A REPORT ON CANCER REGISTRY ACTIVITIES IN THE REGION OF MÜNSTER

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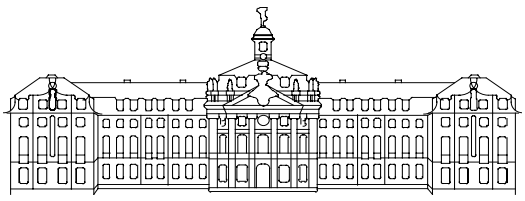

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EXECUTIVE SUMMARY

The routine collection and processing of cancer incidence data for the Münster area is embodied in two parallel cancer registry systems. The systems are the Onkologischer Schwerpunkt Münster and the Epidemiologisches Krebsregister für den Regierungsbezirk Münster. Completeness of cancer reporting has been steadily improving in Münster. A number of independent indicators suggest that completeness of case reporting currently stands at approximately 80 percent. However, completeness of reporting varies considerably by anatomic site, with some major primary sites showing significant deficits in reported incidence. In order to be recognized internationally, reporting in Münster needs to be increased to at least 90 percent according to European standards, the goal being 95 percent. A structured plan with a realistic time schedule needs to be developed for eliminating current sources of underreporting. As an aide to improving completeness of reporting, a standard format needs to be developed for communicating clinically relevant statistical summaries of registry data to physicians and hospitals in the region (Regierungsbezirk Münster). The current pilot initiative to integrate pathologists into the reporting process is a most promising endeavor towards achieving both high quality and completeness of case reporting.

The Krebsregister Münster currently collects data for standard variables normally encountered in internationally recognized tumor registries, and careful attention is given to ensuring the accuracy of the data. It is strongly recommended that an overall quality control program for the system be created by developing a structured approach to conducting special studies and audits at regularly scheduled intervals. Internal reports dealing with other indicators of data quality must be produced on a scheduled basis. Recommendations are provided in the body of the report for restructuring some aspects of the registry system in order to create a commitment to data quality and to help reduce data collection costs.

The failure to utilize the registry data for clinical and epidemiologic research, and the planning and evaluation of cancer prevention and control programs is the most notable weakness of the current system. It is strongly recommended that the Institut für Epidemiologie und Sozialmedizin der Westfälischen Wilhelms-Universität Münster work with staff from the Krebsregister Münster to develop a plan for utilizing the existing data for scientific purposes.

However, there is a critical need to provide support for full time epidemiologists to work closely with the registry. Without this support, it is doubtful that the cancer registration system in Münster will ever reach its full potential as a data base for clinical, epidemiologic and public health research. It is critical that a plan is developed for utilizing the registry data for scientific research, and that the final barriers to acceptable levels of reporting are eliminated within the next two to three years.

1 Introduction

The routine collection and processing of cancer incidence data for the Münster area is embodied in two parallel cancer registry systems. The systems are the Onkologischer Schwerpunkt Münster and the Epidemiologisches Krebsregister für den Regierungsbezirk Münster. Since the overall measurement of cancer incidence in Münster involves necessary linkages between the oncologic and epidemiologic registries, the phrase Krebsregister Münster is used throughout this report to describe cancer registration activities in the area.

The Onkologischer Schwerpunkt represents the backbone of the registry system in Münster with most of the live reported cases being ascertained through this voluntary reporting system. It is primarily devoted to structured follow-up care of cancer patients rather than registration. The Epidemiologisches Krebsregister für den Regierungsbezirk Münster represents a combination of the live reported cases derived from the Onkologischer Schwerpunkt, and the cases identified initially from death certificates under the auspices of the epidemiologic registry. Most live reported cases arrive via the Onkologische Schwerpunkt, only a small number of live reported cases appear to be reported directly to the Epidemiologisches Krebsregister. The vast majority of cases reported directly to the Epidemiologisches Krebsregister come from death certificates. Thus any withdrawal of financial support for the Onkologischer Schwerpunkt by the Sick Fund would mean the cessation of any real registry activity in the Münster area.

2 Objectives and Specific Aims of the Registry System

Standard - A formal document detailing the goals, objectives and specific aims of the cancer registry should be available, and reviewed and modified on a periodic basis to meet the changing needs of the clinical and research communities.

Münster - To date, the only document providing an overview of objectives and aims of the Epidemiologisches Krebsregister is a brochure published by the Ministerium für Arbeit, Gesundheit und Soziales des Landes Nordrhein-Westfalen entitled „Information für Ärztinnen und Ärzte: Ihr Beitrag zur Krebsbekämpfung. Das Epidemiologische Krebsregister für den Regierungsbezirk Münster.“ This brochure serves to give a rationale for cancer registration in general and thus provides a brief introduction to the uninitiated reader, such as members of the public, physicians and patients. A formal document (Aufgabenbeschreibung) - both for internal and external use - detailing the goals, objectives and specific aims of the Onkologischer Schwerpunkt Münster and the Epidemiologisches Krebsregister für den Regierungsbezirk Münster has not been prepared.

3 Data Collection, Processing, and Storage

3.1 Data Elements Currently Collected by the Registry System

Standard - The data elements collected by the Krebsregister Münster should be consistent with those included in high-quality registries which meet international standards.

Münster - The data elements currently being collected by the Krebsregister Münster are consistent with those included in high-quality registries in the United States and Europe. These U.S. registries include some of the older registries operated by individual state governments and the registry programs supported by the National Institutes of Health under the Surveillance Epidemiology and End-Results Program (SEER). The Münster data collection system collects the standard array of sociodemographic, clinical and pathologic data normally found in high-quality oncologic or population-based registries. For example, the Krebsregister Münster uses standard coding systems for anatomic site, histologic type, pathologic grade, and pathologic staging. Pathologic staging is performed using the sophisticated TNM system, rather than the more simplified extent-of-disease systems used in some registries. The extent to which these variables are collected in a complete manner is discussed in section 4.5.

