strategies that promote health and quality of life. This service includes any combination of health education and related activities which are designed to facilitate behavioral and environmental adaptations to protect or improve health. This process enables individuals and communities to control and improve their health status. This service also provides opportunities for individuals to identify problems, develop solutions, and work in partnerships which build on existing skills and strengths.

8:52-6.2 Health education and health promotion services

(a) Each local health agency shall provide a comprehensive health education and health promotion program which is developed and overseen by a health educator and provides integrated support to the daily operation of the local health agency.

(b) Each local health agency shall implement and evaluate culturally and linguistically appropriate population-based health education and health promotion activities that are developed in accordance with the Community Health Improvement Plan.

(c) Each local health agency shall ensure that health education and health promotion services provide the core public health functions and the delivery of the "10 essential health services" at N.J.A.C. 8:52-3.2(a)1 through 10 that shall include, but not be limited to:

1. Assessment and analysis of individual and community needs and assets;

2. Planning of theory-based health education programs which includes the development of appropriate measurable objectives;

3. Implementation of population-based health education programs which match various educational strategies and methods to the identified issues. Strategies may include, but are not limited to, direct programming, train-the-trainer programs, community organization methods, media campaigns, and advocacy initiatives;

4. Provision of process, impact, and outcome evaluation of health education programs in order to measure achievement and success;

5. Management of health education programs, personnel, and budgets;

6. Development of in-service training programs for staff, volunteers, and other interested parties;

7. Recruitment and training of volunteers to build and support community coalitions and partnerships;

8. Identification of and facilitation among agencies and community resources to reduce duplication and enhance services;

9. Provision of client referral and assistance to health and social service resources;

10. Development of risk communication plans to manage community concern and convey appropriate and accurate information;

11. Advise and/or serve as a spokesperson and liaison to the media;

12. Provision of public health advocacy for policies and funding that support social justice principles and which will improve the health status of communities;

13. Provision of grant writing to support local health agency objectives, the Community Health Improvement Plan, and health education programs;

14. Development of audio, visual, and print materials which support program initiatives; and

15. Use of quantitative and qualitative research techniques to advance the quality of public health practice.

(d) Each local health agency shall plan and develop health education programs and interventions regarding the uninsured, underinsured, immigrant, indigent, and other vulnerable populations within its jurisdiction.

(e) Each local health agency shall inventory health promotion and health education services delivered by all agencies in their jurisdiction. This inventory shall compare the existing services with those outlined in the Community Health Improvement Plan in order to identify gaps, reduce duplication, and to identify opportunities for collaborative partnerships.

SUBCHAPTER 7. PUBLIC HEALTH NURSING

8:52-7.1 Scope and purpose

This subchapter addresses the synthesis of nursing practice and public health practice for the purpose of protecting and promoting physical and mental health and preventing disease, injury, and disability. Public health nursing practice incorporates the core public health functions of assessment, assurance, and policy development within the art and science of professional nursing practice through a systematic process which promotes and protects the public health.

8:52.7.2 Public health nursing services

(a) Each local health agency shall provide comprehensive public health nursing services that provide integrated support to the daily operation of the local health agency.

(b) Each local health agency shall ensure that public heath nursing practice provides the core public health functions and the delivery of the “10 essential public health services” as set forth at N.J.A.C. 8:52-3.2(a)1 through 10. These services shall be developed and overseen by a public health nurse and shall include, but not be limited to:

1. Assessing and identifying populations at risk;

2. Providing outreach and case finding using population-based services;

3. Using systematic, relevant data collection from public health nursing practice for community health assessment;

4. Using case information and epidemiological methods to link epidemiology and a clinical understanding of health and illness;

5. Developing and implementing health guidance, counseling, and educational plans using the established nursing process;

6. Providing health plans to assure health promotion efforts that include primary clinical prevention and early intervention strategies;

7. Using the nursing process and triage to determine priorities for interventions and services based on risk assessment and community needs especially for under-served populations;

8. Advocating policies and funding that create clinical programs and improve health status;

9. Establishing procedures and processes which ensure competent implementation of prevention measures and treatment schedules;

10. Providing clinica1 preventive services, including clinical screenings and preventive care;

11. Facilitating access to care through the use of nursing assessment, referral for risk reduction, prevention, restorative, and rehabilitative services, and the establishing clinical programs and services;

12. Participating in all components of communicable disease prevention and control, including clinical surveillance, case identification, and treatment;

13. Planning, developing, and initiating inter-disciplinary nursing plans for care and case management;

14. Establishing and maintaining written procedures and protocols for clinical care; and

15. Identifying, defining, coordinating, and evaluating enhanced clinical services for complex populations and special risk groups.

(c) Each local health agency shall ensure planning and developing public health nursing programs and interventions relate to the uninsured, underinsured, immigrant, indigent, ad other vulnerable populations.

(d) Each local health agency shall ensure the coordination of public health nursing services which are delivered by all agencies in their county as described in the Community Health Improvement Plan so as to identify gaps, provide continuity of services, and reduce duplication.

SUBCHAPTER 8. ASSURE WORKFORCE COMPETENCIES

8:52-8.1 Scope and purpose

This subchapter addresses the assessment of 3existing and needed workforce competencies as set forth at N.J.A.C. 8P52-5.2(d) for each local health agency. These include standards for public health professionals, job performance evaluation, continuing education, and management and leadership training.

8:52-8.2 Workforce assessment

(a) Each health officer shall ensure the performance of a workforce assessment at the local health agency at least once each year. The workforce assessment shall:

1. Identify gaps in workforce expertise;

2. Identify duplication of workforce competencies; and

3. Ensure that the necessary workforce competencies exist in order to be able to deliver the services set forth a N.J.A.C. 8:52-3.3 and 3.4 and to achieve the objectives outlined in the Community Health Improvement Plan.

(b) Each local board of heath shall report the status of training of each local board of health member in their jurisdiction to the Office of Local Health. This report shall be made annually.

8:52-8.3 Workforce standards

(a) Each health officer shall ensure that:

1. Each position in the local health agency has a written job description which include tasks, reporting relationships, and performance standards;

2. Each job description shall be reviewed annually; and

3. Job performance evaluations are conducted annually.

(b) Each local board of health shall ensure that public health staff, in addition to the requirements for licensure, certification, or authorization, possess or are actively pursuing training for the skills necessary to provide each of the “10 essential public health services” as set forth at N.J.A.C. 8:52-3.2(a)1 through 10.

8:52-8.4 Workforce continuing education

(a) Each health officer shall provide a coordinated program of continuing education for staff which includes attendance at seminars, workshops, conferences, in-service training, and/or formal courses to improve employee skills and knowledge in accordance with their professional needs.

(b) Each public health professional specified at N.J.A.C. 8:52-4.1 shall meet continuing education requirements as follows:

1. Each director of public health nursing and public health nursing supervisor shall complete 15 continuing education contact hours of public health-related instruction annually. Eight of the continuing education contact hours shall be comprised of workforce leadership courses. The courses of instruction shall be approved by the Office of Local health or its authorized representative. The eight continuing education contact hours in workforce leadership shall include topics and subjects that include, but are not limited to:

i. Strategic thinking and planning;

ii. Policy development, implementation, and evaluation;

iii. Advocacy;

iv. Interpretation of epidemiological data and health statistics analysis;

v. Community needs assessment and risk assessment;

vi. Outcome evaluation and quality assurance;

vii. Collaboration, coalition building, and community organization;

viii. Multidisciplinary negotiation;

ix. Legal matters and issues; and

x. Nursing research.

2. Each public health nurse shall complete 15 continuing education contact hours of public health related instruction annually. The programs shall be approved by the New Jersey State Nurses Association or its authorized representative or by the New Jersey Association of Public Health Nurse Administrator, Inc.

3. Each director of health education and each health educator shall complete continuing education in accordance with the requirements of the National Commission for Health Education Credentialing, Inc, that is, CHES certification. Eight of the continuing education contact hours annually shall be comprised of workforce leadership courses and shall include topics and subjects that include, but are not limited to:

i. Strategic thinking and planning;

ii. Policy development, implementation, and evaluation;

iii. Advocacy;

iv. Interpretation of epidemiological data and health statistics analysis;

v. Community needs assessment and risk assessment;

vi. Outcome evaluation and quality assurance;

vii. Collaboration, coalition building, and community organization;

viii. Multidisciplinary negotiation;

ix. Legal matters and issues; and

x. Nursing research.

4. Each field representative, health education shall complete a minimum of nine continuing education contact hours annually in courses which are approved by the National Commission for Health Education Credentialing, Inc., New Jersey Society for Public Health Education, or the Office of Local Health.

