# Program Manual

## National Program of Cancer Registries

**Version 1.0**

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**ACRONYMS**

| | |
|---|---|
| ACoS | American College of Surgeons |
| ACS | American Cancer Society |
| AHRQ | Agency for Healthcare Research and Quality |
| AI/AN | American Indian and Alaskan Native |
| AJCC | American Joint Committee on Cancer |
| ASTCDP | Association of State and Territorial Chronic Disease Program Directors |
| ATSDR | Agency for Toxic Substances and Disease Registry |
| CDC | Center for Disease Control |
| CS | Collaborative Staging |
| CSB | Cancer Surveillance Branch |
| CSS | Cancer Surveillance System |
| CSTE | Council of State and Territorial Epidemiologists |
| CTR | Certified Tumor Registrar |
| DAST | Data Analysis and Support Team |
| DCPC | Division of Cancer Prevention and Control |
| DCQA | Data Completeness and Quality Audit |
| DHHS | Department of Health and Human Services |
| FERPA | Family Educational Rights and Privacy Act |
| FIPS | Federal Information Processing Standards |
| FOA | Funding Opportunity Announcement |
| FOIA | Freedom of Information Act |
| HIPAA | Health Insurance Portability and Accountability Act |
| IACR | International Association of Cancer Registries |

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|---|---|
| ICD-O-3 | International Classification of Diseases for Oncology, Third Edition |
| IHS | Indian Health Service |
| MERP | Modeling Electronic Reporting Project |
| MP/H | Multiple Primary and Histology |
| NAACCR | North American Association of Central Cancer Registries |
| NAPIIA | NAACCR Asian Pacific Islander Identification Algorithm |
| NBCCEDP | National Breast and Cervical Cancer Early Detection Program |
| NCCCP | National Comprehensive Cancer Control Program |
| NCCDPHP | National Center for Chronic Disease Prevention and Health Promotion |
| NCCCS | National Coordinating Council for Cancer Surveillance |
| NCCRC | NPCR Central Cancer Registry Council |
| NCHS | National Center for Health Statistics |
| NCIC | National Cancer Institute of Canada |
| NCRA | National Cancer Registrars Association |
| NETS | NPCR Education and Training Series |
| NHAPIAA | NAACCR Hispanic and Asian Pacific Islander Identification Algorithm |
| NHIA | NAACCR Hispanic Identification Algorithm |
| NPCR | National Program of Cancer Registries |
| ORTAT | Operations Research and Technical Assistance Team |
| PEI | Program Evaluation Instrument |
| PHIN | Public Health Information Network |
| RAF | Restricted Access File |
| RRAF | Regional Restricted Access File |
| SDRG | Small Data Release Group |
| SEER | Surveillance, Epidemiology, and End Results |

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|---|---|
| SRAF | State-level Restricted Access File |
| SRT | Surveillance Research Team |
| SWG | Science Workgroup |
| TNM | Tumor, Node, Metastasis |
| UICC | International Union against Cancer |
| USCS | United States Cancer Statistics |

# 1.0 Introduction to the National Program of Cancer Registries

[See Appendix A for citations.]

Population-based cancer registries collect data on all cancer cases in a defined population. This includes data on the occurrence of cancer, primary site, histology, stage at diagnosis, first course of treatment, and vital status.[1] Cancer data are reported to population-based cancer registries from a variety of medical facilities, including hospitals, physicians' offices, radiation facilities, freestanding surgical centers, and pathology laboratories.

Originally, population-based cancer registries were primarily used to describe cancer patterns and trends. More recently, the role of registries has expanded to include the planning and evaluation of cancer control activities.[2] Currently, information derived from cancer registries is critical for directing effective cancer prevention and control programs towards specific geographic areas or populations. These programs focus on preventing behaviors that increase risk for developing cancer (e.g., smoking) and on reducing environmental risk factors (e.g., occupational exposure to known carcinogens).

Cancer registry information is also essential for identifying populations who would benefit from enhanced cancer screening efforts, and for developing and implementing long-term strategies for ensuring access to adequate diagnostic and treatment services. Local-level data motivate action at the community level and provide incentives for community involvement and ownership.[3] Pooled data at the national, regional, and state levels enable federal and state public health professionals to establish, prioritize, and monitor national public health surveillance initiatives and track progress toward the national goals and objectives set forth in *Healthy People 2010*, the nation's health promotion and disease prevention agenda.[4]

## 1.1 Overview of the National Program of Cancer Registries

Citing the need for a national program of cancer registries that would provide the local, state, regional, and national cancer incidence data required for national and state health planning, the U.S. Congress established the National Program of Cancer Registries (NPCR) in 1992 through Public Law (PL) 102-515, the Cancer Registries Amendment Act.[9,10] This law authorized the Centers for Disease Control and Prevention (CDC) to provide funds to states and territories to improve existing cancer registries; to plan and implement registries where they did not exist; to help develop model legislation and regulation for states to enhance the viability of registry operations; to set standards for data completeness, timeliness, and quality; to provide training for registry personnel; and to help establish a computerized reporting and data processing system.

Public Law (PL) 102-515 requires funded states develop legislation authorizing the establishment of a central cancer registry and provide regulations as specified in the law. These regulations assure the following: case reporting from all facilities and practitioners; access to medical records; reporting of uniform data; protection of patient

confidentiality; access to data by researchers; authorization to conduct research; and protection from liability for individuals who abide by the law. PL 102-515 provides the framework for needed legal support for operation of central cancer registries. The full text of the act is available online at http://www.cdc.gov/CANCER/NPCR/npcrpdfs/publaw.pdf.

In 1994, through cooperative agreements, NPCR began providing financial support and technical assistance to state health departments for the operation of statewide, population-based cancer registries. In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. State health departments or their authorized designees were eligible for one of two funding categories. The first category of funding supported the operation of existing cancer registries. These “enhancement” programs were required to maintain their current (i.e., at the time of initial CDC funding) level of support, and to contribute (i.e., match) one state dollar for every three federal dollars of support received. Matching funds could be in the form of financial or direct (i.e., in kind) assistance. The second category of funding supported the planning and implementation of a new cancer registry where none previously existed.

After the first program announcement in 1994 and the approval of a congressional appropriation of $16.8 million, 42 states and the District of Columbia were awarded funds (34 enhancement programs and nine planning programs). In 1997, three additional states and three territories were awarded funds (two enhancement programs and four planning programs). Since 1998, NPCR funds have supported 45 states, the District of Columbia, and three territories (Pacific Islands, Puerto Rico, and the Virgin Islands), covering 96% of the US population (Figure 1).