3.2 Costs of Collecting, Processing, and Storing Registry Data

Standard - Various differences exist between Europe and North America with regard to real versus apparent expenditures for cancer registries. In North America, state laws often require hospitals to utilize existing staff to ascertain and report all cancer cases to the registry without the ability to recover the costs of these operations directly from state funds. However, the hospitals will attempt to recover some of these registry associated costs by folding cancer case reporting and other mandated disease reporting costs into their hospital reimbursement formula. Thus, the cost of these hospital based cancer reporting activities are recovered from various forms of governmental and private third-party reimbursement. It is, therefore, extremely difficult to compare the actual costs of conducting registry operations in these vastly different areas.

The goal should be to identify aspects of the current operation where significant savings might be realized through more efficient organization of critical activities.

Münster - The operating budget of the Epidemiologisches Krebsregister für den Regierungsbezirk Münster is DM 750.000, with support provided by the Society for Cancer Campaign (Gesellschaft zur Bekämpfung der Krebskrankheiten Nordrhein-Westfalen e.V.). In addition to this budget, one has to consider that the true total costs of the registry can probably not be estimated since the registry depends heavily on the Onkologische Schwerpunkt (which has a separate budget and funding mechanism) for the ascertainment of live case reports through hospital medical record abstraction. The epidemiologic registry therefore can not function without the Onkologische Schwerpunkt. The latter, however, has aims and objectives that are quite distinct from those of the epidemiologic registry which in turn complicates any predictions or outlook for the epidemiologic registry. However, the data collection activities of the two systems are complementary and help to enhance the achievement of these distinct objectives and specific aims. The operating budget for the Epidemiologische Krebsregister according to major functions is presented in table 1.

Table 1 - Current annual operating budget for the Epidemiologisches Krebsregister für den Regierungsbezirk Münster by major budget categories

Epidemiologisches Krebsregister:		
Administration	DM	200.000
Documentation (Primarily Central Office Staff)	DM	450.000
Programming and user support	DM	100.000
Total	DM	750.000

3.3 Case Ascertainment, Medical Record Abstracting, and Data Management

Standard - Complete identification of all eligible cancer cases depends on the careful attention of well-trained personnel to case ascertainment. These staff also need to give equal attention to the vitally important tasks of medical record abstraction, and data management.

Münster - Case ascertainment and medical record abstracting activities are conducted by hospital personnel who are supported either in whole or in part by funds from the Onkologischer Schwerpunkt. These hospital based staff prepare a cancer case abstract form for each identified patient. The form is then submitted to the registry for medical coding, data entry, and editing.

Another source of cancer cases ascertainment is the monthly death certificate review which is conducted by the staff of the Epidemiologische Krebsregister. Death certificates which mention cancer as an underlying or contributing cause of death are abstracted and registered. Cases that are previously unknown to the registry are followed back to the attending physician to collect additional data not listed on the death certificate itself.

The Krebsregister Münster is currently utilizing a computerized system to process registry information. The data entry system is useful for entering the required data onto the main data base. The data are entered by students who work under the direction of a trained registry medical coding technician. Although the data are not double entered, a hard copy report of each keypunched record is compared to the original hospital report by trained supervisory staff. This process is used to correct the record for incorrect data entries. Registry staff may also contact the reporting hospital to correct major inconsistencies observed in the data.

4 Quality Control Assurance Programs

4.1 Regular Manual and Computer Editing of Data

Standard - It is important for the registry to have in place a regular program for conducting both manual and computer edits of the registry data. These edits should be consistent with those normally employed in internationally recognized cancer registries.

Münster - As detailed above, the current registry system provides for the routine monitoring of various aspects of data abstracting and processing regarding both live case reports and death certificate reports. Trained medical record technicians are responsible for the important task of coding medical data items such as pathologic stage, anatomic site, and histologic type. These staff also monitor the data entry activities of the students, and provide training for the hospital based data abstractors. The registry computer system provides a mechanism for identifying errors in entered data, and for returning error lists to the reporting institutions for correction. Registry staff are clearly committed to maintaining an ongoing program of manual and computer editing of data.

4.2 Procedure Manuals, Coding Manuals, other Documentation

Standard - It is vitally important that all registry procedures be fully documented in the form of procedure and coding manuals. Both central office staff and staff at the reporting hospitals need to have full access to these documents.

Münster - The Krebsregister Münster has developed a draft document which describes registry operations and includes various flow charts showing the relationships between various elements in the data structure. It is strongly recommended that such an operations manual be completed and distributed to appropriate staff. A truncated version should be prepared for the hospital personnel responsible for case ascertainment and data abstracting.

4.3 Regular Opportunities for Continuing Education

Standard - Central office staff need to be afforded the opportunity to attend formal continuing education programs regarding cancer registration. This continuing education includes formal

training classes, workshops, educational programs and symposia, and regularly scheduled in-service training.

Münster - Staff from the Krebsregister Münster are afforded the opportunity to attend continuing education sessions. During the past few years, staff have attended four continuing education sessions. These sessions were exclusively involved with informatics (basic course for personal computers, Novell Netware, Microsoft Windows 3.1, and Word for Windows).

4.4 Procedures for Monitoring Data Quality

Standard - An important aspect of quality assurance monitoring is the existence of a continuous program of designed studies and audits. These activities often involve reabstracting audits where central registry staff reabstract sociodemographic, clinical, and pathologic data from the original medical record for a sample of cases already reported to the registry. This approach allows the registry staff to monitor the extent to which the hospital based staff are accurately abstracting data from the hospital records onto the standard registry forms by comparing the originally ascertained data with the reabstracted data. The extent of agreement is a useful indicator of data quality. It is vitally important that the results of these audits be provided to the hospital abstractors in a timely fashion. This information provides the registry with estimates of data quality not available through other methods.