5. Each health officer and each registered environmental health specialist shall obtain continuing education contact hours in accordance with N.J.A.C. 8:7. Each health officer shall also obtain leadership continuing education contact hours in accordance with N.J.A.C. 8:7.

(c) Each member of a local board of health may participate in a leadership orientation and participate in on-going training courses.

(d) Each health officer shall ensure that all employees are proved the opportunity to participate in distance learning as one method of obtaining continuing education.

(e) Each health officer shall ensure supervisory and managerial competency through leadership and staff development.

8:52-8.5 Workforce diversity training

Each health officer shall ensure that all employees participate in cultural diversity training.

SUBCHAPTER 9. COMMUNITY PUBLIC HEALTH PARTNERSHIP

8:52-9.1 Scope and purpose

This subchapter addresses how entities that impact the public heath and have access to populations and/or resources in performing defined prevention, screening, rehabilitation, or support activities ill convene, build coalitions, and identify and organize community resources to support the goals and activities of the local public health system.

8:52-9.2 Development and participation in community public health partnerships

(a) Each countywide or multi-countywide area shall establish a community public health partnership representing key corporate, private and non-profit entities. Each partnership shall perform a countywide or multi-countywide community health assessment in accordance with N.J.A.C. 8:52-10 and develop a Community Health Improvement Plan in accordance with N.J.A.C. 8:52-11. Each community public health partnership shall foster relationships that impact the community's health consistent with the needs identified in the C9ommunity Health Improvement Plan. Existing community public health partnerships shall be permitted to satisfy these requirements if they comply with the assessment methodologies set forth at N.J.A.C. 8:52-10.2

(b) Each local health agency shall:

1. Actively participate in a new or existing community health partnership; and

2. Assure that the community health partnership assesses public health needs and delivers public health services in their jurisdiction.

(c) Each local health agency shall assure that the partnership:

1. Participates in the community health assessment and the Community Health Improvement Plan pursuant to N.J.A.C. 8:52-10 and 11;

2. Develops and maintains linkages among the member partners as described in (a) above.

3. Assumes a leadership role in addressing priority public health issues;

4. Leverages community resources;

5. Provides support programs for the under served;

6. Provides preventive screening and rehabilitative services;

7. Continually reviews input and feedback from the entities that contribute to or benefit from improved community health status;

8. Holds regularly scheduled meetings;

9. Identifies the strategic issues of each local health agency and the means by which the issues can be addressed;

10. Coordinates applicable aspects and priorities with contiguous counties;

11. Develops and maintains relationships with other local health agencies to educate and inform local policy officials, key health providers, and the public of the content of the Community Health Improvement Plan; and

12. Develops a formal mechanism to evaluate the effectiveness of the partnership.

i. Pursuant to N.J.A.C. 8:52-3.1(c), local health agencies may submit this information in a joint report which encompasses a countywide or multi-countywide area.

8:52-9.3 Other community partnerships

Each local health agency shall meet regularly with representatives of health-related organizations within its jurisdiction in order to coordinate roles and responsibilities for health service delivery.

8:52-9.4 Developing service directories

Each local health agency shall assure that the community public health partnership develops, maintains, and promotes a directory of health service providers and resources that serves the countywide or multi-countywide area. The directory shall address the health priorities as identified in the Community Health Improvement Plan.

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SUBCHAPTER 10. MONITOR HEALTH STATUS

8:52-10.1 Scope and purpose

This subchapter addresses the collection, compilation, interpretation, and communication of vital statistics and health status measures within one or more New Jersey counties; the identification of threats to health; the assessment of health service needs; and the analyses, communication, and publication of information on access, utilization, quality, and outcomes of personal health issues.

8:52-10.2 Community health assessment

(a) To minimize costs and for consistency with existing data, the minimum unit of analysis for New Jersey shall be the county. This does not preclude any municipality from performing its own less formal assessment in addition to participating in the countywide or multi-countywide Community Health Assessment. This less formal assessment can be integrated into the countywide or multi-countywide assessment and/or used for other local public health programming purposes.

(b) A formal countywide or multi-countywide Community Health Assessment shall be performed and continually evaluated with a formal update every four years. Existing community health assessments meeting the criteria set forth in this section shall be valid until a new assessment is performed.

(c) Local health agencies shall submit a description of the Community Health Assessment process and the timeframe for its completion to the Office of Local Health for review and approval prior to initiating the assessment. This process description shall be submitted to the Office of Local Health by February 18, 2004 and every four years thereafter.

1. Local health agencies working in partnership may submit this information in a joint report for the entire countywide or multi-countywide area.

(d) The formal countywide or multi-countywide Community Health Assessment shall be conducted in accordance with standardized methodologies approved by the Office of Local Health. Such methodologies include “Mobilizing for Action through Planning and Partnerships” (MAPP). The Community Health Assessment shall include, but not be limited to, the following elements:

1. A copy of any existing community health assessments;

2. An evaluation of funding sources;

3. A review of public health community partnership organizations and agencies and their roles;

4. An identification of barriers to transportation, language culture, and service delivery within the countywide or multi-countywide area that affect access to health services, especially for low income and minority populations;

5. A Community Health Profile which includes measures of health status indicators and socio-demographic characteristics as specified by the Office of Local Health;

6. Current information on the health resources of and the services provided by each entity located within easy access of its population;

7. An assessment of the use of the health resources described in 6, above;

8. Current information on risk factors affecting the population served; and

9. An analysis of health status indicators for the population served in comparison with overall State and national rates for indicators set forth in "Healthy New Jersey 2010."

(e) The results of the countywide or multi-countywide Community Health Assessment shall be published in a "County Health Status Indicators Report." The results shall be presented in a manner that is sensitive and appropriate to individual, family, and community needs, language, and culture. The Report shall contain:

1. Measures of the health status indicators;

2. A description of the process used to complete the Community Health Assessment;

3. The standards with which the health status indicators are compared;

4. An inventory of public health capacities; and

5. An analysis of gaps in public health service.

8:52-10.3 Data collection and management

(a) Each local health agency shall develop, operate, and ensure a quality data management system. This system shall be capable of collecting, analyzing, and monitoring baseline data standardized to a format developed by the Department in accordance with the requirements set forth at N.J.A.C. 8:52-5.2 (f) and (g).

(b) Each local health agency shall ensure electronic linkage with local and Statewide databases, as they become available. These databases include, but are not limited to: NJ LINCS, New Jersey Immunization Information System (NJIIS), Communicable Diseases Reporting System, Electronic Birth Registry, Vital Statistics, and other registries which track the distribution of diseases, injuries, and health conditions.

(c) Each local health agency shall ensure safeguards for the confidentiality of all data and information that contains personal identifiers or any other information which could be used to identify an individual with reasonable accuracy, either directly or by reference to other readily available information.

SUBCHAPTER 11. POLICY DEVELOPMENT

8:52-11.1 Scope and purpose

This subchapter addresses the systematic countywide or multi-countywide and State level planning process for health improvement. It sets forth the development and tracking of measurable health objectives as a part of continuous quality improvement strategy, the development of consistent policy regarding prevention and treatment services, and the development of model codes to guide the practice of public health.

8:52-11.2 Countywide or multi-countywide community health planning

(a) To minimize costs and for consistency with existing data, the minimum unit of planning **for New Jersey shall be the county.**

(b) Each local board of health shall assure that public health policies promote and support the population's health and safety goals identified in the health improvement strategies that were developed through the countywide or multi-countywide Community Health Improvement Plan and incorporate by reference prior planning information obtained through other processes.

(c) Each Community Health Improvement Plan shall consist of:

1. A countywide or multi-countywide Community Health Assessment as described at N.J.A.C. 8:52-10.2;

2. A Community Health Profile as described at N.J.A.C. 8:52-10.2(d)5;

3. A mechanism which monitors external environment for forces and trends that might impact the ability of a local public health system to protect the health of the public;

4. An analysis and a prioritization of current and potential health problems based upon planning methodologies such as those described at N.J.A.C. 8:52-10.2(d);

5. A plan which specifies the roles and responsibilities agreed upon by each local health agency and each public, private, non-profit, and voluntary agency;

6. Specific strategies to address health problems and to sustain effective interventions;

7. A plan to evaluate the intervention strategies and health outcomes; and

8. A method that allows for changes to the plan.

(d) The objectives of the Community Health Improvement Plan shall be:

1. To link State and local services;

2. To mobilize and coordinate a variety of health and social service providers;

3. To improve each local public health system's capacity to respond to public health needs; and

4. To include all providers of public health services, that is, local health agencies, schools, Medicaid managed care providers, environmental health agencies community-based groups, business and industry and nursing agencies.