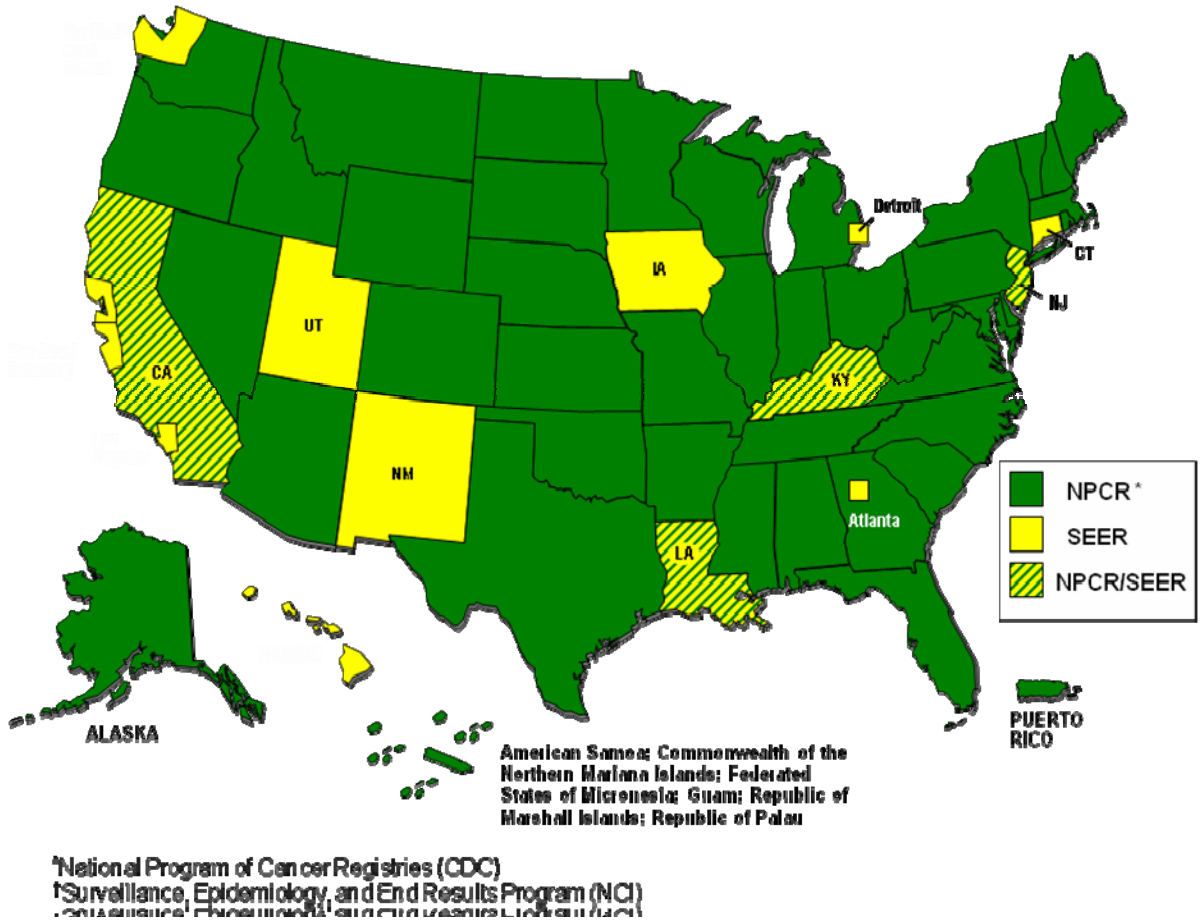



**Figure 1 Map of United States**

Program contact and other information, including available program highlights for a specific state or territory, are available on the NPCR website at http://www.cdc.gov/cancer/npcr/. Requests for information may be submitted to the Program Consultant assigned to individual states or territories at cdcinfo@cdc.gov.

NPCR-funded central cancer registries are required to collect and report information on all state/territory residents who are diagnosed or treated with cancer, including residents who are diagnosed and treated outside of their state/territory of residence.

PL 102-515 defined reportable cancer as “each form of in situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin and carcinoma in situ of the cervix).”

Data required to be collected include:

- cancer incidence;
- demographic information;
- administrative information (including date of diagnosis and source of information); and

- pathologic data (including cancer site, stage at diagnosis, and type of treatment).

In response to the need for national population-based incidence data on all central nervous system (CNS) tumors, Congress passed the Benign Brain Tumor Cancer Registries Amendment Act in 2002.[11] This law changed NPCR's definition of reportable tumors to include benign and borderline CNS tumors. Both the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) Program and the American College of Surgeons (ACoS) Commission on Cancer (CoC) agreed to require reporting of nonmalignant brain tumors, beginning with cases diagnosed on or after January 1, 2004.

In 2000, the NPCR-Cancer Surveillance System (NPCR-CSS) was established to receive, evaluate, and disseminate data from participating central cancer registries. NPCR-CSS is designed to provide cancer incidence data to meet CDC's public health surveillance responsibilities and to help monitor progress toward NPCR goals.

### Collaborations among the National Cancer Surveillance Partners

Collaboration among the national cancer surveillance partners has been formalized in the National Coordinating Council for Cancer Surveillance (NCCCS).[12] NCCCS members include the American Cancer Society (ACS), ACoS, CDC, NCI, National Cancer Registrars Association (NCRA), and the North American Association of Central Cancer Registries (NAACCR). The mission of NCCCS is to coordinate cancer surveillance activities within the United States through communication and collaboration among major national cancer organizations. In so doing, NCCCS seeks to ensure the needs of cancer patients and the communities in which they live are fully served, that scarce resources are maximally used, and that the burden of cancer in the United States is adequately measured and ultimately reduced.

NCCCS was created to provide a forum for examining the current state of cancer surveillance operations and identifying the broad issues involved, to recommend practical approaches to facilitate the work of registries, and to contribute to the goal of coordinating data collection and improving data quality across the nation. The Council enables these organizations to collaborate on cancer monitoring and registry operations.

NCCCS has developed consensus reports around such topics as benign brain tumor reporting and data quality. Through NCCCS, CDC, NCI, and other partners have collaborated to develop a broad national framework for cancer surveillance in the United States.[13] This framework addresses a continuum of disease progression - from a healthy state to the end of life - and incorporates primary, secondary, and tertiary prevention. The framework also addresses crosscutting information needs.

Collaborations among the major national cancer organizations also led to the publication in 1998 of the first Annual Report to the Nation on the Status of Cancer (Section 7.2.1).[14] This report documented the beginning of the decline in overall cancer

mortality in the United States. Each year, since 1998, the report has been published under rotating leadership of CDC, NCI, ACS, and NAACCR.[15-22]

In 2000, CDC and NCI entered into a Memorandum of Understanding (MOU) to coordinate cancer surveillance activities around a shared vision for a comprehensive, federally integrated national cancer surveillance system. This system builds upon and strengthens the existing infrastructure, improves the availability of high quality data for measuring the nation's cancer burden, and advances the capacity for surveillance research. The scope of this coordinated cancer surveillance system includes coverage of the entire U.S. population with high quality data to measure cancer risk, health behaviors, incidence, treatment, morbidity, mortality, and other outcomes.

NCI and CDC have a joint responsibility for the dissemination of national cancer surveillance statistics through multiple mechanisms. NCI's emphasis is on a surveillance research program that characterizes the nation's cancer burden over time by integrating traditional cancer statistics, the widest possible collection of cancer-related data, and in-depth methodological studies in population subgroups. CDC's emphasis is on its responsibilities for public health surveillance, characterizing the cancer burden nationwide and in states, and meeting the needs of state health departments and the nation in developing, implementing, and evaluating effective cancer prevention and control efforts. The MOU was the genesis for the annual *United States Cancer Statistics* (USCS) report, a joint publication of CDC and NCI, in collaboration with NAACCR.[1] The first report was published in 2002 and featured 1999 incidence data from NPCR and SEER cancer registries that met standards for high quality data.