A regular program of evaluating coding accuracy can be developed for staff of the cancer registry. These studies can take the form of reliability studies where a coder is asked to recode the medical items for a sample of cases previously coded by this individual. This approach helps to determine the extent to which an individual coder can consistently provide the same codes for a specific cancer report. A second approach involves comparing results for two or more medical coders who are asked to code the same sample of cases. The extent of agreement can be used as a measure of data quality. It may also be possible to use a set of records prepared by experts in the field of medical coding as a standard against which to measure the performance of registry staff. The American College of Surgeons and the National Cancer Registries Program (U.S.) has conducted a recent study where 1,600 cancer registrars recoded a test set of 25 cases. Standard statistics, such as the Kappa statistic, can be used to measure the extent of agreement between two or more medical coders. This approach serves as a highly effective method of staff training.

Münster - The Krebsregister Münster does not currently conduct special studies of coding reliability or validity. Registry staff also do not conduct special hospital case audit studies.

Since conducting quality control studies at regular intervals should be an integral element of an epidemiologic cancer registry, this is a task the Epidemiologisches Krebsregister may be able to integrate in the near future which would simultaneously provide a service to the Onkologischer Schwerpunkt as both registries would benefit from improved data quality.

Standard - Various statistical parameters have also been developed to help estimate the quality of the data. These include the percent of cases reported with histologic confirmation, and percent of cases with non-specific diagnoses with regard to anatomic site. The percent of unknown values for each variable also needs to be examined. For example, the percent of cases with unknown anatomic site should generally be less than 5 percent.

Münster - For the Krebsregister Münster, histologic confirmation rates and the percent of cases with a non-specific diagnosis tend to reflect other indicators of case reporting such as death-certificate-only (DCO) rates, and known sources of reporting problems in specialty clinics. For primary sites where age-standardized incidence rates are at expected levels, the histologic confirmation rates and percent of cases with non-specific diagnoses are approaching internationally acceptable levels. For other sites with less than complete reporting, reliance on the death certificate as the main reporting source appears to lead to a concomitant loss of data quality.

Data completeness for the various sociodemographic, clinical, and histologic variables tend to show a high degree of variation. Among the sociodemographic variables, marital status, place of birth, and nationality, show high percentages of missing values. Date of birth, gender, and residence at diagnosis show almost no missing values.

Date of diagnosis and primary site (=text of diagnosis) show high levels of completeness. The percent of missing values is significantly higher for laterality (side) and TNM staging (for primary Tumor size, presence and extent of lymph Node involvement, and distant Metastasis), and extremely high for grading (the degree of tumor differentiation). Information on place, cause, and date of death show no missing values among those who have died and for whom

death certificates were received. Additional effort needs to be given to obtaining more complete information on TNM staging and other tumor-related variables which serve as important predictors of patient survival.

4.5 Procedures for Monitoring Data Completeness

4.5.1 Ascertainment of Live and Dead Cases

Standard - An equally important aspect of quality assurance monitoring is the existence of a continuous program of studies and audits designed to assess the completeness of case ascertainment. The most frequently utilized approach to monitoring the extent to which the registry system is capturing all eligible cancer cases is to routinely match reported cancer cases against mortality files maintained by the local, state, and federal health authorities. Any death certificate, with a mention of cancer as an underlying or contributing cause of death, and which fails to match an existing registry case report is considered a potentially missing case report. Cases identified only through the death certificate are referred to as "Death Certificate Only" (DCO) reports. The physician who signed the death certificate is then contacted to determine if the deceased did indeed have a confirmed cancer, and that the decedent's original cancer diagnosis occurred within the geographic area and time period which define the Münster registry system. Cases which meet these selection criteria are then added to the registry as previously unreported cases.

Münster - The Krebsregister Münster conducts a routine program of matching reported cases against the death certificate files. This matching is performed on a monthly basis by registry office staff who travel to the local health offices to abstract the required data from the actual death certificates. During a typical year, the registry sends data requests to physicians for approximately 6,000 death certificates, and receives responses for approximately 5,000. The physicians are also asked to provide information on selected variables which are not available from the standard death certificate, but are needed to complete the registry record. These variables include clinical and pathologic information such as stage and histologic type.

4.5.2 The Death Certificate Only Rate

Standard - The Death Certificate Only (DCO) rate is universally used by cancer registration systems to estimate completeness of reporting. DCO rates of up to 5 percent are considered acceptable for population based registries. It is also important for registry staff to analyze DCO rates by selected variables such as age, gender, calendar year, and primary anatomic site. These analyses can help to identify population subgroups, and selected types of cancers where the data are of sufficient quality to be used in epidemiologic research projects. DCO rates should also be higher for cancer sites with high case fatality rates.

Münster - The DCO rate for the Krebsregister Münster has declined from a high of 19,0% in 1988 to 11,5% in 1992. These decreases in the overall DCO rate represent a promising trend, and it seems feasible to decrease the present DCO rate to an acceptable 5% or lower in the next two to three years. The DCO rates vary only slightly by gender with males showing a DCO rate of 11,6% in 1992, and females showing a rate of 11,4%. As expected, the DCO rates vary considerably by primary site. Among males, DCO rates of less than 10% are observed for most of the gastrointestinal organs, with significantly higher rates observed for cancers of the biliary tract and pancreas. Given the generally low 5-year survival rates for these forms of cancer, the higher DCO rates are not unexpected. For males, DCO rates by primary site tend to be close to the overall DCO average for cancers of the respiratory, reproductive, and genitourinary tracts. DCO rates are significantly lower than the average for cancers of the lymphatic and hematopoetic systems. Among women, the DCO rates for gastrointestinal, respiratory, reproductive, and genitourinary tract cancers are significantly higher than the average for all primary sites combined. DCO rates are significantly lower than the overall average for cancers of the female breast, and the lymphatic and hematopoetic systems.