(e) Each local health agency within the countywide or multi-countywide area shall be responsible for implementation of the Community Health Improvement **Plan in their jurisdiction by February 18, 2007.**

(f) Each local board of health shall ensure that there is a mechanism to guide the development of the Community Health Improvement Plan which includes, but is not limited to:

1. Ensuring expertise to implement the planning process;

2. Ensuring coordination and consistency with State policy initiatives;

3. Ensuring that local health agency resources are continuously aligned with their defined roles and responsibilities in the Community Health Improvement Plan; and

4. Reporting the content of the Community Health Improvement Plan to the Office of Local Health. Local health agencies working in partnership may submit this information in a joint report for the entire countywide or multi-countywide area.

(g) Each Community Health Improvement Plan shall be used to guide the development of needed public health programs and services. CHIP shall foster coordination with existing programs and services, and reduce or eliminate programs and services which are not needed or have been found to be ineffective.

(h) Each local board of health that demonstrates a local need for public health services, as defined in "Healthy People 2010," that is not addressed by the Community Health Improvement Plan shall address that need.

SUBCHAPTER 12. DIAGNOSIS AND INVESTIGATION OF HEALTH PROBLEMS AND HAZARDS

8:52-12.1 Scope and purpose

This subchapter addresses the epidemiological identification of emerging health threats; public health laboratory capability to support prevention efforts; active infectious disease prevention and control efforts; and technical capacity for epidemiological investigation of disease outbreaks and patterns of chronic disease and injury.

8:52-12.2 Emergency response capability

(a) Each local health agency shall ensure its capacity to immediately respond to a public health emergency in accordance with applicable State and Federal requirements. Each local health agency shall also:

1. Maintain a mechanism which allows for emergency communication 24 hours per day, seven days per week, including weekends and holidays;

2. Develop a preparedness plan with the local public health system to address public health emergencies. The plan shall be consistent with and be integrated with the Health Alert Network; and

3. Orient and train their staff (through exercises) to their roles and responsibilities under the plan at least annually.

(b) Each local health agency shall work with their municipal and county Office of Emergency Management to ensure the coordination and integration of public health and emergency management planning and response activities.

8:52-12.3 Surveillance

(a) Each local health agency shall collect data and information pursuant to N.J.A.C. 8:52-5.2(e).

(b) Each local health agency shall ensure that valid and reliable surveillance systems are in place to monitor the occurrence of diseases and indicators of health. The indicators shall be in accordance with "Healthy New Jersey 2010," the health objectives developed through the Community Health Improvement Plan, and for health conditions determined to be priorities by the Department.

(c) Each local health agency shall investigate the cause of illnesses or health threatening conditions and shall implement control measures to prevent the spread of disease or to address the known risk factors in the population served.

(d) Each local health agency shall ensure that there is a mechanism to receive reports and to respond to immediately reportable communicable diseases and conditions in accordance with N.J.A.C. 8:57-1.3. This mechanism shall be capable of operating 24 hours per day, seven days per week, including weekends and holidays.

8:52-12.4 Technical capacities

(a) Each local health agency shall ensure access to public health laboratory analyses in order to support disease control and environmental health activities within its jurisdiction.

1. Designated laboratories shall meet all State and Federal requirements for technical competency and safety in accordance with the Federal Clinical Laboratory Improvement Amendment of 1988, Final Rule at 42 C.F.R. 493, and Clinical Laboratory Services, N.J.A.C. 8:44 and 8:45.

2. Designated laboratories shall be licensed by the Department pursuant to the provisions of P.L. 1975, c.166, N.J.S.A. 45:9-42.26 et seq. and regularly participate in quality assurance programs offered through the Department.

(b) Each local health agency shall ensure access to epidemiological services that support countywide and multi-countywide assessment, planning, surveillance, and prevention activities in accordance with the provisions set forth at N.J.A.C. 85:52-3.4.

SUBCHAPTER 13. PREVENTIVE PERSONAL HEALTH SERVICES AND ACCESS TO HEALTH CARE

8:52-13.1 Scope and purpose

This subchapter address the accessibility of the personal health care system to socially disadvantaged individuals. Culturally and linguistically appropriate materials and staff shall be accessible to assure linkage to services for special populations. This subchapter also addresses continuous care management, transportation services, and technical assistance and health information for high risk groups as well as occupational health programs.

8:52-13.2 Assure personal and clinical preventive health care

(a) Each local health agency, through the Community Health Improvement Plan, shall:

1. Assess the barriers to personal health care and public health services within its jurisdiction;
2. Define a minimum set of clinical preventive health services, including disease prevention and health promotion, which shall be directed to specific populations. These services shall include, but not be limited to:
    i. Health care and epidemiological follow-up for individuals infected with the human immunodeficiency virus or suffering from acquired immune deficiency syndrome;
    ii. Health care and epidemiological follow-up for individuals having sexually transmitted disease;
    iii. Health care and epidemiological follow-up for individuals having tuberculosis; and
    iv. Adult and childhood immunizations;
3. Develop a plan that provides primary health care services to populations that do not have access to the health care system;
4. Participate in the development of a plan for the early detection of chronic and life threatening diseases in the most vulnerable populations;
5. Assist the local public health system in facilitating access and entry for populations having barriers to personal health care; and
6. Assist the local public health system in assuring personal health care services and clinical preventive health services that are culturally and linguistically appropriate.

8:52-13.3 Community outreach for public health services

(a) Each local health agency shall engage in community outreach activities that:

1. Assure the maximum participation of eligible residents in State-and Federally-funded health care programs, including, but not limited to, New Jersey FamilyCare and Medicaid;
2. Assure culturally and linguistically appropriate resources and health informational materials for specific populations as specified in this chapter;
3. Assure technical assistance to employers who conduct health promotion, disease prevention, or injury prevention programs;
4. Assure that there is an active referral system between the mental and/or behavioral health delivery system and the personal health care delivery system; and
5. Assure that social services are coordinated with health care services.

8:52-13.4 Information systems for personal health and related services

Each local health agency shall assist the local public health system and the State in developing capacities for information systems that share client information with managed care organizations, hospitals, and other health care providers.

SUBCHAPTER 14. ENFORCEMENT OF PUBLIC *HEALTH LAWS*

8:52-14.1 Scope and purpose

This subchapter address the enforcement of the State Sanitary Code (N.J.A.C. 8:21, 8:22, 8:23, 8:23A, 8:24, 8:25, 8:26, 8:27, 8:51, 8:57-1 through 4, 10:122, 5:17 and 7:9A, and N.J.S.A. 24:14A-1 et seq., 26:3-69:1 and 58:11-23); the protection of food and potable water supplies; environmental health activities related to air, water, noise, and public health nuisances and health hazards, preventable injuries, and exposure-related diseases in both the workplace and community settings.

8:52-14.2 Public health laws and rules

(a) Each local board of health shall ensure the enforcement of the provisions of the State Sanitary Code. (b) Each local board of health and each local health agency shall maintain and be knowledgeable regarding current public health laws, regulations, codes, and ordinances and shall ensure enforcement thereof.

(c) Each local health agency shall employ licensed personnel consistent with the provisions set forth at N.J.S.A. 26:3-19 to enforce State and local public health laws; regulations, codes, and ordinances and shall:

1. Maintain written procedures for enforcement actions;

2. Collect evidence of non-compliance; and

3. Maintain documentation of all legal proceedings.

(d) Each local board of health shall consult with the health officer during the development of any new public health ordinances or amendments to any existing public health ordinances. The health officer or his or her designee shall attend all public hearings held which proposes new or amended ordinances that affect the practice of public health within his or her jurisdiction.

(e) Each local health agency shall ensure training for all professional staff assigned public health regulatory enforcement responsibilities. This training shall include, but not be limited to:

1. The purpose of public health law;

2. Activities and techniques for evaluating compliance with the law;

3. Activities and techniques for gathering evidence of violations of public health laws;

4. Documenting violations; and

5. Proper methods of testifying at a trail or hearing.

SUBCHAPTER 15. HEALTH RELATED RESEARCH

8:52-15.1 Scope and purpose

This subchapter addresses the continuous linkage between the practice of public health with academic and research institutions; the capacity to perform timely epidemiological and economic analysis; the ability to conduct public health and health practice research; and the appropriate use of research findings.

8:52-15.2 Capacity to initiate timely epidemiological, economic, and health services research

(a) Each local health agency shall assure its capacity to conduct:

1. Studies of epidemiological data of identified health problems; 2. Analyses of the economic components of public health issues;

3. Analyses of health services management; and

4. Analyses of the effectiveness of public health practices, programs, and services.

(b) Each local health agency shall report epidemiological, economic, and health services findings to the Office of Local Health whenever such findings are available.