**Highlights of NPCR Accomplishments**

- NPCR continues to fulfill the intent of PL 102-515. NPCR supports population-based central cancer registries in 45 states, the District of Columbia, and three U.S. territories with funding, technical assistance, standards for data collection and use, training, and support for establishing computerized reporting and data-processing systems. All NPCR programs have authorizing legislation for a statewide cancer registry, and have legislation or regulations in support of all criteria specified in PL 102-515.
- By 2005, eight NPCR-funded registries met all NPCR completeness, timeliness, and quality standards. This number increased to 24 by 2007 (http://www.cdc.gov/cancer/npcr).
- CDC's Cancer Surveillance Branch (CSB) implemented NPCR-CSS in 2000 for receiving, assessing, enhancing, aggregating, and disseminating data from NPCR-funded programs. In 2001, NPCR-CSS began to receive state cancer registry data annually. (http://www.cdc.gov/cancer/npcr/training/css.htm)

- CSB has developed and made available Registry Plus™, a suite of publicly available free software programs, for collecting and processing cancer registry data (http://ww.cdc.gov/cancer/npcr/tools/registryplus).
- CDC and NCI signed a MOU in 2000 to formalize collaboration between NCI's surveillance activities and research programs and CDC's NPCR. The MOU was renewed for another 5-year period in 2005.
- Since 2002, CSB, in collaboration with NCI and NAACCR, has published *United States Cancer Statistics* a series of annual reports based on high-quality NPCR and SEER cancer incidence data (http://apps.nccd.cdc.gov/uscs), and CDC's National Vital Statistics System (NVSS) cancer mortality data (http://www.cdc.gov/nchs/deaths.htm).[1] The first report in this series provided cancer incidence data covering approximately 78% of the U.S. population. The most recent report contains official federal government cancer statistics for more than 1.2 million invasive cancer cases diagnosed during 2004, covering 98% of the U.S. population for incidence and 100% of the population for mortality statistics.
- CDC, NAACCR, NCI, ACS, and central cancer registries collaborated to publish monographs on breast, ovarian, and colorectal cancers based on high-quality data from the NPCR and SEER programs, in order to provide more population-based information about these cancers. The breast cancer monograph was published as a series of articles in *Cancer Causes and Control* and *Breast Cancer Research and Treatment*,[23-28] and the ovarian[29-37] and colorectal[38-49] cancer monographs were published as special supplements to the journal *Cancer*.
- CDC, NCI, NAACCR and ACS collaborate each year to produce the Annual Report to the Nation on the Status of Cancer, a seminal publication which includes an update of cancer death rates, incidence rates, and trends in the United States. The Annual Report was first published in 1998, and addresses a special featured topic each year.[14-22] The report can be found at: http://www.cdc.gov/Features/CancerReport/
- CSB has completed two patterns of care studies that were conducted in conjunction with the international CONCORD study for assessing differences in cancer survival between Europe and North America.[50-55]
- CSB is funding and collaborating on the third, and most comprehensive, patterns of care study with seven state population-based cancer registries to examine patterns of care for female breast cancer and prostate cancer. See Appendix B for an inventory of publications and professional presentations on CDC-NPCR's Pattern of Care Studies.

## 1.2 CDC Health and Programmatic Goals Relating to Cancer

The NPCR contributes to the achievement of disease prevention and health promotion goals established through the national planning process spearheaded by the Department of Health and Human Services (DHHS), currently embodied in the "Healthy People 2010" document. As noted in the Funding Opportunities Announcement (FOA) purpose statement for the NPCR, programmatic goals for NPCR are translated into standards for central registries to attain to provide measurable outcomes for the investment of public resources in cancer surveillance activities. NPCR and central registry activities are centered in a national planning process, directed toward specific outcomes, and evaluated according to measurable achievements.

The document and information about the "Healthy People 2010" planning process and participants are available at http://www.healthypeople.gov/Default.htm.

Information about the CDC agency-wide goals and strategies are available from the website http://www.cdc.gov/about/goals/goals.htm.

The primary goal is to become a performance-based agency focusing on healthy people, healthy places, preparedness, and global health, utilizing six key strategies to guide decisions and priorities:

- Health Impact Focus
- Customer-Centricity
- Public Health Research
- Leadership
- Global Health Impact
- Accountability

## 1.3 Organization

CDC includes 11 Centers, Institutes, and Offices which focus on a wide range of public health concerns ranging from environmental health to infectious diseases. Each center has divisions that focus on specific public health areas.

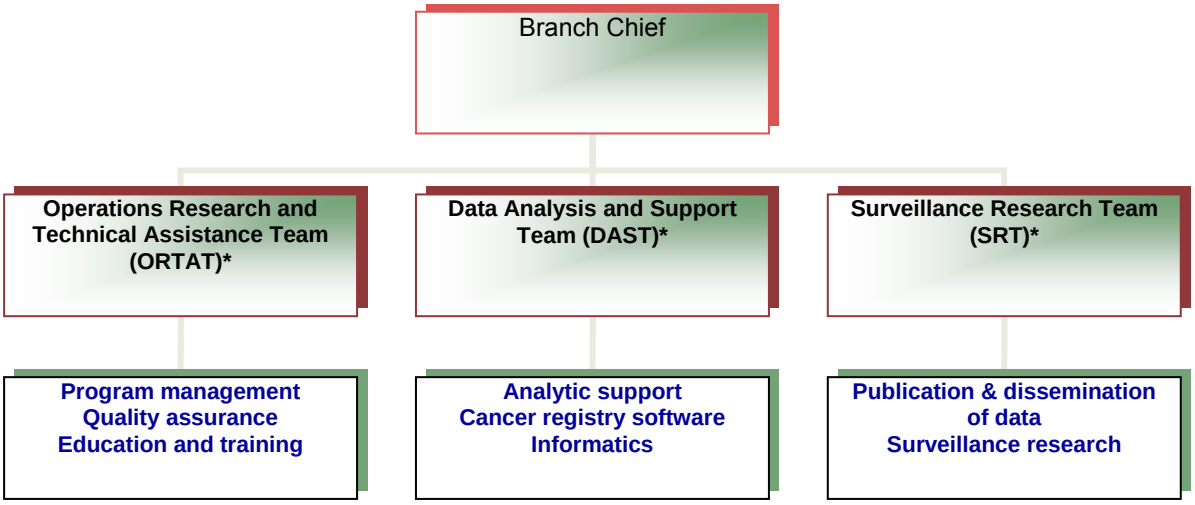
The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), with 10 divisions, assists States/District of Columbia/Tribes/Territories to promote health and well-being through the prevention and control of chronic disease.

The Division of Cancer Prevention and Control (DCPC) is one of these 10 divisions and administers the National Program of Cancer Registries, within the Cancer Surveillance Branch (CSB).

See Appendix C for the organization charts relating federal health care and how NPCR is positioned to meet the federal requirements relating to cancer.

As shown in the organizational chart below, the CSB is comprised of the Office of the Chief and three structural teams: the Operations Research and Technical Assistance Team (ORTAT), the Data Analysis and Support Team (DAST), and the Surveillance Research Team (SRT).

## CDC - CANCER SURVEILLANCE BRANCH




The CSB is responsible for program management and capacity building within the participating central cancer registries. CSB surveillance functions include data collection and enhancement, data receipt and evaluation, and data analysis and dissemination. The performance of these functions is distributed among the three structural teams.

ORTAT functions include:

- leading program management;
- developing and monitoring program standards;
- performing quality assurance;
- coordinating creation of educational products; and
- coordinating the annual Program Directors meeting.

For each NPCR program, ORTAT functions include:

- monitoring the accuracy and completeness of data;
- monitoring work plans and progress;
- monitoring budgets; and
- providing technical assistance.