It should also be noted that the European Network of Cancer Registries in Lyon uses a cutpoint of 90% completeness of reporting with a maximum DCO rate of 10% as a basic measure of data quality. The current level of reporting completeness for the Münster Krebsregister is closer to the generally accepted European standard for completeness than to the standard usually accepted in North America.

4.5.3 Statistical Evaluation of Completeness of Ascertainment

Standard - The extent to which all cases are being identified can also be estimated through special case-finding audits to determine deficiencies in the current system. This approach allows the registry staff to monitor the extent to which the hospital based staff are correctly ascertaining all cancer cases being diagnosed in participating institutions. There are numerous approaches to designing these case-finding audits including the targeting of specific institutions where statistical indicators suggest possible underreporting. More recently, capture-recapture techniques have been used to assess completeness of reporting in Ontario (Robles et al. 1988) and Florida (Hilsenbeck et al. 1992) and in the Saarland in Germany (Brenner et al. 1994; Brenner et al. 1995).

Various other statistical approaches are also used to measure completeness of reporting in population-based cancer registries. Completeness of reporting can also be estimated by comparing the observed number of cancers to the number expected based on an external set of cancer rates. The age and gender-specific incidence rates obtained from a cancer registry with recognized high levels of case ascertainment are multiplied against the age and gender-specific population estimates for the catchment area of the cancer registry under study. The age and gender-specific expected numbers of cancers are then summed to obtain an overall observed to expected ratio of cancers in the registry area. The extent to which the ratio of observed to expected cancers falls below 1,00 provides an estimate of the level of underreporting for the registry. Confidence limits can also be calculated for the observed to expected ratios as a measure of the possible variation in this measure. These analyses can be conducted for total cancers and for various anatomic sites where the number of observed cancers is large enough to provide stable estimates of observed to expected ratios. The validity of this measure is based on the assumption that the comparison registry rates used to calculate the expected numbers of cancers are derived from a population with an underlying cancer risk similar to that of the study area population.

Münster - Age-standardized incidence rates by primary site of cancer for the study and comparison registry can also be used to estimate the completeness of reporting. Comparison of age-standardized incidence rates for the areas covered by the Krebsregister Münster and the Krebsregister Saarland suggest that case reporting is at least 80 percent complete for the Münster

area. Completeness of reporting varies significantly by gender with the total cancer rate (ICD Codes 140-208) among Münster males observed to be 21,6% lower than the comparable rate reported for the Saarland. Among women, the overall Münster rate is only 7,4% lower. The completeness of reporting also varies considerably by anatomic site. Among males in Münster, 21 of 38 primary site groups show incidence rates that are similar to or higher than those observed in the Saarland, with significant deficits observed for the remaining sites. Among female residents of Münster, incidence rates are similar to or higher than those observed in the Saarland, for 19 of 38 primary site groups, with 19 sites showing significant deficits.

The deficits observed for several primary sites of cancer can be directly linked to the refusal of several medical specialty clinics at participating hospitals to report to the registry. The under-ascertainment of urinary tract cancers can be directly linked to the failure of a large urology group to participate in reporting, while the deficit of oral cancers can be linked to non-participation by two large hospitals which specialize in head and neck tumors.

Standard - The ratio of cancer incidence to cancer mortality for each primary site of cancer is another method for estimating the completeness of reporting. Incidence to mortality ratios for the study registry can be compared to similar ratios reported from a high quality comparison registry. Primary sites which demonstrate incidence to mortality ratios that are significantly different from those observed in the comparison registry, incidence to mortality ratios which approach unity, or where mortality is higher than the reported incidence deserve attention.

Cancer registry data can also be analyzed to determine if known patterns of incidence can be observed by age group in the underlying population served by the registry. The percent of childhood cancers and cancers in persons 80 years of age or older are reasonably fixed measures in most population based registries of high quality and can be used to estimate the representativeness of data in the study registry.

Münster - Within the catchment area of the Krebsregister Münster, ratios of age-standardized incidence to mortality rates are low for many primary sites of cancer, with many ratios approaching unity. For some primary sites, with generally poor 5-year survival rates, some mortality rates actually exceed incidence rates. Primary sites showing higher mortality than incidence rates include cancers of the pancreas, and multiple myelomas in males, and cancers of

the buccal cavity and pharynx, esophagus, liver, and pancreas in females. In the Saarland the ratios of age-standardized incidence to mortality rates for all cancer sites combined are 1.89 and 2.56 for males and females, respectively. Similar data for Münster show incidence to mortality ratios of 1.14 for males and 1.54 for females, suggesting lower levels of case ascertainment in Münster when compared to the Saarland. In addition, the percent of all cancers reported among children less than 15 years of age is similar in Münster and the Saarland. However, the Saarland shows 16.6% of all cases diagnosed in residents 80 years of age and older, whereas only 12.2% of cases in Münster are diagnosed in this age group.

4.6 Timeliness of Registry Reporting

Standard - Although completeness of reporting and accuracy of data are the most important and essential goals of a population based cancer registry, timeliness of the data also deserves attention. However, data completeness and accuracy should not be sacrificed for timeliness. Since most cancers develop as the result of exposures that begin decades prior to diagnosis, reasonable intervals between diagnosis and reporting of cases should not have a significant effect on some types of epidemiologic research. A one to two year interval between case diagnosis and reporting to the registry should not have a serious effect on studies designed to estimate cancer incidence patterns in various segments of the population, retrospective cohort studies, and ecologic studies designed to look for possible correlations between cancer incidence patterns and suspected risk factors. Case-control studies of childhood cancers usually involve parental interviews, and are also less likely to be affected by intervals between diagnosis and case reporting.