(c) Each local health agency shall make all data and information available to public health researchers only in accordance with Institutional Review Board requirements as set forth at 45 C.F.R. Part 46 and/or 21 C.F.R. 50 and 56.

(d) Each local health agency shall ensure the safety and protection of public and personal health data and information through established procedures for access, retention, and destruction in accordance with applicable State and Federal laws, rules, and codes.

(e) In order to assure the capacity required at N.J.A.C. 8:52-15.2(a), each local health agency is encouraged to form partnerships and share services in accordance with the "Companion Document to Public Health Practice Standards of Performance for Local Boards of Health, N.J.A.C. 8:52-1 et seq."

8:52-15.3 Operational implementation of research findings

(a) Each local health agency shall assist the local public health system in identifying new public health problems ad in developing solutions for new and existing problems.

(b) Each local health agency, in coordination with the Office of Local Health, shall ensure the implementation, on a priority basis, of newly developed and innovative strategies, methodologies, programs, and projects which have been demonstrated to be effective in improving the public health.

(c) All research findings shall be implemented in accordance with the Community Health Improvement Plan.

8:52-15.4 Linkage with institutions of higher education

(a) Each local health agency is encouraged to provide the opportunity for joint appointments for its staff to institutions of higher education.

(b) Each local health agency is encouraged to provide field training or work-study experiences for students enrolled in institutions of higher education.

(c) Each local health agency is encouraged to partner with an institution of higher education to conduct health-related research

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SUBCHAPTER 16. EVALUATION

8:52-16.1 Scope and purpose

This subchapter addresses the evaluation of the effectiveness, accessibility, and quality of population-based health services; the development of objectives and measurements and the collection and analysis of data and information which are used to compare performance with agreed upon standards; the determination of the success or failure of any program activity; and recommendations for the improvement or the termination of any activity or program.

8:52-16.2 Evaluation and performance

(a) The Office of Local Health shall develop a data collection method which shall benchmark adherence to standards of performance for local boards of health and local health agencies. This benchmark shall be consistent with the provisions set forth in this chapter and shall use a continuous quality improvement process to improve the performance of local boards of health and local health agencies.

(b) As part of the benchmarking process, the Office of Local Health shall develop a standard format for Local Health Evaluation Reports. This report is a tool which shall be used to evaluate and measure local boards of health and local health agencies adherence to standards of perfor-mance.

(c) The Local Health Evaluation Report shall be used by each local health agency to:

1. Evaluate annual performance;

2. Provide information and data to improve future performance;

3. Report performance and evaluation data and information to the local boards of health within its jurisdictions; and

4. Foster other purposes determined appropriate by the local health agency and/or the Office of Local Health.

(d) Each local health agency shall submit their Local Health Evaluation Report to the Office of Local Health as specified at N.J.A.C. 8:52-5.2(f).

APPENDIX

PROGRAMMATIC GUIDELINES
FOR BEST PRACTICES

I. Environmental Health Activities

Recreational Bathing

(a) The local board of health shall:

1. Conduct a sanitation and safety program at public bathing places (that is, swimming pools, lakes, rivers and ocean bathing places), based upon the current “Recreational Bathing” regulations contained in the State Sanitary Code (see N.J.A.C. 8:26);

2. Inspect, using an inspection form designed by the Department of Health and Senior Services, each public bathing place at least twice during the operating season, make follow-up inspections when deficiencies are found, and take necessary enforcement actions;

3. Assure sanitary surveys of natural bathing areas as indicated by bacterial counts and/or epidemiological evidence;

4. Inspect public spas and/or whirlpools at least yearly in accordance with the provisions of the Recreational Bathing regulations (N.J.A.C. 8:26); and

5. Conduct investigations within 24 hours of all deaths and serious injuries and report such occurrences as outlined in the Recreational Bathing Regulations (N.J.A.C. 8:26) on a form developed by the Department of Health and Senior Services.

Campgrounds

(a) The local board of health shall:

1. Conduct a sanitation and safety program for campgrounds based upon State law and Chapter 11 of the State Sanitary Code (N.J.A.C. 8:22-1); and

2. Inspect each campground at last annually to insure compliance; conduct follow-up inspections and initiate enforcement action as necessary.

YOUTH CAMPS

(a) The local board of health shall conduct a youth camp sanitation and safety program (N.J.A.C. 8:25) and shall:

1. Inspect each youth camp once prior to opening; and

2. Perform necessary follow-up inspections at the request of Consumer and Environmental Health Services; and
3. Submit copies of each inspection to Consumer and Environmental Health Services, Department of Health and Senior Services.

Food surveillance

(a) The local board of health shall maintain surveillance of retail food establishments, food and beverage vending machines and shall:

1. Conduct a retail food establishment program based upon State laws and regulations, including Chapter 12 of the State Sanitary Code and local ordinances, if applicable (N.J.A.C. 8:24);

2. Inspect retail food establishments using forms approved by the Department of Health and Senior Services at least once a year, inspect vending machines dispensing potentially hazardous foods at least once a year and those dispensing non-potentially hazardous foods on a complaint basis or as required by local ordinance;

3. Initiate appropriate enforcement action to secure compliance with State law and local ordinance; collect and prepare evidence for legal action; follow a protocol for taking appropriate enforcement actions to secure compliance (such as abatement letters, administrative hearings, summons, court actions and condemnations);

4. Maintain food establishment and vending machines files at the local health agency office containing inspection reports, food sample reports, and reports of enforcement actions take and other pertinent data associated with the program;

5. Provide for, or conduct training courses for food service supervisors using curricula approved by the Department of Health and Senior Services such as the Food Manager's Certification Program;

6. Collect samples and provide for laboratory analyses of any food suspected of being associated with a foodborne illness or, as necessary, any food suspected of being adulterated, misbranded or unwholesome;

7. Embargo all food known or suspected of being adulterated, misbranded, unwholesome or associated with foodborne illness within the meaning of local ordinance or State law;

8. Assist the Department of Health and Senior Services upon request in conducting recalls and recall effectiveness checks of foods to be contaminated, adulterated or misbranded; and

9. Condemn and supervise the destruction or otherwise dispose of food which is adulterated, misbranded, unwholesome or associated with foodborne illness within the provisions of local ordinance or State law.

Occupational health (operative January 1, 1989)

(a) The local board of health shall conduct an occupational health program operative January 1, 1989; and shall:

1. Maintain a comprehensive profile of all employers in each designated four digit Standard Industrial Classification (SIC) operating in local jurisdiction. This profile should utilize Department of Labor and Right to Know data filed (see N.J.A.C. 8:59) and include for each employer;

Name of company, SIC Code

Address of company,

Number of employees,

Major product of service

Right to Know Data—DEP/DOH,

History of emergency calls,

History of complaints;

2. Maintain a list of all information and/or agency occupational health resources and make appropriate referrals in response to requests for information on complaints;

3. Train or obtain at least one staff person in Occupational Health and Industrial Hygiene through a continuing education program provided or made available by the Occupational Health Services of the Department of Health and Senior Services;

4. Conduct initial and follow-up interviews, utilizing standardized procedures and forms developed by the Department of Health and Senior Services, upon receipt of reports of occupational disease cases (N.J.A.C. 8:57-1.13); and

5. Conduct preliminary surveys in response to reported occupational diseases or referrals from the Department of Health and Senior Services, using standardized forms provided by the Department of Health and Senior Services to record observations and collect information. (These standardized forms shall be forwarded to the Department of Health and Senior Services' Occupational Health Services for follow-up).

PUBLIC HEALTH NUISANCES

(a) The local board of health shall conduct a public health nuisance program to include the following:

1. Investigations of public health nuisances including, but not limited to, noxious weeds, housing, solid waste and insect and rodents, which shall be conducted in accordance with applicable State laws and local ordinances, which are at least equivalent to the "Weed Control Code of New Jersey," the "Solid Waste Code of New Jersey," and the "Public Health Nuisance Code of New Jersey" (which are model codes available from the Department of Health and Senior Services);

2. Conduct complaint investigations and surveys to identify nuisances, and through appropriate follow-up, ensure abatement in accordance with State law and local ordinances;

3. Maintain and make available educational infor-mation on the prevention and abatement of public health nuisances; and

4. Maintain current files on all public health nuisances which shall include the investigation, follow-up, abatement and enforcement action taken in each instance.