DAST functions include:

- providing technical, statistical, and data analysis support to CSB and DCPC;
- providing support in the collection, evaluation, and release of data;
- developing and supporting cancer registry software products and Web-based applications; and
- promoting electronic reporting of surveillance data to central registries.

SRT functions include:

- describing cancer incidence and mortality at the state, regional, and national levels, and for special populations;
- promoting the use of surveillance data for cancer prevention and control; and
- building capacity for NPCR registries to conduct advanced surveillance research and activities.

Support to NPCR-CSS is provided by a functional team of designated staff from ORTAT, DAST, and SRT. ORTAT, DAST, and SRT work closely together and collaborate with other branches in DCPC and with other CDC Divisions.

## 1.4 Funding Opportunity Announcement (FOA)

CDC releases a Funding Opportunity Announcement to identify and establish the long-term goals of the National Cancer Prevention and Control Program (NCPCP) through performance measures. A work plan is developed by each Program to measure progress in meeting the requirements in the FOA.

The Funding Opportunity Announcement CDC-RFA-DP07-703, released in 2007, incorporated funding guidance for the following three Programs (http://www.cdc.gov/cancer/dcpc/about/ http://www.cdc.gov/cancer/procontacts.htm):

- National Program of Cancer Registries (NPCR)
- National Comprehensive Cancer Control Program (NCCCP)
- National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

**Funding Opportunity Announcement Reference:**

National Program of Cancer Registries (NPCR)

The purpose of the program is to support the establishment or enhancement of statewide/territorial/jurisdictional/tribal population-based central cancer registries and to promote the use of registry data. This program addresses the "Healthy People 2010" focus area(s) of 3-14: Increase the number of states that have a statewide population-based cancer registry that capture case information on at least 95 percent of the expected number of reportable cancers.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for Chronic Disease Prevention and Health Promotion:

- enhance National and Worldwide cancer surveillance;
- improve accessibility and use of population-based cancer surveillance data; and
- develop and disseminate standards for cancer data completeness, timeliness and quality.

### 1.4.1 CDC-NPCR Responsibilities under the Funding Opportunities Announcement

NPCR staff is substantially involved in the program activities, above and beyond routine grant monitoring. NPCR activities for the program include:

- Provide technical assistance to central cancer registries for effective program management including, but not limited to: registry operations, data management, and budget management.
- Develop publicly available software programs for collecting and processing cancer registry data.
- Evaluate, monitor, and report on central cancer registry progress toward meeting NPCR Program Standards through review of interim progress reports, NPCR Cancer Surveillance System Data Evaluation Reports, NPCR Data Completeness and Quality Audit results, site visits, NPCR Program Evaluation Instrument, and any other CDC-initiated evaluations.
- Collaborate with national partners and organizations to standardize the reporting of cancer, promote education for cancer registrars, and advocate for central cancer registries by actively participating as chairs/members of committees/workgroups.

- Conduct site visits of central cancer registries to assess program progress, to develop a better understanding of the central cancer registry's operations and issues, to review NPCR Data Completeness and Quality Audit results, and, if needed, to mutually resolve problems.
- Assess the completeness and quality of central cancer registry data by conducting NPCR-sponsored Data Completeness and Quality Audits of central cancer registries.
- Receive, evaluate, and disseminate cancer surveillance data received from central cancer registries through the NPCR Cancer Surveillance System.
- Convene a meeting of the Program Directors, at least annually, for information sharing and updates, to provide the participants a forum to discuss issues of relevance, share successes and challenges, and to identify common solutions to problems.
- Convene an annual train-the-trainer meeting to provide education and training to central cancer registry trainers with the goal of building capacity within the central cancer registry to provide education and training to central cancer registry staff and reporters.

### 1.4.2 NPCR Funded Central Cancer Registry Activities under the Funding Opportunities Announcement

To receive NPCR funding, central cancer registries must engage in a minimum of activities in each of the following areas:

- Operations and Administration
- Data Management
- Data Quality Assurance
- Data Linkages
- Data Submission to NPCR
- Data Use and Collaborative Relationships

Performance will be measured by the extent to which the program has met the NPCR Program Standards as evidenced by review of the annual NPCR Cancer Surveillance System (NPCR CSS) Data Evaluation Reports; the results of the NPCR Data Completeness and Quality Audit (NPCR DCQA); the NPCR Program Evaluation Instrument (NPCR PEI); progress reports, and site visits.

| OPERATIONS AND ADMINISTRATION | |
|---|---|
| • Enhancement (Part I) – Support and enhance the operation of an existing population-based central cancer registry that has supporting legislative authority.<br>• Planning (Part II) – Plan, implement, and support the operation of a new or limited population-based cancer registry that has supporting legislative authority. | |
| **Activity** | **Requirement** |
| Core Staff | • Applicants for Enhancement (Part I) must have existing adequate and qualified core staff to support the operations of the central cancer registry. Core staff must fill the roles of Program Director/Project Director/Principal Investigator; Quality Assurance/Control Manager; and Education/Training Coordinator. The positions of Quality Assurance/Control Manager and Education Training Coordinator must be filled by a qualified, experienced CTR.<br><br>• Applicants for Planning (Part II) must demonstrate the ability to hire/contract adequate and qualified staff to support the operations of the central registry. |
| Written Policies and Procedures | • Applicants for Enhancement (Part I) must have documented and implemented operational policies and procedures. These must be made available to NPCR upon request. |
| Hardware and Software Resources | • Applicants for Enhancement (Part I) must have adequate hardware and software resources in place that support the key central cancer registry activities including data collection, database management, quality assurance, data analysis, and management reports. |

| DATA MANAGEMENT ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| Confidentiality, Security and Data Release Activities | • Ensure the confidentiality of the central cancer registry data through documented and implemented policies and procedures in every part of registry operations, and through a data release policy and procedure that includes access to and disclosure of information.<br><br>• Ensure the security of both physical and electronic data |

| DATA MANAGEMENT ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| | through documented and implemented policies and procedures.<br><br>• Data security must include database backup, storage, and disaster recovery. |
| Completeness, Timeliness Activities | • Collect complete and timely data from the NPCR reference year forward. At a minimum, the program should meet the *United States Cancer Statistics (USCS)* criteria for publication for the 1998 diagnosis year forward.<br><br>• Perform death clearance activities (see *NAACCR Standards for Cancer Registries Volume III, Standards for Completeness, Quality, Analysis, and Management of Data* (http://ww.naaccr.org).<br><br>• If complete death clearance has not been performed for all NPCR-diagnosis years, at a minimum, conduct a linkage with the state's death records for the NPCR reference year up to the diagnosis year that complete death clearance was performed. Following this linkage, at a minimum, update the data fields Date of Last Contact [NAACCR Item 1750], Vital Status [NAACCR Item 1760], and Cause of Death [NAACCR Item 1910].<br><br>• At a minimum, exchange data with the central cancer registries of all bordering states.<br><br>• Conduct case finding audits of reporting sources to make certain all reportable cases are identified and submitted to the central cancer registry. |

| DATA QUALITY ASSURANCE ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| Consolidation | • Perform consolidation of data reported to the central cancer registry following best practices or standards as they become available. Definition of consolidation from the *NAACCR Standards for Cancer Registries Volume III, Standards for Completeness, Quality, Analysis, and Management of Data*: "the process of reconciling or compiling data obtained from |