However, most case-control studies of adult cancers require direct interviews with the patient. This problem is particularly acute for cancer sites with poor 5-year survival rates. Studies utilizing cancer registries with long reporting delays often suffer from information bias because a large percent of patients are deceased and family members or other surrogates must be approached for the data. In addition, the emergence of molecular epidemiology has increased the demand to collect biologic specimens from the patients and controls in addition to collecting more traditional epidemiologic data. These combined epidemiology/laboratory studies are proving to be powerful tools for sorting out gene-environmental interactions for various cancers. Provisions should be made to conduct "rapid ascertainment" of cancers which are of interest to

researchers using the registry data for case-control investigations. Unfortunately, this rapid ascertainment approach has only been developed by a few population based registries, most notably in Los Angeles.

Münster - The original file layout for the Krebsregister Münster did not make provisions for key dates needed to calculate various measures of data timelines. In addition, staff have initiated the major task of converting all files from an older computerized data management system to a newer system. Until the transition is complete, it will not be possible to calculate these indices. This is an area which should be given more attention in the future.

4.7 Patient Follow-up

Standard - In order to obtain unbiased estimates of the relation between various prognostic factors and survival patterns for various primary sites of cancer, the registry must achieve reasonably complete follow-up of all patients accessioned into the system. A follow-up rate of 90 percent is generally viewed to be acceptable, with 95 percent highly desirable. Passive follow-up involves linkage of case records to death certificate files and other routinely collected sources of data (such as motor vehicle driver's license and automobile registration files in the United States). More active approaches also need to be used in order to achieve acceptable levels of patient follow-up. These active procedures include contacting the attending physician, and where feasible initiating contact with the patient or the patient's family. Survival analyses can be conducted with regard to primary site of cancer, age, extent of disease at diagnosis, first course of therapy, and other available data thought to be related to the patient's probability of surviving.

Münster - The Krebsregister Münster utilizes two major approaches to determining the vital status of patients reported to the registry. First, staff conduct a routine program of matching reported cases against the death certificate files to identify cancer cases who have died from any cause. Patient vital status is also determined through regular contacts with the attending and family physician. Due to confidentiality constraints, Krebsregister Münster patient files can not be computer matched against other routinely maintained government files

5 Data Utilization

5.1 Clinical Reports

Standard - Providing participating physicians and hospitals with regular, periodic clinical reports is a vitally important approach to maintaining their interest in the registry system. Reports to participating hospitals often provide tables and graphs which allow institution staff to review their reported cases by factors such as primary site, age, and extent of disease. Such a report would also allow an institution to compare their data with similar data reported for all institutions combined, the region as a whole or other areas such as the Saarland. Ideally, these institutional reports should be prepared on a quarterly basis. Similar data presentations can be prepared for physicians on a semi-annual or annual basis. Periodically, the registry staff should also produce major clinical analyses of selected primary sites of cancer. These reports should include not only descriptive data, but detailed survival analyses. These detailed reports should be submitted to respected, peer reviewed journals for publication.

Münster - The Krebsregister Münster does not currently prepare detailed statistical reports for physicians and reporting institutions. Lists are prepared on a monthly basis for the reporting physician which contain key data on reported patients. The Krebsregister Münster is aware of the need to begin producing routine statistical summaries, and plans to do so this year.

Data provided by the Krebsregister Münster suggest that follow-up of patients diagnosed during the years 1986 through 1990 is reasonably complete and could probably be used to conduct a major clinical report for selected primary sites of cancer. Cancers of the brain and nervous system and all leukemias combined showed excellent levels of 3-year follow-up at better than 95% for the years 1986 through 1990. Other sites such as colon cancer (completeness of 3 year-follow-up estimated at 90%) and breast cancer (completeness estimated at 82%) could be brought to a level adequate for data analysis with a reasonable amount of effort.

Since 1986, the Krebsregister Münster has received 16 requests for data, 14 of these in the last three years. Six requests came from public health departments in the region regarding the frequency of selected cancers in their respective areas. One public health department receives annual incidence and mortality data for the district on magnetic tape. Ten requests were received

from citizens interested in knowing the incidence of cancer in their areas of residence.

5.2 Cancer Prevention and Control

Standard - Cancer registry and mortality data form the basis for planning and evaluating cancer prevention and control interventions in the population. Cancer registry data are extremely useful in helping to identify segments of the population with increased risk of developing selected preventable cancers. Malignancies amenable to primary prevention include smoking and alcohol related cancers, cancers related to occupational exposures, and cancers related to solar and ionizing radiation. In addition, the registry can be used to help identify populations at high risk for cancers of the breast, uterine cervix, colon, rectum, and other primary sites where screening, early diagnosis and appropriate state-of-the-art treatment can significantly reduce mortality. When cancer registry and mortality data are combined with data on risk factors such as cigarette smoking, or utilization levels for various types of cancer screening services, segments of the population most in need of preventive services can be identified.

These types of data can also be used to monitor the impact of cancer prevention programs. In some areas, cancer registry data have been combined with data on mammography utilization patterns to show dramatic increases in mammographic screening by women 50-69 years of age, and an equally dramatic increase in the percent of all breast cancers diagnosed in an early treatable stage. Cancer registry and behavioral risk factor data can also be used to demonstrate clear relationships between decreased smoking levels in the male populations of North America and recent declines in the incidence of lung cancer. Cancer registry, behavioral risk factor, and screening data can also be used to estimate the expected impact of planned prevention programs. Modeling programs now exist which allow the investigator to estimate the potential impact of planned prevention programs on future cancer incidence and mortality. Finally, cancer registry data can be used to help plan for the development of various services such as expected future requirements for mammography units or radiation treatment facilities.

Münster - To date, the Krebsregister Münster data have not been used to identify sub-groups within the population who have unusual risks of developing certain preventable cancers. The data have also not been used to plan or evaluate the efficacy of specific cancer prevention and control programs.