II. Communicable Disease Activities

Reportable diseases

(a) The local board of health shall conduct a program for the surveillance, investigation and control of reportable diseases and shall:

1. Document episodes of reportable diseases including occupational diseases and/or incidents and transmit the information to the State and other agencies as required by chapter 2, Reportable Diseases (N.J.A.C. 8:57-1) of the State Sanitary Code and N.J.S.A. 26:4;

2. Conduct prompt investigations of reportable illnesses as well as unusual manifestations of disease not listed as reportable in chapter 2 of the State Sanitary Code (N.J.A.C. 8:57-1) and institute appropriate control measures and promptly report all findings to the Department of Health and Senior Services;

3. Disseminate and exchange information relative to outbreaks of disease with physicians, hospitals, boards of education, and other responsible health agencies as appropriate; and

4. Analyze reported data to provide a basis upon which to plan and evaluate an effective program for the prevention and control of infectious diseases.

Immunization

(a) The local board of health shall promote and provide immunizations for protection against childhood vaccine-preventable diseases and shall:

1. Promote and provide primary and booster immunizations to preschool and school age children for protection against diseases in accordance with current recommendations of the Department of Health and Senior Services;
2. Assist all schools, with an emphasis on preschool facilities, in implementing and enforcing the immunization requirements contained in chapter 14, of the State Sanitary Code (N.J.A.C. 8:57-4) by providing immunization services and conducting periodic surveys and representative record audits every three years;

3. Secure prompt reporting of vaccine-preventable disease as required by chapter 2 of the State Sanitary Code (N.J.A.C. 8:57-1.2); and

4. Utilize vaccine information statement forms and maintain related documentation for individuals receiving State-issued vaccines according to State Directives and in compliance with Federal law.

Rabies and zoonosis control

(a) The local board of health shall conduct a program for the control of rabies and other zoonoses and shall:

1. Require rabies vaccination of dogs to comply with current rabies statutory requirements and encourage the vaccination of cats, and provide for rabies vaccination clinics at least once a year;

2. Ensure that a report of an annual canvass of all dogs owned, kept, or harbored within the limits of the respective municipality is received by

the local board of health by September 1 of each year;

3. Inspect kennels, pet shops, shelters and pounds, to ensure compliance with the State laws and regulations prescribed by the Department of Health and Senior Services, and ensure that licenses issued to these facilities are in compliance with existing laws;

4. Report and investigate animal bites, ensure that persons bitten are advised to see a physician, quarantine biting animals as indicated and report immediately to the Department of Health and Senior Services clinically suspicious cases of rabies in animals as determined by a veterinarian, ensure availability of impounding facility where biting animals may be appropriately quarantined and observed for rabies;

5. Ensure that heads of animals that have died within 10 days after biting a person are delivered immediately to the Department of Health and Senior Services' Public Health and Environmental Laboratories for examination (Unwanted dogs or cats or any other animal which has bitten a human may be sacrificed immediately and the head promptly delivered to the Public Health and Environmental Laboratories for examination);

6. Provide an organized program for control of stray dogs and other animals;7. Inspect annually, or more often if necessary, records of dealers in psittacine birds as required by chapter 3 of the State Sanitary Code (N.J.A.C. 8:23); and

8. Initiate appropriate enforcement actions to secure compliance with the State rabies statutes, collect and prepare evidence for legal action.

Tuberculosis control

(a) The local board of health shall control the spread of tuberculosis and shall:

1. Ensure that all of the tuberculosis control services or services elements listed in the "Guidelines for Ambulatory or Outpatient Tuberculosis Control" (available at the New Jersey Department of Health and Senior Services) and available and accessible to all persons living within the jurisdiction of local agency;

2. Secure prompt reporting of tuberculosis and transmit reports as required by the State Sanitary Code (N.J.A.C.8:57-1.2) and encourage the reporting of suspects;

3. Ensure effective treatment and continuing medical supervision of suspect and diagnosed cases of tuberculosis;

4. Ensure that contracts are identified and brought to examination, diagnostic conclusion, and treatment in accordance with the policy of the Department of Health and Senior Services;

5. Ensure the provision of preventive therapy in accordance with current recommendations of the Department of Health and Senior Services;

6. Ensure reporting of the current status of diagnosed cases of tuberculosis in accordance with the policy of the Department of Health and Senior Services using forms provided by the State;

7. Provide for the discharge from tuberculosis supervision of patients whose treatment has been completed in accordance with current recommendations by the Department of Health and Senior Services;

8. Provide for testing using currently approved intradermal tuberculin tests, of pupils, teachers, employees, and volunteers in the non-public schools, and for follow-up of those in both the public and non-public schools as recommended in the current edition of "School Tuberculin Testing in New Jersey," published by the Department of Health and Senior Services.

9. Analyze data to provide a basis upon which to plan and evaluate an effective program for the prevention and control of tuberculosis.

Sexually transmitted diseases

(a) The local board of health shall control sexually transmitted diseases and shall:

1. Provide for medical services for all persons seeking medical care for Sexually Transmitted Disease (STD);

2. Secure prompt reporting of any case of STD and forward reports immediately to the Department of Health and Senior Services, Communicable Disease Field Program, as required by chapter 2 of the State Sanitary Code (N.J.A.C. 8:57-1.2);

3. Provide interview and investigation services to priority STD cases in accordance with the policy established by the Department of Health and Senior Services and report results of these services on appropriate forms provided by the Department;

4. Provide counseling to all patients infected with STD and treated at public health department STD clinics, to include, but not be limited to, disease prevention, sex partner referral, need for follow-up testing, and appropriate action to take when symptoms appear;

5. Provide public education services tot he community or target population; and

6. Analyze reported data and provide a basis upon which to plan and evaluate an effective program for the prevention and control of sexually transmitted diseases.

Human Immunodeficiency Virus (HIV Infection)

(a) The local board of health shall administer a planned program to prevent and control HIV infection and shall:

1. Utilizing seroprevalence and case reporting data provided by the Department of Health and Senior Services, identify ways to reach persons at high risk within the community and develop and implement a strategy to disseminate HIV prevention and control information to these groups;

2. Maintain supplies of educational materials to meet information requests on the transmission, prevention and control of HIV;

3. Provide or arrange for other suitable local health education resources (for example, Planned Parenthood, Red Cross) to conduct education programs addressing the epidemiology, prevention and control of HIV to civic and community organizations and occupationally at risk groups utilizing State prepared or equivalent curricula;

4. Provide or arrange for in-service training addressing the epidemiology, prevention and control of HIV to all local health department personnel;

5. Develop and implement a protocol to refer individuals concerned about their HIV status to counseling and testing sites and other health care providers;

6. Refer HIV infected persons and their families seeking services to appropriate provider agencies such as mental health, drug treatment and other social service agencies; and

7. Participate in the planning, development and implementation of a county or regional program to control HIV infection and the progression to AIDS.

III. Maternal and Child Health Activities

Infants and preschool children

(a) The local board of health shall provide health supervision for infants and preschool children and shall:

1. Provide child health conferences for comprehensive preventive health care of infants and preschool children, with particular emphasis on the medically indigent, based upon the current Department of Health and Senior Services publication, “Guidelines For the Child Health Conference”;

2. Prepare a Child Health Service Report CH-7 or subsequent form number for each session, and submit promptly on at least a monthly basis to the Maternal and Child Health Program in the New Jersey Department of Health and Senior Services;

3. Maintain an informational and outreach service to encourage physicians, hospitals and social agencies to refer families to the child health conference, women, infants and children supplemental Food Program (WIC) and the public health nursing agency; and

4. Provide for information and guidance on physical, emotional, nutritional, and cognitive development of infants and preschool children through child health conferences and home nursing visits.

Childhood lead poising

(a) The local board of health shall provide for the prevention and control of lead poising in young children and shall:

1. Conduct a program, the major components of which shall include:

   - i. Case identification;
   - ii. Medical management;
   - iii. Environmental surveillance; and
   - iv. Education in conformance with N.J.S.A. 214:14A-1 et seq. And chapter 13 of the State Sanitary Code (N.J.A.C. 8:51-7.7). (Also, a current issue of “Preventing Lead Poisoning in Children, a statement by the Centers for Disease Control:” and findings of the New Jersey Physician Task Force on Lead Poisoning shall be used as guidelines for program delivery as appropriate.)