| DATA QUALITY ASSURANCE ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| | more than one source on the same person or tumor…A large task of the central registry system is to prepare a composite set of values for each patient and tumor, incorporating information from a variety of sources." |
| Edits | • Edit central cancer registry data using computerized standard edits. At a minimum, run and resolve the NPCR Required Standard Data Edits on a quarterly basis (see *Standards for Cancer Registries, Volume IV, NAACCR Standard Edits*, (http://www.naaccr.org). |
| Education and Training Activities | • Provide education and training opportunities to reporting sources and to the central cancer registry staff with the goal of improving the quality of the central cancer registry data. |
| Audits | • Central Cancer Registry: Conduct internal audits and/or quality checks of data collected and processed by central registry staff, participate in national quality assurance studies (e.g. Collaborative Staging Assessment) and conduct external audits of reporting sources to assure the quality of central cancer registry data. |

| DATA LINKAGE ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| Death Records | • Perform central cancer registry data linkage with the state's death records, at least annually, to enhance the completeness and quality of the central registry data. Following this linkage, at a minimum, update the data fields. Date of Last Contact [NAACCR Item 1750], Vital Status [NAACCR Item 1760], and Cause of Death [NAACCR Item 1910]. |
| NBCCEDP | • Perform central cancer registry data linkage with NBCCEDP awardees in accordance with CDC specifications, to enhance the completeness and quality of the central registry data. Results from the linkage between central cancer registries and the breast and cervical cancer screening programs should be used to:<br>o Update Minimum Data Elements (MDE) data with central cancer registry data<br>o Update cancer registry database as necessary<br>o Identify missing cancer cases in the central cancer registry<br>o Reconcile differences between the two data sources |

| DATA LINKAGE ACTIVITIES | |
|---|---|
| **Activity** | **Requirement** |
| Other | • Perform other optional or NPCR required data linkages that will enhance the completeness and/or quality of the central registry data. |

| DATA SUBMISSION TO NPCR | |
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| **Activity** | **Requirement** |
| Data Submission to the NPCR | • Submit a data file annually to the NPCR Cancer Surveillance System that meets the reporting requirements outlined in the NPCR-CSS Submission Specifications document and that meets the criteria for publication in the *United States Cancer Statistics (USCS) Report.* |

| DATA USE AND COLLABORATIVE RELATIONSHIPS | |
|---|---|
| **Activity** | **Requirement** |
| Annual Report/ Data Set | • Produce annual data set(s)/file(s) in an electronic format as described in the NPCR Program Standards.<br><br>• Use the *USCS Report* for comparison with national and regional data. |
| Cancer Control Activities | • Promote the use of the central cancer registry data for planning and evaluation of cancer control planning objectives and public health practice in State/Territory/Jurisdiction/Tribe.<br><br>• Establish and maintain a collaborative relationship with the State/Territory/Jurisdiction/Tribe's National Comprehensive Cancer Control Program (NCCCP), if funded.<br><br>• Establish and maintain a collaborative relationship with the State/Territory/Jurisdiction/Tribe's National Breast and Cervical Cancer Early Detection Program (NBCCEDP), if funded. |
| NPCR Data Release Activities | • Participate in NPCR data release activities including, but not limited to, the following:<br>o Public Use Data Sets<br>o Restricted Access Data Sets |

| DATA USE AND COLLABORATIVE RELATIONSHIPS | |
|---|---|
| **Activity** | **Requirement** |
| NPCR Economic Analysis | • Participate in the NPCR Economic Analysis as required. |
| CDC Meetings/ Training | • Appropriate/key central cancer registry staff must attend and participate in CDC Meetings or trainings.<br><br>• The Principal Investigator and/or the Program Director must attend CDC Cancer Conferences, if scheduled, during the budget period.<br><br>• Appropriate/key central cancer registry staff should attend cancer registry related meetings or trainings. |
| Advisory Committee | • For Enhancement (Part I) applicants, convene, at a minimum annually, an advisory committee to assist in enhancing and utilizing the central cancer registry. Committee members should include representation from the central cancer registry, facility cancer registrars, reporting facilities, physicians, pathologists, key organizations and individuals considered to be stakeholders in the state/territory/jurisdiction/tribe's comprehensive cancer control effort.<br><br>• For Planning (Part II) applicants, establish and regularly convene an advisory committee to assist in building consensus, cooperation and planning for the central cancer registry. |
| Program Evaluation Instrument (PEI) | • Complete and submit the NPCR Program Evaluation Instrument by the stated deadline. |

| DATA USE AND COLLABORATIVE RELATIONSHIPS | |
|---|---|
| **Activity** | **Requirement** |
| Advanced Activities | • To be eligible for funding of advanced activities, programs must do the following:<br>o Conduct all NPCR Recipient Activities as described<br>o Meet the *USCS* publication criteria for the diagnosis years 1998 and forward<br><br>• States applying under Part I – Enhancement programs are encouraged to conduct advanced activities when the central cancer registry consistently meets and maintains or exceeds the NPCR Program Standards. The purpose of these activities is to further enhance the central cancer registry data and/or the use of the data. Examples of advanced activities include, but are not limited to, the following:<br>o Passive follow-up activities (e.g. NDI Linkage)<br>o GIS Analysis and/or Mapping<br>o Special Studies sponsored by the NPCR<br>o Data linkages that assist in addressing other public health issues as they relate to cancer (tobacco use, obesity)<br><br>• Performance of advanced activities will be measured by the extent to which the program has documented enhancement resulting from the activities in progress reports. |

### 1.4.3 Funding Restrictions

The Funding Opportunity Announcement restricts use of funds for several activities. Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual. Additionally, the direct recipient must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.

Recipients are specifically barred from using funds for any research activities. CDC provides guidance on the definitions for public health research and public health non-research, which can be found in Appendix D or at:
http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm

## 1.5 Applicable Federal Laws

As a program within a federal agency, NPCR is constrained by federal legislation, regulations and guidelines. Those having a significant role are described in this section; others may be referenced in other sections of this manual.

### 1.5.1 HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to:

- ensure health insurance coverage after leaving an employer;
- provide standards for facilitating health-care-related electronic transactions in order to improve the efficiency and effectiveness of the health-care system; and
- mandate adoption of federal privacy protections for certain individually identifiable health information.

The NPCR-funded registries must be aware of the implications of the developing electronic data technologies for registry systems and operations, and the application of data privacy requirements to public health surveillance and research activities.

HIPAA provides for the study of issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information. NPCR promotes electronic data exchange among central registries and to the NPCR-CSS, and incorporates new program standards relating to registries' use of electronic data as enabling technologies are realized.

The HIPAA Privacy Rule addresses the concerns for patient privacy and data confidentiality that arise with the collection and transmission of electronic health information. HIPAA recognizes the legitimate need for public health authorities to have access to personal health information for the purposes of health surveillance. It authorizes the disclosure of such information without patient authorization as required by state and local public health laws, including reporting of cancer surveillance data to central cancer registries. The Privacy Rule, however, does require reporting sources to document disclosure of information to the central registries.

The Privacy Rule also distinguishes between public health practice (public health surveillance, disease control, or program evaluation) and activities which may develop into an ongoing research study and are, therefore, subject to research disclosure provisions.

Further information on the HIPAA Privacy Rule and Public Health is available in a report prepared by the Epidemiology Program Office of the CDC and published in the MMWR on April 11, 2003. This report is available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm, and is intended to help public health agencies and others understand and interpret their responsibilities under the Privacy Rule.

"Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule", addresses the impact of the Privacy Rule on health data research activities. This report is available at http://privacyruleandresearch.nih.gov/pr_02.asp.

Fact sheets on “Institutional Review Boards and the HIPAA Privacy Rule” and “Research Repositories, Databases, and the HIPAA Privacy Rule” are found at http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp and http://privacyruleandresearch.nih.gov/research_repositories.asp.

The full text of HIPAA along with comprehensive Department of Health and Human Services (DHHS) guidance is located at the HIPAA website of the Office for Civil Rights, http://www.hhs.gov/ocr/hipaa/. Guidance from the CDC can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm.

### 1.5.2 FOIA

The Freedom of Information Act (FOIA), 5.U.S.C. § 552, enacted in 1966, establishes an effective legal right of access to government information. The 1996 amendments in Public Law 104-231 clarify that FOIA provisions apply to records maintained in electronic format and also require agencies to provide reference materials or a guide for requesting records or information, including an index and description of all major information systems.

Data collected by state cancer registries and submitted to the NPCR become Federal record and subject to Federal laws and rules governing data release and records retention, including the Freedom of Information Act. The NPCR solicits registry agreement with proposed data re-release plans in accordance with Federal rules; state registries are responsible for determining that data agreements are consistent with all state laws and regulations under which they operate. Data re-release plans describe the content and format of data to be released as either non-identifiable public-use data or identifiable/potentially identifiable restricted-access data.

The Freedom of Information ACT (FOIA) home page for the CDC is http://www.cdc.gov/OD/foia/index.htm. This website also references the FOIA regulations promulgated by the Department of Health and Human Services and posted on the DHHS webpage at http://www.hhs.gov/foia/45cfr5.html.

The CDC FOIA staff, Office of Public Affairs, is the focal point for all CDC FOIA requests; The Director, Office of Public Affairs (OPA), as the CDC Freedom of Information Act Officer, is the sole official with delegated authority to release or deny CDC records.

The full text of the FOIA as amended by Public Law 104-231 is available at http://www.usdoj.gov/oip/foia_updates/Vol_XVII_4/page2.htm.

### 1.5.3 Office of Management and Budget (OMB)

The NPCR Is governed by the policies and directives of the Office of Management and Budget (OMB), which oversees and coordinates the Administration’s procurement, financial management, information, and regulatory policies. The OMB also evaluates the effectiveness of agency programs, policies, and procedures. In each of these

areas, OMB's role is to help improve administrative management, to develop better performance measures and coordinating mechanisms, and to reduce any unnecessary burdens on the public. The NPCR funding requests are evaluated by OMB as it assesses competing funding demands among agencies, and sets funding priorities.

The Office of Information and Regulatory Affairs (OIRA) within the OMB oversees the implementation of government-wide policies in the areas of information technology, information policy, privacy, and statistical policy. OIRA also oversees agency implementation of the Information Quality Law, including the peer review practices of agencies.

## 1.6 Federal Data Quality Guidelines

Under the Federal Data Quality Guidelines, the Department of Health and Human Services has a commitment to disseminate "accurate, reliable, clear, complete, unbiased and useful" information by integrating the principles of information quality into every aspect of its "creation, collection, maintenance, and dissemination". The NPCR is in compliance with these standards in data released to the public, and in turn promulgates data quality standards for funded registry programs which facilitate compliance.

The Office of Management and Budget issued data quality guidelines for all Federal agencies on January 3, 2002, in accordance with Section 515, the "Data Quality Act", of Public Law 106-554, the Treasury and General Government Appropriations Act for Fiscal Year 2001. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" is available at http://www.whitehouse.gov/omb/fedreg/reproducible.html.

In accordance with requirements, the Department of Health and Human Services issued specific agency guidelines, and these are available at: http://www.aspe.hhs.gov/infoquality. The HHS quality website also provides information on the HHS Peer Review Agenda.

## 1.7 CDC/ATSDR Policy on Releasing and Sharing Data

The NPCR is governed by federal rules and agency policies relating to the release and sharing of public health data collected in pursuit of its mission to understand and support programs addressing the cancer burden within the United States. The CDC policy is available on the website at http://www.cdc.gov/od/foia/policies/sharing.htm. As noted in the background information:

> "The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) are the nation's principal disease prevention and health promotion agencies. To fulfill their missions, these agencies must collect, manage, and interpret scientific data.

> "CDC believes that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. . . ."
>
> "The goal is to have a policy on data release and sharing that balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect sensitive information. . . ."

The policy references federal laws and directives with which it ensures compliance, including the Freedom of Information Act (FOIA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Family Educational Rights and Privacy Act (FERPA), and the Office of Management and Budget (OMB) circulars on release of state-provided data and ensuring the quality and integrity of released data. Not all federal laws and directives referenced by this policy directly relate to NPCR. However, NPCR policies on releasing and sharing data may be compatible with the law and/or directives' intentions. Links to pertinent legislation are provided through the Freedom of Information Act Requestor Service Center webpage at http://www.iimefpublic.usmc.mil/public/iimefpublic.nsf/UnitSites/FOIA

## 2.0 NPCR Program Standards

NPCR publishes Program Standards to guide priorities and activities of funded programs; provide objective measures of program progress; improve program processes that ultimately affect outcomes; and allow the NPCR to set and monitor its own goals and objectives.

FOA CDC-RFA-DP07-703 is based on authority provided to the CDC-NPCR under the Public Health Service Act and its subsequent amendments. The program standards specified in this announcement apply to all reportable cancers as defined in the Act and amendments. The NPCR Program Standards are published as an appendix to the Funding Opportunity Announcement, but may change during the project period of the cooperative agreement.

All funded programs must meet standards for:

- Legislative Authority
- Administration
- Electronic Data Exchange
- Data Content and Format
- Completeness/Timeliness/Quality
- Quality Assurance
- Data Use and Data Monitoring
- Data Submission

- Collaborative Relationships

The following tables describe each Program Standard and provide the reference section.

## 2.1 NPCR Program Standards and Reference Manual Links

| I. | LEGISLATIVE AUTHORITY |
|---|---|
| a. | The state/territory has a law authorizing a population-based central cancer registry. |
| b. | The state/territory has legislation or regulations in support of the Public Law authorizing the National Program of Cancer Registries (NPCR). |
| **Program Manual Reference** | |
| Section 2.2 Legislative Authority for Cancer Registry | |

| II. | ADMINISTRATION |
|---|---|
| a. | The central cancer registry maintains an operational manual that describes registry operations, policies and procedures. At a minimum the manual contains the following: |
| 1. | Reporting laws/regulations |
| 2. | List of reportable diagnoses |
| 3. | List of required data items |
| 4. | Procedures for data processing operations including: |
| i. | Procedures for monitoring timeliness of reporting |
| ii. | Procedures for receipt of data |
| iii. | Procedures for database management including a description of the Registry Operating System (software) |
| iv. | Procedures for conducting death certificate clearance |
| v. | Procedures for implementing and maintaining the quality assurance/control program |
| a. | Procedures for conducting follow-back to reporting facilities on quality issues. These procedures include rules for identifying when action or further investigation is needed |

## II. ADMINISTRATION

b. Procedures for conducting record consolidation

c. Procedures for maintaining detailed documentation of all quality assurance operations

vi. Procedures for conducting data exchange including a list of states with whom case-sharing agreements are in place

5. Procedures insuring confidentiality and data security including disaster planning

6. Procedures for data release including access to and disclosure of information

7. Procedures for maintaining and updating the operational manual

b. The central cancer registry has management reports that monitor the registry operations and database including processes and activities.

c. The central cancer registry has an abstracting and coding manual to be disseminated to and used by all reporting sources.