5.3 Epidemiologic Research

Standard - Population based cancer registries are an important resource for conducting various types of epidemiologic research studies. Cancer Registries are ideally suited to show the relationship between cancer incidence and the standard descriptive variables related to person, place and time. Registry data can also be combined with exposure data routinely collected for ecologic units (e.g. geopolitical areas) to look for possible correlations between incidence rates for specific cancers and suspected environmental risk factors. These descriptive and ecologic studies are primarily designed to help develop working hypotheses for further examination in analytic study designs.

Cancer registries also play a prominent role in record linkage studies where members of a defined cohort group who share a common exposure or trait are searched against the cancer registry files to determine if the subjects have been diagnosed with cancer. The cancer registry can also be used to provide a source of cases for inclusion in a standard case-control design. As mentioned previously, studies of childhood cancers are not dependent on rapid ascertainment of cases. However, most case-control studies of adult cancers require direct interviews with the patient for the collection of epidemiologic data, and often include the need to collect biologic specimens from the patients and controls. These combined epidemiology/laboratory studies require that provisions be made to conduct "rapid ascertainment" of the cancers of interest.

Münster - An organized approach to utilizing the Krebsregister Münster data for scientific research purposes is noticeably absent. To date, the Krebsregister Münster data have not been used to develop any epidemiologic research studies of specific cancers in the Münster region. The data also have not been used to produce a major review of the clinical and pathologic aspects of some of the major primary sites of cancer.

5.4 Data Confidentiality

Standard - Current Federal legislation appears to provide more than sufficient confidentiality protections for cancer registry data. A data utilization review committee should be established within each cancer registry to ensure that a proper balance is maintained between the need to maintain confidentiality and scrutiny of patient records and the legitimate needs of public health research.

Münster - Utilization of data from the Krebsregister Münster should be encouraged, but always with careful attention to confidentiality issues. To date, the business manager of the Krebsregister Münster has been making all decisions concerning access to registry data. However, he fully acknowledges the need to form a permanent standing committee concerning research use of the data.

6 Recommendations

6.1 Completeness of Reporting

Completeness of reporting has been steadily improving. A number of independent indicators suggest that the Krebsregister Münster has made consistent improvements in the level of data completeness over the past several years, and that overall completeness currently stands at approximately 80 percent. Completeness of reporting varies considerably by anatomic site, with some major primary sites showing significant deficits in reported incidence.

Recommendation No. 1: In order to be internationally recognized as a high quality cancer registry, reporting in Münster needs to be increased to at least 90 percent, 95 percent being the goal. A structured plan with a realistic time schedule needs to be developed for eliminating current sources of case underreporting. The cooperation of the 16 hospitals in the Münster area which do not currently participate in reporting needs to be given the highest priority. Although many of these hospitals tend to have small numbers of hospital beds, several of these hospitals have more than 400 beds, and the combined effect is to have a serious impact on completeness of reporting. Additional sources of underreporting in the Münster area are several medical specialty clinics at participating hospitals. The lack of cooperation from these medical practices is likely to lead to significant underestimation of selected forms of cancer.

Recommendation No. 2: The Krebsregister Münster also needs to develop reciprocal reporting agreements with oncologic registries and key hospitals in surrounding geographic areas where significant numbers of Münster area residents are diagnosed and treated for cancer. Preliminary attempts have been made to develop such agreements with several hospitals which border Münster on the south and with the Nachsorgeleitstelle in Osnabrück which is responsible for tumor registration in the area of Niedersachsen. These agreements have been informal and have not produced the degree of cooperation expected. Arrangements also need to be made to obtain death certificates for residents of the Münster area who die with a cancer in another area of the State of Nordrhein-Westfalen.

Recommendation No. 3: Another significant contribution to under-ascertainment of cancer cases involves the requirement that the attending physician obtain the patient's permission before

reporting the patient to the registry. The current pilot study which is designed to involve the pathologists at participating institutions has promise. Extension of this approach to all hospitals currently participating in the registry should eliminate a major source of lost cases.

It is therefore recommended that the law be amended to allow pathologists to report all cancer cases to the registry without obtaining informed consent from the patient. Since most cancers tend to be diagnosed through histologic confirmation, this process would ensure identification and reporting of most cancers. Protection against improper use of the registry data could be achieved by developing written rules governing the accepted use of the collected data. A data utilization review committee could be formed to review all internal and external requests for utilizing registry data in clinical or epidemiologic research.

Recommendation No. 4: It is also strongly recommended that a standard format be developed for communicating relevant statistical summaries of registry data to physicians on an annual basis, and to hospitals on a quarterly basis. These reports should also be sent to hospitals and physicians currently not participating in case reporting, and to key institutions and oncology registries in other areas of Nordrhein-Westfalen. Consideration might also be given to the development of a semi-annual newsletter which could include special articles not only about the Krebsregister Münster, but also about registry activities in other parts of Germany, and internationally.

6.2 Data Quality

As previously stated, the Krebsregister Münster currently collects data for standard variables normally encountered in internationally recognized tumor registries. Careful attention is given to ensuring the accuracy of the data through manual and computer based edits, and a system for obtaining required corrections from the reporting institutions. The current system for initially transferring data from the hospitals to the registry, and for correcting data errors makes extensive use of paper forms and lists. The current system requires the data to be first abstracted onto a paper form, and then keypunched. The multiple data transfer steps required by the current system leads to additional staff requirements, and tends to introduce additional opportunities for data errors. Data quality may also be affected by the high degree of staff turn over for the part time hospital personnel and the students who are utilized for data entry. The need to be

constantly retraining these staff also places additional burdens on registry staff who might be better employed in developing and conducting special field studies related to data quality.