2. Develop a program plan based on elements in (a)1 above and on the degree of risk in the community as identified through the "Community Health Profile" and "Community Hazard Score for Lead Poisoning in Children" issued by the Department of Health and Senior Services;

3. Conduct case finding efforts among children one through five years of age by annual blood testing in accordance with approved collection techniques in such settings as child health conferences, WIC clinics, day care centers, nursery school and door-to-door in high risk neighborhoods, with testing priority given to children at higher risk including:

i. Those one through three years of age;

ii. These residing in or frequenting housing units or other sites where lead-based paint may be present;

iii. Those whose parents or other household members may be occupationally or otherwise exposed to lead sources;

iv. Those at increased risk of exposure to lead sources for whatever reason;

v. Those with a history of pica or increased lead absorption; and

vi. Those who are siblings of a child with increased lead absorption;

4. Assure that confirmed positive test results based on current risk classification standards is immediately referred to medical supervision and that a child so referred shall receive on-going, medical management as appropriate;

5. Conduct environmental surveillance among patient cases identified; and

i. Provide staff capable of conducting environ-mental investigations;

ii. Assure that, simultaneous with referral for medical attention, and environmental investigation will be initiated to identify the probable source(s) of lead exposure and to ensure that expedient and safe removal of the lead hazard(s);

iii. Assure that along with the owner of the property wherein the child resides, the parent or guardian of the child shall be notified in writing and kept abreast as to the findings of the environmental investigation and subsequent surveillance;

iv. Ensure that during periods when actual renovation work is underway, the affected child or children are removed from the premises; and

6. Provide a program of education directed toward parents, the general public, physicians and other health personnel regarding lead intoxication, sources of lead in the environment and control measures; and

i. Assure the provision of appropriate counseling and instruction to parents of lead intoxicated children and to parents of children at risk by trained professional personnel; and

ii. Assure the provision of adequate in-service training and continuing education of program per-sonnel.

Improved pregnancy outcome

(a) The local board of health shall reduce infant mortality by improving access to prenatal care and related services in accordance with guidelines established by the Department of Health and Senior Services and shall:

1. Maintain an information and referral system for those requesting family planning, or prenatal and WIC services, to include:

i. A file of all providers of such services in the jurisdiction; and

ii. An active referral file;

2. Maintain a liaison with prenatal clinic services, family planning clinics, WIC school nurses, school health educators, and others;

3. Provide public health nursing services as requested by agencies for prenatal follow-up to high risk women who are determined to be medically indigent, to include, at a minimum:

i. Pregnancy counseling;

ii. Prenatal information;

iii. Follow-up of all referred positive pregnancy tests to promote initiation of prenatal care in the first trimester as requested by agencies;

iv. Nursing support and education through pre-natal and postpartum home nursing visits as needed; and

v. Referrals as appropriate to WIC or other nutrition services, social services, and family planning services;

4. Establish and maintain a community outreach and education program targeting high risk women including adolescents to encourage and facilitate early entrance into prenatal care; and

5. Cooperate with the Department of Health and Senior Services, Newborn Biochemical Screening Program to locate and secure repeat specimens from infants when the sample cannot be obtained through the normal channels of a hospital and/or physician.

IV. Adult Health Services Activities

Cancer services

(a) The local board of health shall provide cancer prevention for populations at high risk according to criteria outlined in the Department of Health and Senior Services' publication "Adult Health Services Guidelines" and as identified through the Community Health Profile and shall:

1. Provide screening personnel to meet the criteria for staffing as specified in the "Adult Health Services Guidelines";

2. Establish a coordinated plan for counseling, referral and follow-up of all persons with non-negative screening results;

3. Provide screening services yearly for three percent of women ages 15 to 34 and the three percent of women ages 35 to 64 who are at high risk for cervical cancer;

4. Provide education services yearly for five percent of women ages 15 to 34 and five percent of women 35 and older to receive instruction in these particular areas;

i. The risk factors for cervical cancer and breast cancer;

ii. The importance of the Pap Smear in the early detection of cervical cancer (in accordance with the American Cancer Society Guidelines on cervical cancer screening);

iii. The importance of comprehensive breast cancer screening which include mammography at intervals specified by the American Cancer Society Guidelines and a physical breast examination by a health care professional;

iv. Breast self examination as one component in a total health care awareness program; and

v. Dietary and lifestyle modifications to reduce the risk of breast and cervical cancer.

5. Provide yearly instruction to three percent of individuals over age 40 in these particular areas;

i. The risk factors for colon/rectal cancer;

ii. The importance of compliance with the guidelines on colon/rectal cancer prescribed in Department of Health and Senior Services' Adult Health Services Guidelines; and

iii. The dietary and lifestyle modification to reduce the risk of colon/rectal cancer;

6. Provide annual reports to the State on the demographic characteristics of populations receiving screening and/or education services and the results of these screening programs;

7. Sever as a community resource to disseminate information available from the State on types of screening services available;

8. Provide for cancer-related continuing education for nursing and other program personnel at least once every three years. Include current cancer-related information in the orientation of all newly-hired cancer program staff to be involved in Cancer Services; and

9. Offer smoking prevention and cessation programs as defined in the "Adult Health Services Guidelines" (N.J.A.C. 8:52-6).

Diabetes services

(a) The local board of health shall provide for diabetes education services per the Department of Health and Senior Services' "Adult Health Services Guidelines" and shall:

1. Conduct public education related to diabetes and its risk factors such as age, obesity and family history;

2. Conduct diabetes risk assessment on all adult clients who utilize clinical or hypertension or

cancer screening services, and counsel, refer, and follow-up clients where appropriate;

3. Educate or appropriately refer known diabetics to available diabetes-related education and other community resources (such as ophthalmologist, podiatrist, etc.); and

4. Provide for diabetes-related continuing education for nursing and other program staff at least once every three years, and include current diabetes-related information in the orientation of all newly-hired staff to be involved in Diabetes Services.

Cardiovascular disease services

(a) The local board of health shall provide cardiovascular disease control services according to the Department of Health and Senior Services "Adult Health Services Guidelines" and shall:

1. Provide hypertension screening services yearly to one percent of the high risk population;
2. Provide cardiovascular risk factor assessment and counseling on all individuals screened for hyper-tension and include the following areas:

    i. Family history of cardiovascular disease;

    ii. Smoking;

    iii. Excessive cholesterol intake;
    iv. Obesity;

    v. Diabetes; and

    vi. Exercise, and counsel, refer and follow-up clients where appropriate

3. Provide cardiovascular health education programs for the general public;

4. Provide cardiovascular health education programs for hypertensive individuals; and

5. Provide for cardiovascular-related continuing education for nursing and other program staff at least once every three years, and include current cardiovascular-related information in he orientation of all newly-hired staff to be involved in cardiovascular disease services.

Health services for older adults

(a) The local board of health shall provide for a health program at locations selected by the health department which identifies the health needs of adults age 65 and older, and shall:

1. Provide a health needs assessment yearly on one percent of the non-institutionalized elderly in accordance with "Guidelines for Health Services for Older Adults" contained in the Adult Health Services Guidelines (available at the New Jersey Department of Health and senior Services);

2. Provide education on alcohol abuse and medication management;

3. Follow-up and make referrals as appropriate for abnormal screening results or for needs identified in the individual's history and/or intake;

4. Assure participation at service sites through advance notification (for example: publicity);

5. Provide for gerontology related continuing education for staff at least once every three years, and include current gerontology related information in the orientation program for all new staff providing these services; and

6. Provide immunizations (for example, influenza and pneumococcal vaccines) at the discretion of the local health agency in accordance with the Immunization Practices Advisory Committee of the U.S. Public Health Services.

V. Health Education/Health Promotion

(a) A structured program shall be provided by the Health Educator or Field Representative, Health Education, in accordance with community health education needs, which shall include health components for Alcohol Abuse Control, Drug Abuse Control, Smoking Prevention and Cessation, Nutrition, Injury Control, and Physical Fitness and Exercise and shall include the following:

1. An assessment of health education needs and identification of target population based on information from the New Jersey Department of Health and Senior Services Community Health Profile and other relevant health related data;

2. Written health education plans with measurable objectives for the six components in (a) above, based on the Health Promotion Guidelines, contained in the Adult Health Services Guidelines and other identified health education needs;

3. Identification and involvement of local leadership in the planning, implementation, and

maintenance of needed health education services and programs to include collaboration with other agencies service the community where such opportunities exist, and consultation with content specialists in the six required components in (a) above; and other areas as needed;

4. Application of appropriate health education interventions to provide for the effective implementation of health education programs (that is, community developments, skill development, simulation, peer group discussion, behavior modification, lecture, media awareness, programmed learning, individual instruction, etc);

5. Integration of a health education component into health department programs and services, covering the six required promotion topics in (a) above;

6. Consultation and training in the application of health education techniques for the profession al staff of the health department;

7. Evaluation and report of the degree of success in achieving predetermined health education objectives; and

8. The health educator or Field Representative, Health Education shall serve as a community health information resource.

Public health nursing

(a) Provision of public health nursing services shall include the following:

1. The services of a public health nurse director or supervisor to assess, plan, implement and evaluate public health nursing services in accordance with community health needs;

2. Up-to-date written objectives, policies and procedures developed in cooperation with the health officer, for each activity in which there is nursing participation which relate to the overall goals of the local health agency;

3. The maintenance and use of individuals, family and other service records according to current professional standards;

4. Orientation in-service and continuing education programs for nursing staff;

5. Annual reports of services rendered which include pertinent statistics and descriptive narrative as related to objectives; and

6. Integration, in conjunction with the health educator, of the relevant components of the health pro-motion program into all activities involving public health nursing services.