**Program Manual Reference**

Section 2.3 Expectations for a Written Policy and Procedure Manual

Section 2.4 Expectations for Management Reports

## III. ELECTRONIC DATA EXCHANGE

a. The central cancer registry uses and requires a standardized, NPCR-recommended data exchange record layout for the electronic exchange of cancer data. NPCR-recommended data exchange layouts include:

1. For abstract reports: The NAACCR record layout version specified in year-appropriate *Standards for Cancer Registries Volume II: Data Standards and Data Dictionary*

2. For pathology reports: *NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting*

3. At a minimum, 95% of reports from hospitals are submitted to the central cancer registry in an electronic format (where the

## III. ELECTRONIC DATA EXCHANGE

medical records are owned by the hospital).

b. At a minimum, 85% of reports from non-hospital reporting sources are submitted to the central cancer registry in an electronic format (e.g., radiation therapy centers, ambulatory surgery centers, and in-state and out-of-state pathology laboratories where medical records are owned by the reporting source).

c. At a minimum, 75% of reports from physician offices, identified as required to submit cancer cases to the central cancer registry, do so in an electronic format (where the medical records are owned by the physician). This includes responses from physicians to central cancer registry inquiries.

d. The central cancer registry primarily uses a secure Internet-based, FTP, or encrypted email mechanism to receive data from all reporting sources.

**Program Manual Reference**

Section 3.5 Standard for data exchange format

## IV. DATA CONTENT AND FORMAT

a. For all NPCR required reportable cases, the central cancer registry collects or derives all required data items using standard codes as prescribed by NPCR (see III. a).

b. The central cancer registry uses a standardized, NPCR-recommended data exchange format to transmit data to other central cancer registries and NPCR (see III. a.).

**Program Manual Reference**

Section 3.0 Data Collection Requirements

Section 3.1 Reportability Standards

Section 3.2 Reference Manuals

Section 3.3 Required Data Items

Section 3.4 Unresolved Data Item Issues

Section 3.5 Data Exchange Format

## V. DATA COMPLETENESS/TIMELINESS/QUALITY

a. Within 24 months of the close of the diagnosis year, at least 75% of physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients submit all reportable cases to the central cancer registry, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities (based on PL 102-515).

b. Within 12 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following two data quality criteria:

   1. Data are 90% complete based on observed-to-expected cases as computed by NPCR.
   2. 97% pass an NPCR-prescribed set of standard edits.

c. Within 24 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following five data quality criteria:

   1. Data are 95% complete based on observed-to-expected cases as computed by NPCR.
   2. There are 3% or fewer death-certificate-only cases.
   3. There is a 1 per 1,000 or fewer unresolved duplicate rate.
   4. The percent missing for critical data elements are:
      i. 2% or fewer age
      ii. 2% or fewer sex
      iii. 3% or fewer race
      iv. 2% or fewer county
   5. 99% pass an NPCR-prescribed set of standard edits.

d. Within 12 months of the close of the diagnosis year, the central cancer registry exchanges data with other central cancer registries where a data-exchange agreement is in place. The data file must also include all cases not previously exchanged.

   1. Regardless of residency, the central cancer registry collects data on all patients diagnosed and/or receiving first course of treatment in the registry's state/territory.
   2. The recommended frequency for data exchange is, at a minimum, two times a year.

| V. | DATA COMPLETENESS/TIMELINESS/QUALITY |
|---|---|

3. Exchanged data must meet the following minimum criteria:
   - i. Exchange agreements are in place with all bordering central cancer registries.
   - ii. Exchanged data include a dataset that consists of NPCR core data items.
   - iii. 99% of data pass an NPCR-prescribed set of standard edits.
   - iv. The dataset is transmitted via secure encrypted Internet-based, FTP, or encrypted email mechanism.
   - v. A standardized, NPCR-recommended data exchange format is used to transmit data (see III. a.).

**Program Manual Reference**

Section 4.0 Data Completeness, Quality and Timeliness Requirements

Section 4.1 Data Evaluation

Section 4.2 Data Completeness

Section 4.3 Data Quality

Section 4.4 Data Timeliness

## VI. DATA QUALITY ASSURANCE

a. The central cancer registry has an overall program of quality assurance that is defined in the registry operations policy and procedure manual. The quality assurance program consists of, but is not limited to:

1. A designated certified tumor registrar (CTR) is responsible for the quality assurance program.
2. Qualified, experienced CTR(s) conduct quality assurance activities.
3. At least once every 5 years, case-finding and/or re-abstracting audits from a sampling of source documents are conducted for each hospital-based reporting facility, and may include external audits (NPCR/SEER).
4. Data consolidation procedures are performed according to an accepted protocol.
5. Procedures are performed for follow-back to reporting facilities on quality issues.

b. The central cancer registry has a designated education/training coordinator who is a CTR to provide training to the central cancer registry staff and reporting sources to assure high quality data.

**Program Manual Reference**

Section 4.3 Data Quality Assurance
Section 2.5 Education and Training
Section 4.2 Data Completeness Audits

## VII. DATA USE

a. Within 12 months of the end of the diagnosis year with data that are 90% complete, the central cancer registry produces preliminary pre-calculated data tables in an electronic data file or report of incidence rates, counts, or proportions for the diagnosis year by Surveillance Epidemiology and End Results (SEER) site groups as a preliminary monitor of the top cancer sites within the state/territory.

b. Within 24 months of the end of the diagnosis year with data that are 95% complete, the central cancer registry produces pre-calculated data in tables in an electronic data file or report. The report includes, at a minimum, age-adjusted incidence rates and age-adjusted mortality rates for the diagnosis year by sex for SEER site groups, and, where applicable, by sex, race, and ethnicity.

c. The central cancer registry, state health department, or its designee annually uses registry data for planning and evaluation of cancer control objectives in at least three of the following ways:

1. Comprehensive cancer control
2. Detailed incidence/mortality estimates
3. Linkage with a statewide cancer screening program to improve follow-up of screened patients
4. Health event investigation(s)
5. Needs assessment/program planning
6. Program evaluation
7. Epidemiologic studies

**Program Manual Reference**

Section 7.4 State Data Use

## VIII. DATA SUBMISSION

a. The central cancer registry annually submits a data file to the NPCR-Cancer Surveillance System (CSS) that meets the reporting requirements outlined in the NPCR-CSS Submission Specifications document and meets criteria for publication in *United States Cancer Statistics*.

| IX. COLLABORATIVE RELATIONSHIPS |
|---|
| a. The central cancer registry actively collaborates in the state's comprehensive cancer control planning efforts.<br>b. The central cancer registry establishes a working relationship with all components of the National Cancer Prevention and Control program to ensure the use of registry data to assess and implement cancer control activities.<br>c. The central cancer registry establishes and regularly convenes an advisory committee to assist in building consensus, cooperation, and planning for the registry. Representation should include key organizations and individuals both within (such as representatives from all cancer prevention and control components) and outside the program (such as hospital cancer registrars, the American Cancer Society, clinical-laboratory personnel, pathologists, and clinicians). Advisory committees may be structured to meet the needs of the state/territory such as the Comprehensive Cancer Control Program committee structure, an advocacy group, or a focus group. |
| **Program Manual Reference**<br>Section 7.4 State Data Use<br>Section 8.0 NPCR Collaborative Relationships<br>Section 8.10 State Collaborative Relationships |

## 2.2 Legislative Authority for Central Registry

**Program Standard Reference:**

**I. LEGISLATIVE AUTHORITY**

a. The state/territory has a law authorizing a population-based central cancer registry.

b. The state/territory has legislation or regulations in support of the Public Law authorizing the National Program of Cancer Registries (NPCR).