Recommendation No. 5: It is recommended that the staff of the Krebsregister Münster consider an approach being used by many population-based registries where hospital personnel are provided with computer software which can be mounted on commonly available personal computer systems. The personal computers currently available in most of the hospitals are not equipped to handle the system requirements (e.g. processing speed) of the software currently being used by the registry. Several systems developed by state cancer registries in the United States can operate with reasonable efficiency on older machines. Similar cancer registry software systems are also available commercially. These software systems have a number of built in data editing features that permit staff with limited computer experience to enter data with a minimum number of errors. These systems edit data as they are being entered by providing alpha-numeric, and value range checks for each variable, and logical checks between related variables. The programs do not allow the entry of obvious inconsistencies between variables such as a primary site and gender, but also allow for more subtle comparisons between variables such as histology and anatomic site. These systems also have numerous "HELP" screens which assist in the selection of appropriate codes for all variables. Finally, these systems are also linked to various data communication software systems to allow electronic transfer of the entered data to the cancer registry. This approach eliminates the dual process of abstracting and data entry, thus reducing data errors. Resources currently allocated for this purpose could instead be utilized to support an enhanced quality control program for the registry system.

Recommendation No. 6: It is also strongly recommended that the overall quality control program for the system be enhanced by developing a structured approach to conducting special studies and audits at regularly scheduled intervals. Although it is recognized that these special studies can be labor intensive, these investigations are an excellent method for identifying previously unrecognized reporting problems. These investigations also serve as excellent teaching and training tools for enhancing the professional abilities of both central office and hospital staff. Internal reports dealing with other indicators of data quality such as percent of unknown values for each variable, percent of cases without histologic confirmation, and percent of cases with non-specific diagnoses should also be produced on a scheduled basis. Finally, there

is a critical need to develop an operations manual for the registry which is updated periodically to reflect changes in procedures.

Recommendation No. 7: Attention should be given to having key staff attend courses specifically related to cancer registration techniques. These courses allow staff to improve already existing skills, develop new skills, and generally keep informed of new developments in the field of cancer registration. Central office staff provide all training for the data abstractors located at the individual hospitals. The registry staff provide 2-4 workshops per year on various topics for the hospital data coordinators.

Recommendation No. 8: The registry staff should have access to a medical consultant who could advise registry staff on questions related to difficult medical coding decisions, particularly the resolutions of multiple primary tumors.

6.3 Data Costs

Recommendation No. 9: Registry staff should investigate the possibility of developing a cadre of mobile data abstractors who would work out of the central office and travel to the various hospitals on a fixed schedule to ascertain cases and to abstract the required data. This approach would not only result in reduced costs, but would provide for continuity of trained hospital abstractors, thus improving data quality. The use of part time data abstractors in the smaller hospitals is of particular concern. The proposed approach would eliminate the frequent turn over of staff in these smaller institutions, and would reduce the training burden for central office staff.

6.4 Potential for Scientific Research

The full research potential of the Krebsregister Münster is highly dependent on not only achieving acceptable levels of reporting, but also on the development of a systematic approach to utilizing the data for scientific purposes. The failure to utilize the registry data for clinical and epidemiologic research, and the planning and evaluation of cancer prevention and control programs is the most notable weakness of the current system. In addition, the failure to develop a routine program for communicating statistical summaries to participating and non-participating physicians and hospitals represents a lost opportunity to solidify support for the registry where it currently exists, and to help convince others of the potential benefits of reporting to the system.

Recommendation No. 10: To date, a formal document detailing the goals, objectives and specific aims of the Onkologischer Schwerpunkt Münster and the Epidemiologisches Krebsregister für den Regierungsbezirk Münster has not been prepared. It is recommended that such a brief document be developed as soon as possible. The document should also be reviewed and modified on a periodic basis to meet the changing needs of the clinical and research communities. These types of documents are useful for developing specific expectations for the registry system, providing a guide to data utilization, and forming a basis for informing physicians and hospital administrators concerning the potential benefits of participating in the reporting process.

Recommendation No. 11: The strengths and limitations of a particular data set and its potential utility for research can best be measured by attempting to utilize the data for a specific research purpose. It is strongly recommended that the Institut für Epidemiologie und Sozialmedizin der Westfälischen Wilhelms-Universität Münster work with staff from the Krebsregister Münster to develop a major clinical report covering the most frequently occurring cancers in the Münster area. This should be a comprehensive report which describes the sociodemographic, clinical and histologic characteristics of the patients. Information on the relation between survival patterns and various prognostic factors such as age, and pathologic stage of disease should also be included. This report should be prepared for submission to a peer reviewed journal with reasonable standing in the clinical and scientific communities. The results of this study should be shared with both participating and non-participating hospitals in the Münster area, and with out-of-area hospitals which diagnose and treat large numbers of Münster residents for cancer.

Recommendation No. 12: Scientists from the Institut für Epidemiologie und Sozialmedizin der Westfälischen Wilhelms-Universität Münster should also work with staff from the Krebsregister Münster to explore the possibility of utilizing the registry for conducting a case-control study of one or more cancers in the Münster area. Confidentiality rules would allow research scientists within the Institut für Epidemiologie und Sozialmedizin to contact patients for possible participation in case-control studies after receiving clearance from the original reporting physician and the family physician now attending the patient. It is also feasible to develop arrangements with oncologic registries in adjoining regions to increase the overall study size by including patients from these systems. Sufficient numbers of cases exist in the Münster

catchment area to conduct research studies of several primary sites including cancers of the stomach, colon, rectum, pancreas, larynx and lung, prostate, urinary system, breast, uterus, and ovary. A number of these primary sites are related to cancer prevention and screening activities and could be analyzed with respect to evaluating progress in these areas.

Recommendation No. 13: It is strongly recommended that funds be made available to support one full time research scientist with doctoral level training in epidemiology, and one assistant with a master of science degree in epidemiology. Given the significant amount of financial support currently being provided for data collection activities, it is only prudent to expend a fraction of that amount to help develop a structured plan for utilizing the data for clinical, epidemiologic, and public health research purposes.