Appendix J

Summary of Conference on Risk Communication

CANCER CLUSTERS: IMPROVING COMMUNICATION WITH COMMUNITIES AND INDIVIDUALS CONFERENCE

The *Cancer Clusters: Improving Communication with Communities and Individuals* conference, sponsored by the Task Force on Cancer Clusters in New Jersey, was held on October 28, 2003 in Piscataway, New Jersey. The presentations are summarized below.

Branden Johnson, Ph.D., New Jersey Department of Environmental Protection
General Thoughts on "Risk Communication" and Its Potential Application to Cancer Cluster Policies.

Dr. Johnson discussed three methods of risk communication and the benefits and risks of each. He began with ***one-way communication*** which exemplifies the genesis of risk communication and in which the organization conducting a cancer cluster investigation is responsible for the entire process, including screening, holding press conferences and disseminating results. With a ***two-way*** exchange, the values and viewpoints of all parties are brought to the table. The third, and most advanced method, is deliberative-analysis (DA), which involves “combining analysis of available knowledge and deliberation over relevant values so as to facilitate joint problem-solving.” DA does not require consensus among participants; it does not specify whether the “joint problem-solving” leads to an actual policy or management decision by participants (including citizens), or whether they merely present their conclusions in an advisory capacity to the real decision-makers. But DA does presume that both values “consultants” (e.g. citizens) and knowledge “consultants” (e.g. experts, officials) are engaged together in grappling with how data and values suggest some options are better than others.

A sequence of planning tasks should be properly attended to in order to achieve communication success. These steps include: *issue identification; goal setting; profiling issues, audiences and constraints; assessing the audience; identifying messages and methods; implementing strategy; and evaluating, debriefing and following-up.*

Additional issues to consider:

Individual precautionary behavior: The community may have a hypothesis about what is the source of a cancer cluster. The community wants to be protected from the hypothesized source. The role of epidemiologists is to try to establish if there is a problem. Investigators can suggest ways that the public can protect themselves, and give the public options and choices, but have no control over whether these precautionary behaviors are adopted.

Institutional precautionary behavior: It is not always clear, especially to the public, which institution has responsibility for protecting the community based on the true or hypothesized cause for a cluster. It is necessary to clarify these responsibilities to the community. Institutional roles may change due to the nature of the real or hypothesized cause; and when environmental factors are thought to be involved, roles may change depending on whether exposures are within or above regulatory standards.

Attribution of cause and responsibility: The community is looking for an answer, e.g. a cause of the perceived cluster, and epidemiological data is often unable to provide one. Investigators need to understand this desire for closure and empathetically and honestly communicate their understanding. Additionally, cluster investigators and communicators should be knowledgeable about the community's "lay hypotheses" and attempt to correct misconceptions.

Trust: Unconditional trust is not always helpful and a certain level of mistrust may be useful. Techniques to build trust exist. For example, cluster investigators can build relationships with more trusted groups. Methods also exist to get compliance without trust. For example, in Japan, radiation monitors were distributed so that citizens would not have to rely on the government for reports on radiation levels. Different criteria for trust may exist. Trust should not be expected solely based on an investigator's level of education. Often, how investigators treat people in the community is more important to building a foundation of trust than an academic degree.

Uncertainty: Some experts believe that trust could be strengthened by more frank communication about uncertainty. They believe that investigators should be clear about what they know, what they do not know, and their plan for resolving these uncertainties. However, this approach has not been fully evaluated and evidence suggests that the public may vary widely in whether they judge discussions of uncertainty to be honest or dishonest, competent or incompetent.

In conclusion, Dr. Johnson reiterated the need to speak empathetically and sincerely, since the community involved in an investigation is hurting. He recommended that investigators make clear what they can and cannot do. He noted that perceived constraints must be examined to see if they are truly constraints. Dr. Johnson distributed a copy of the communication planning guide he co-authored, *Establishing Dialogue: Planning for Successful Environmental Management.*

Linda Gillick, Ocean of Love
Community View of Cancer Cluster Investigation

Ms. Gillick's son was diagnosed with Neuroblastoma when he was three months old. Since 1979, 122 confirmed cases of childhood cancer have been diagnosed in Dover Township, NJ, where Ms. Gillick resides. In this area, central nervous system cancer is seven times higher, and leukemias five times higher, than the national average.

Ms. Gillick called upon the New Jersey Department of Environmental Protection and the U.S. Environmental Protection Agency to investigate the water supply. As a result of her community action, she was appointed chairperson of the Citizen's Action Committee on the Childhood Cancer Cluster in March 1996. Her presentation offered insight and guidelines for communicating and working with the community around cancer cluster issues.

Key Communication Points

- Communication is most important at the beginning.
- Inform parents about available data for their town and what is expected or not expected from the investigation.
- Choose words very carefully.
- Community members will groan when they hear, "it meets all standards".
- Respect the community, and be aware of body language when communicating.
- Err on the side of caution: in Toms River the wells were shut down 6 months after the investigation began.
- The community perceives state workers such as NJDEP and NJDHSS employees as working for them. The community also needs these groups to work collaboratively, rather than passing the ball to another agency. The community needs them to go to the legislature and get laws passed to protect communities.
- Keep presentations simple and short.
- Give communities information, truth and facts so they can make decisions about what to eat, drink, etc. This puts the responsibility on the community.
- Listen.
- When you go into a community, pretend you live there.

Beverly Kingsley, Ph.D., M.P.H., National Center for Environmental Health, Centers for Disease Control and Prevention
Perspectives on Cancer Cluster Risk Communication from NCEH

Dr. Kingsley's presentation began with an historical overview of CDC's cancer cluster activities as well as an update of current cluster activities. Current activities include the Cancer Cluster Public Inquiry Triage System (CCPITS). The goal of CCPITS is to "centralize CDC response, coordinate, and track" cluster inquiries. Since its inception in May 2002, CCPITS has received 350 calls. Next, Dr. Kingsley presented lessons in collaboration and risk communication learned as a result of the Churchill County, Nevada Leukemia Investigation. She explained Covello and Allen's 1988 "Seven Cardinal Rules of Risk Communication":

1. Accept and involve the public as partner;
2. Listen to the public's specific concerns;
3. Plan carefully and evaluate your efforts;
4. Be honest, frank and open;
5. Work with credible sources;
6. Meet the needs of the media;
7. Speak clearly and with compassion.

Jane Lewis, Dr.P.H., University of Medicine and Dentistry School of Public Health
Risk Perception and Other Stuff in Cancer Clusters

Dr. Lewis noted that communicating risk around possible cancer clusters is both important and difficult and that it requires understanding of how the public views risk, or the "logic behind what may seem illogical." Risk communication was operationalized to mean a two-way interactive communication "among interested parties about the nature, magnitude, significance, or control of a risk." Important assumptions of risk communication are that both the public and experts benefit from two-way communication and can learn from each other; that public participation improves the likelihood of successful communication; and that risk communicators must recognize and consider community members' perceptions.

Lewis iterated four problems that are inherent to cancer cluster risk communication. First, the public and experts estimate and perceive risk differently, so that the public may feel or experience a risk differently than cancer cluster investigators do. The public takes into account a number of factors that are not included in traditional measures of risk, including whether the exposure is voluntary or involuntary, naturally occurring or manmade. Voluntary, naturally occurring risks are considered to be more acceptable (and promote less outrage or concern) than those that are involuntary or manmade. Voluntary risks such as smoking may be discounted while involuntary risks (e.g., pesticides in drinking water) raise greater concerns. Secondly, often the technical nature of the cluster investigation process and the terms used to describe it are difficult for the public to understand. For this reason, scientists and cluster investigators need to be prepared to explain their work and findings to the public in ways that they can understand. Thirdly, trust is a critical factor and is likely to be highest when cancer cluster investigators and communicators work with the community, keep promises, and demonstrate sincere interest in and respect for the community. While trust is difficult to build, it is easy to lose. Fourth, results from a cluster investigation are often inconclusive, which is not surprising nor inherently satisfying for a community. Experts need to be sensitive to this.

