CANCER CLUSTER RESPONSE PROTOCOL
New Jersey Department of Health
Environmental and Occupational Health Surveillance Program

The protocol described below parallels the cluster investigation guidelines published by the Centers for Disease Control and Prevention (CDC) in the July 1990 *Recommendations and Reports* series of Morbidity and Mortality Weekly Report (MMWR). The protocol outlines three major steps: Initial Response, Standardized Incidence Ratios, and In-Depth Study, with decisions following each step. Also included is a brief description of Local Health Officer roles in cancer cluster inquiries.

Responses to inquiries are designed to be:

- Timely, courteous, empathetic;
- Efficient at triaging and communication;
- Informational to citizens and their families, co-workers, neighbors, health care providers, and public officials; and
- Efficient for maintaining electronic documentation which can facilitate future responses and coordination.

Cancer Epidemiology Services staff will review inquiries for which an appropriate response may be more than routine and will organize meetings as needed for this purpose with other NJDHSS Services, including Consumer and Environmental Health Services, Occupational Health Service, Family Health Services, and/or other experts.

I. Initial Contact and Response to Inquiries

Listen to determine: (a) personal involvement with the people with cancer; (b) the degree of anxiety; and (c) level of knowledge about cancer and cancer incidence.

Record specific information, including number and types of cancer and when diagnosed, gender, ages at diagnosis, population characteristics, and any hypothesized causal factors. A standard Cluster Inquiry (CIN) form is completed and information is entered into a database (see the Procedures Manual for sample form).

Provide information on cancer: A customized letter is sent to the person(s) inquiring, with a copy to the Local Health Officer. The written response includes a summary of the telephone conversation, a brief summary of current scientific understanding of pertinent cancers and/or exposures, information on specific exposures of concern (e.g. a factory, hazardous waste site, etc.), excerpts from or copies of public education materials, referrals for more information including cancer prevention and control, an invitation to contact us again with more information or questions, and a request to complete a feedback form addressing the caller's satisfaction with our response.

Among the key educational enclosures used are:

- Cancer cluster inquiry fact sheets (general and occupational if pertinent);
- Excerpts of American Cancer Society's current *Cancer Facts and Figures* and/or excerpts from National Cancer Institute's PDQ database;
- Cancer risk factors fact sheet;
- New Jersey *Cancer Facts and Figures 2002*;

- Other excerpts, fact sheets, or papers on specific types of cancer or environmental or occupational exposures as indicated and available;
- Brochure of the New Jersey State Cancer Registry (NJSCR).

For a public employee filing a complaint with the NJDHSS Public Employee Occupational Safety and Health Program (PEOSH) of the Occupational Health Service (OHS), industrial hygiene assessments usually are conducted by PEOSH. Complaints to PEOSH are confidential, and letters are not copied to the Local Health Officer. However, health officers can request summaries of PEOSH inspection results (see Agreement with PEOSH in the Procedures Manual). For a private employee workplace, a referral to the federal Occupational Safety and Health Administration (OSHA) or National Institute of Occupational Safety and Health (NIOSH) may be made.

The response to some inquiries are concluded with the above activities, however additional activities may be undertaken, including:

Case characterization and verification: If the initial information suggests an unusual pattern regarding number and types of cancer, gender, or ages at diagnosis, additional information may be collected from the caller on each case, which may include:

- Cancer type (site),
- Date of diagnosis,
- Sex,
- Cancer histology,
- Age at diagnosis or year born,
- Address of residency at diagnosis and residential history,
- Occupational history,
- Smoking status,
- Name, address and phone number of diagnosing physician or hospital.

The reported cases are usually verified using the NJSCR. Additionally, all the cases in the NJSCR that are from a defined geographic area and meet a case definition may be pulled for review.

Review of the NJSCR data: If indicated, staff may also review county and municipal level cancer data from the NJSCR to see if the proportions of cancer types in the geographic area of concern are similar to the county and state proportions. The NJSCR data may also be evaluated for trends in time.

Contact Local/State Officials: If indicated, Local Health Officers and/or other NJDHSS programs or State agencies may be contacted in order to evaluate related information such as unusual or possibly hazardous conditions. Pertinent reports are obtained by staff and made available to the person inquiring about cancer.

Additional information from the above activities is usually included in the customized letter. The results of this first step are used to determine if a formal Standardized Incidence Ratio (SIR) analysis should be conducted.

II. Formal Standardized Incidence Ratio (SIR) Analyses

SIR analyses are rarely indicated, but are conducted under the following circumstances:

- There are **at least** 5 cases of one type or related types of an uncommon adult cancer, OR **at least** 3 cases of one type or related types of childhood cancers;
- There is a plausible reason to suspect more than normal fluctuation of cases;
- The latency issues are potentially consistent with a common factor (ages, dates of diagnoses and residency); OR
- Community concern is high.

When NJDHSS conducts SIR analyses:

- Observed numbers of cases are those confirmed via NJSCR;
- Addresses are checked for accuracy if feasible;
- Expected numbers of cases are derived from statewide age-specific rates from the NJSCR;
- Appropriate population data are used to calculate numbers of expected cases for comparison with observed cases;
- SIRs are calculated separately for each gender OR combined where appropriate;
- Time trends are observed;
- 95% confidence intervals are calculated.

A formal SIR report to the requestor may be prepared which may include:

- Tables with observed and expected numbers of cases, SIRs and 95% CIs;
- Explanation of likelihood of chance outliers for SIRs;
- Discussion of verification of community-reported cases;
- References to general and occupational cancer fact sheets, and other pertinent fact sheets;
- Comments on observed trend or lack of trend;
- Major risk factors for the pertinent types of cancer, and current major hypotheses being investigated/followed;
- Behaviors recommended for primary and/or secondary prevention (e.g. early detection);
- Enclosures, where appropriate.

All reports are sent or copied to Local Health Officer. Reports with positive outcome in analysis are followed up with a phone call to Local Health Officer.

Among the possible outcomes of SIR analyses are:

- No further actions are indicated.
- Public education and outreach are recommended, in coordination with the Local Health Officer. On-site educational sessions are conducted if there are remaining questions after written material is sent, there are a large number of individuals in the concerned group, or that group makes a written request. In advance of such a session, major questions to be addressed are elicited. Additionally, senior NJDHSS management must be in agreement to support these meetings.
- Annual surveillance for communities with high SIRs but do not meet the criteria for further investigation. Annual surveillance will be undertaken for five years with an assessment of the need to continue after five years. The results of the annual assessments and the level of community concern will be considered.

III. In-Depth Study

Evaluation of the need for and feasibility of an in-depth study may be conducted in consultation with other NJDHSS officials and experts or external agencies, where appropriate.
Minimum criteria for evaluating the need and feasibility 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 uncommon 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.

Case-control or other in-depth studies are undertaken only in the event of all the following:

- Sufficient cases;
- A biologically plausible hypothesis with documented complete exposure pathways;
- Residency and latency characteristics are consistent with the timeframes of exposures and diagnoses of cancers;
- Sufficient resources;
- IRB approval; and
- Departmental approval.

The Role of Local Health Officers in Cancer Cluster Inquiries

The Local Health Officer may assist with:

- 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 educational events (if any);
- Communication with the public and media, (if necessary);
- Communication with NJDHSS and other agencies, as needed.