Recommendation No. 14: A Data Utilization Committee should be formed to review all outside requests for use of the cancer registry data. This committee could consist of faculty from the Institut für Epidemiologie und Sozialmedizin, and representatives of the local medical community. Each request for utilization of the data should be in writing. Specialized data request forms should be created for this purpose. These request forms would provide for specific information relating to the study hypothesis and design. Particular emphasis should be placed on the types of data being requested, plans for securing the data, and any plans the investigators have for to having direct contact with patients.

7 Summary

Staff of the Krebsregister Münster have already made significant progress in improving the overall completeness of case reporting, and appear to have developed a reasonable approach to maintaining data quality. Based on the large amount of public funding already invested in the registry, and evidence of recent improvements in data completeness and quality, it is not recommended that support for the registry be withdrawn at this time. However, a coordinated effort is needed to increase reporting to levels which meet international standards for population based cancer registries. If the final barriers to acceptable levels of reporting are not eliminated within the next two to three years, serious consideration should be given to dismantling the registry. Funds currently allocated to the registry should then be utilized to support specific epidemiologic research studies of various chronic diseases in the State of Nordrhein-Westfalen. In the interim, it is vitally important that a plan be developed for utilizing the existing registry data for scientific research. As mentioned previously, the major strengths of the Krebsregister Münster staff are in the areas of medical informatics, and essential cancer registration techniques. However, the absence of appropriately trained epidemiologic staff is clearly evident in the lack of research productivity. The provision of funding for trained epidemiologic personnel are essential to the ultimate success of the registry program.

8 Appendix: Observations on Cancer Registration in Nordrhein-Westfalen

The following observations are based on a review of the Krebsregister Münster over a period of four weeks, and a visit to the Onkologischer Schwerpunkt Aachen. Several observations emerge from these brief contacts. First, Münster and Aachen represent the two most fully developed cancer registries in Nordrhein-Westfalen. As stated in the main report, Krebsregister Münster has an established network of participating hospitals, and has developed methods for including cases identified only by the death certificate into the data base. However, completeness of reporting is estimated to be only 80%, with wide variation in reporting completeness observed among the primary sites of cancer. The main sources of missing cases are the 16 hospitals in the Münster area who have thus far refused to report to the registry, and the inability to identify and register Münster area residents who seek medical care in hospitals outside the Münster catchment area.

In Aachen, all 20 area hospitals are participating in the system, but completeness of reporting is estimated to be only 75%, with again some variation in completeness by primary site. The main sources of unidentified cases are the inability of Onkologischer Schwerpunkt Aachen to obtain death certificates for residents of the Aachen area, and the inability to identify and register Aachen area residents who seek medical care in hospitals outside the Aachen catchment area.

Several other cancer registry systems have been developed in recent years for other areas of Nordrhein-Westfalen. However, it appears that these systems are relatively new and unlikely to achieve the level of reporting completeness observed in Münster and Aachen in the near future.

Based on these observations, it is recommended that available funds be used to continue supporting the Krebsregister Münster. An intensified effort to obtain the cooperation of non-reporting institutions can create acceptable levels of case reporting in the Münster area within a reasonable time frame. It is also vitally important that the Onkologischer Schwerpunkt Aachen be provided with access to the death certificates for Aachen area residents. With access to this vital source of unidentified cases, there is good reason to believe that Aachen can move forward within a suitable time frame to develop a population-based cancer registry with acceptable levels of reporting.

In the interim, it would be advisable for these two registries to seek opportunities for collaborative clinical, epidemiologic, and public health research. These registries could eventually serve as models for other areas attempting to develop similar systems. As the Krebsregister Münster and the Onkologischer Schwerpunkt Aachen begin to reach accepted international standards for population based cancer registries, it is recommended that a training fund be created which could be used by these established registries to provide seminars, and workshops that could be attended by staff from the newer cancer registries.

In summary, it is strongly recommended that limited resources and efforts be directed primarily toward bringing the Krebsregister Münster and the Onkologischer Schwerpunkt Aachen in line with international standards for population based registries.

9 Bibliography

North American Association of Central Cancer Registries: Standards for cancer registries volume I: data exchange standards and record description. B. Gordon (Ed.) Version 4.0, 1995

American Association of Central Cancer Registries: Standards for cancer registries volume II: data standards and data dictionary. H.R. Menck, J.E. Seiffert (Eds.) 1994

American Association of Central Cancer Registries: Standards for cancer registries volume III: Standards for completeness, quality, analysis, and management of data. J.E. Seiffert (Ed.) 1994

10 References

Aldrich T.E., Vann D., Moorman P.G., Newman B.: Rapid reporting of cancer incidence in a population-based study of breast cancer: one constructive use of a central cancer registry. Breast Cancer Res Treat. 1995 Jul; 35(1): 61-4

Brenner H., Stegmaier C., Ziegler H.: Estimating completeness of cancer registration in Saarland/Germany with capture-recapture methods. Eur J Cancer. 1994;30(11): 1659-63

Brenner H., Stegmaier C., Ziegler H.: Estimating completeness of cancer registration: an empirical evaluation of the two source capture-recapture approach in Germany. J Epidemiol Community Health. 1995;49: 426-30

Hilsenbeck S.G., Kurucz C., Duncan R.C.: Estimation of completeness and adjustment of age-specific and age-standardized incidence rates. Biometrics 1992;48:1249-62

Hisserich J.C., Martin S.P., Henderson B.E.: An areawide cancer reporting network. Public Health Rep. 1975 Jan-Feb; 90(1): 15-7

Robles S.C., Marrett L.D., Clarke E.A., Risch, H.A: An application of capture-recapture methods to the estimation of completeness of cancer registration. J Clin Epidemiol 1988;41(5):495-501