Dr. Lewis concluded her presentation by offering recommendations for communicating carefully.

- Use understandable language.
- Listen to the public's perception of risk.
- Keep the public involved throughout the whole process.
- Minimize or avoid risk comparisons.
- Understand and work with the media.

Neil Weinstein, PhD, Rutgers University
Communicating Risk Magnitudes to Lay Audiences

Dr. Weinstein's interests include risk perceptions, risk communication, and health-protective behavior. He reviewed research investigating patient-physician communication and acknowledged the difficult nature of effective risk communication. The goal of his recent research is to "find formats for conveying risk that increase the ability of lay people to perform probability operations that may arise in treatment discussions." One aspect of his research assesses the public's ability to use risk statistics. He reported that one study showed that 22 percent of a well-educated sample of people did not know which is bigger: 1 in 100; 1 in 1,000; or 1 in 10. He elaborated that options exist for methods of communicating risk statistics. For example, risk can be expressed numerically (percents, ratios, probability, odds) or graphically (bar graphs, pie charts, line charts). Research has found that framing information differently influences risk perception. He provided three statements to exemplify this:

- relative risk is more influential than absolute risk;
- people often pay insufficient attention to the denominator; and
- decisions are affected by positive vs. negative framing.

Overall, it is important for risk communicators to be mindful that risk is comprehended in a variety of ways depending on who is doing the comprehending. Overheads from Dr. Weinstein's presentation contain some more concrete examples.

Rochelle Ereman, M.S., M.P.H., County of Marin Department of Health and Human Services
Breast Cancer in Marin County: A Communication Challenge

Ms. Ereman's current research is focused on the epidemiology of breast cancer in Marin County, an area with historically elevated breast cancer incidence rates, and the translation of epidemiologic concepts to the community. Her presentation focused on the communication of known and unknown breast cancer risk factors to the Marin County community. In 1994 an elevation in breast cancer incidence was noticed and in 2001, the same year that funding was awarded to hire epidemiologists at the county health department, a 20 percent increase in breast cancer rates occurred. Residents of Marin County became a powerful advocacy force.

Perceived risk is influenced by a number of factors, including having been affected by breast cancer or knowing someone who has. In Marin County, perceived risk was high and numerous theories circulated as to why the rates were elevated. Ms. Ereman shared that "everyone has a bias." Researchers tended to associate increased screening, high socioeconomic status and reproductive factors with the increased rate of breast cancer, while the public's perception was that air, water and soil must be contaminated. While their explanations were different, they shared a common goal, to begin to understand "why Marin?" and “why breast cancer?”

Ms. Ereman concluded her presentation by sharing lessons learned and next steps. Many of the lessons learned echo points made earlier in the conference (e.g. avoid technical jargon, involve the community). Her next steps are:

Next Steps

- Focus not only on why rates are high but also on what messages are given to the media. Messages should be carefully crafted.
- Be able to listen to what the community's concerns are and check your perceptions by reporting back to them what you are hearing.
- Evaluate.
- Develop a more robust risk communication strategy.

Colleen McLaughlin, MPH, New York State Cancer Registry
New York State's Cancer Surveillance Improvement Initiative

Ms. McLaughlin is an epidemiologist and a Certified Tumor Registrar. Her presentation described "an on-going project involved in the use of spatial analysis and geographic information systems, including the spatial scan statistic and spatial filtering, to produce maps of cancer occurrence at the ZIP code level throughout the state." She explained the technical aspects of the risk communication materials that accompany the maps and the mapping of cancer risk factors, including sociodemographic, lifestyle and environmental data. As part of this project, she evaluated and made recommendations for revising the New York State registry's policies for the confidentiality and protection of publicly released local area data. Consistency in the release of cancer maps is important. In New York State, the

Commissioner of Health holds a press conference for each release and communication materials including a phone number for public inquiries are developed and distributed. To date, cancer maps exist at the ZIP code level for female breast, male and female lung and bronchus, male and female colorectal and prostate cancers. Follow-up work includes: refining the area under investigation; examining environmental and epidemiological factors that could explain the increase in disease; seeking public input and evaluating possible ongoing exposure to environmental contaminants; assessing feasibility of conducting an epidemiological study; and implementing a study or identifying reasons why conducting a study is not feasible. The department seeks new data and new risk factor maps to include data based on exposure route.

Joann Held, M.S., New Jersey Department of Environmental Protection
Interpreting Risk from Exposure to Air Pollution

Ms. Held described aspects of the New Jersey Department of Environmental Protection's (NJDEP) risk communication with citizens. For example, NJDEP prefers to use the term "negligible" rather than "acceptable" when referring to risk in its communications. When communicating with citizens, NJDEP uses the term "health benchmark" and reports that an exposure is "above" or "below" the health benchmark. This prevents using ambiguous words like "safe" and "acceptable." Ms. Held described the EPA-sponsored Camden Waterfront South Air Toxics Pilot Project. This project relies on input from a Community Advisory Committee (CAC) that had the task of identifying sources of concern and participating in risk reduction strategy brainstorming activities. The CAC met monthly for the purpose of conducting a dual meeting/training session. Information sharing was reciprocal with the CAC and investigators educating one another. Drafts of reports were shared with the CAC and items were added or deleted based on permission being granted via the CAC. Two important lessons learned are: first, the public needs tangible examples of risk. Ms. Held shared an excellent graphic (EPA publication 450/3-90-022) of EPA’s effort to apply tangible examples of risk for public understanding. And second, risk assessment frameworks should include all stressors identified by the community even if they are not part of a final plan.

Jerry Fagliano, Ph.D., New Jersey Department of Health and Senior Services
Environmental Health Risks Relating to Cancer: Health Perspective

Dr. Fagliano presented an overview of the Dover Township Childhood Cancer Investigation. He stressed the importance of positive media coverage and used this headline as an example of the type of newspaper headline to avoid, "Anger and frustration explode at meeting."

At the beginning of the Dover Township investigation, investigators did not commit to conducting an epidemiological study. First, they wanted to update and evaluate childhood cancer incidence data and then evaluate exposure paths and try to understand the problem. Multiple stakeholder groups were at the table and each committed to sharing information and reviewing proposed protocols. Dr. Fagliano stressed the importance of meaningful public involvement. This means that investigators take time to build trust, coordinate with stakeholders and other government agencies, avoid technical jargon and are simultaneously aware not to oversimplify, acknowledge uncertainty, and, most importantly, explain protective actions that the community can take.

Appendix K

Glossary

Tumor: An abnormal growth of tissue; benign or malignant.

Cancer: A group of more than 100 diseases characterized by uncontrolled growth and spread of abnormal cells.

Carcinogen: Any substance that causes cancer or helps cancer to develop.

Diagnosis: Identifying a disease by its signs, symptoms, and laboratory findings; usually the earlier a diagnosis of cancer is made, the better the chance for the cure.

Epidemiology: The study of patterns of the occurrence of disease in human populations and the factors that influence these patterns.

Incidence: The number of newly diagnosed cases of disease occurring in a specific population during a specific time period.

Incidence rate (or crude incidence rate): The number of newly diagnosed cases of disease in a specific population during a specific time period per “***x***” number of people; usually the time period is one year and the “***x***” number of people is 100,000.

- **Age-specific incidence rate:** The number of newly diagnosed cases of a disease in a specific age group in a specific population over a specific time period per “***x***” number of people in the specific age group; usually five-year age groups (0-4, 5-9, 10-14, etc.), usually the time period is one year and the “***x***” number of people is 100,000.

- **Age-standardization (or age-adjustment):** The statistical adjustment of crude rates for differences in age distributions in order to compare rates in different populations; there are two types of standardization, direct and indirect.

- **Age-adjusted incidence rate:** A summary incidence rate that takes into account the age distribution of the population. This is routinely done so that comparisons can be made from year to year. Age-adjustment also enables comparisons among geographic areas. There are several methods to age-adjust; direct standardization is the method most commonly used. With this method, the age-specific incidence rates of the populations of interest (e.g. New Jersey) are applied to a standard population (e.g. 2000 U.S. standard population).

Mortality: The number of deaths due to a disease in a specific population over a specific time period.

Mortality-rate, age-specific mortality rate, and age-adjusted mortality rate:
Analogous to the incidence rate, age-specific incidence rate, and age-adjusted incidence rate, except deaths rather than newly diagnosed cases are the numerator.

Power: The statistical ability to discern an effect, given that there is one.