In passing the National Cancer Registries Amendment Act (which can be found at http://www.cdc.gov/cancer/npcr/npcrpdfs/publaw.pdf), Congress required applicants, under state law, to provide for the authorization of the statewide cancer registry, including promulgation of eight categories of regulations to:

- require reporting of newly diagnosed cancer cases by hospitals and other health-care facilities;
- require reporting of cancer cases by physicians and other health-care practitioners;
- guarantee access by the statewide cancer registry to all records of medical status of persons with cancer;
- require the use of standardized reporting formats;
- ensure confidentiality of cancer case data;
- allow use of confidential case data by certain researchers;
- authorize the conduct of studies using cancer registry data; and
- ensure protection of persons complying with the law from liability.

On its website page, http://apps.nccd.cdc.gov/cancercontacts/npcr/contactlist.asp, NPCR maintains a list of contacts for all funded program registries, including links to their individual website pages. Many programs provide access to their legislative statutes and regulations via their home pages. Thus, the NPCR page serves as the primary reference link to the body of legislation which supports central registry activities at the state level throughout the United States.

The CDC developed a database of state and federal legislation relating to cancer prevention and control, including the establishment of surveillance registries, from 1996 through 2004. This database is no longer updated, but is maintained as a searchable source of information with links to state legislature homepages, at http://www.cdc.gov/cancer/dcpc/library/legislation/.

## 2.3 Central Cancer Registry Operations Manual

**Program Standard Reference:**

II. ADMINISTRATION

a. The central cancer registry maintains an operational manual that describes registry operations, policies and procedures. At a minimum the manual contains the following:

1. Reporting Laws/Regulations
2. List of reportable diagnoses
3. List of required data items
4. Procedures for data processing operations including:
   - i. Procedures for monitoring timeliness of reporting
   - ii. Procedures for receipt of data
   - iii. Procedures for database management including a description of the Registry Operating System (software)
   - iv. Procedures for conducting death certificate clearance
   - v. Procedures for implementing and maintaining the quality assurance/control program:
     1. Procedures for conducting follow-back to reporting facilities on quality issues. These procedures include rules for identifying when action or further investigation is needed.
     2. Procedures for conducting record consolidation
     3. Procedures for maintaining detailed documentation of all quality assurance operations
   - vi. Procedures for conducting data exchange including a list of states with whom case-sharing agreements are in place
5. Procedures insuring confidentiality and data security including disaster planning
6. Procedures for data release including access to and disclosure of information
7. Procedures for maintaining and updating the operational manual

b. The central cancer registry has management reports that monitor the registry operations and database including processes and activities.

c. The central cancer registry has an abstracting and coding manual to be disseminated to and used by all reporting sources.

The Operations Manual provides the essential documentation for the operation of the cancer registry and ensures consistency of internal registry operations over time. The manual should include, at a minimum:

- state legislation;
- reportability of cancer cases and data included in the registry;
- a description of the software system in use;
- database management procedures;
- quality assurance procedures;

- procedures for death clearance, data release, and data exchange; and
- guidelines for confidentiality and security.

The manual should also specify the procedures for maintaining and updating the information and procedures.

The Operations Manual serves as a training guide for new staff and an informational resource for data users who need to understand changes in data items and definitions over time. It provides the documentation needed to support NPCR program applications and progress reports. The manual provides documentation of the critical activities of the registry and can be used to obtain funding support from state, federal, and private sources.

A standard Abstracting and Coding Manual for data collectors and reporters is critical in promoting and preserving the reliability and consistency of cancer data collected and reported. Cancer data are assembled from many health record sources within single facilities, and consolidated from many facility abstracts at the central registry. Comparability and usefulness of the data at state and national levels can only be achieved through the uniform application of standardized data definitions and codes. As coding sets are changed with some frequency, an Abstracting and Coding Manual is essential for uniform application of these standards.

## 2.4 Management Reports

| **Program Standard Reference:** | |
|---|---|
| II. | Administration |
| | b. The central cancer registry has management reports that monitor the registry operations and database including processes and activities. |

Management reports can range from simple counts to sophisticated statistical analyses; they can provide descriptive information about a system; or compare and cross-tabulate values. Reports can be presented as tables of data or summary statistics. Data displayed in charts and graphs may facilitate understanding of report content. Management information can be used to trigger action or interventions to improve operations.

The cancer registry software system should generate regular and ad hoc reports on the state of the registry database, including, but not limited to the following:

- numbers of patient and cancer records entered into or deleted from the database;
- abstracts consolidated into single cancers;
- abstracts flagged for review and reviewed;
- sources and timeliness of reported records;

- processing times as abstracts move through the system;
- completeness of reporting based on expected numbers of cases;
- receipt and processing of updated records;
- edit failures/error rates, and corrections made to reported data; and
- staff workload assignments in relation to reported cases.

The cancer registry software system should generate regular and ad hoc reports on the state of the system, including:

- user volume and response time;
- user access and permissions;
- backup procedures and backup availability; and
- potential security breaches.

Project management systems should be in place to track the progress of development activities from initiation to conclusion, such as design, writing, and implementation of new or enhanced software capability.

Personnel and financial accounting systems should yield regular reports on employee time assignments and budgeted versus actual expenditures.

NPCR has updated a presentation on management reports, initially developed by NAACCR under contract with CDC, available at: http://www.cdc.gov/cancer/npcr/registry/management/. This presentation focuses on the use of management reports particularly for tracking timeliness and completeness of reporting by submitting facilities, and for monitoring data quality through the use of edits and visual editing.

The following three NAACCR documents address in detail issues in central registry data collection and processing and the use of reports to manage defined registry tasks and procedures:

- Standards for Cancer Registries Volume III: Standards for Completeness, Quality, Analysis, and Management of Data
- Procedure Guidelines for Cancer Registries: Series III: The Policy and Procedure Manual
- Series IV: Cancer Case Ascertainment
- These documents are available from the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=28&Col_ContentID=312.

## 2.5 Education and Training

| Program Standard Reference: | | |
|---|---|---|
| **VI.** | **Data Quality Assurance** | |
| | b. | The central cancer registry has a designated education/training coordinator who is a CTR to provide training to the central cancer registry staff and reporting sources to assure high quality data. |

Central registry educators are responsible for developing training plans and delivering training sessions or workshops to central registry staff and facility reporters. The sessions should promote the collection of cancer information that meets standards for timely, complete, and quality data. NPCR's web site provides a link to a full complement of training and educational materials. These resources are fully described in Section 9.4. Affirming its commitment to the importance of registrar training for the acquisition of high-quality cancer data, in 2007 the NPCR promulgated Standard VI.b.

In support of Standard VI.b, in the fall of 2006 the NPCR launched the NPCR Education and Training Series (NETS), a project to assist funded programs in developing training capacity within their staff members. The NETS project was designed to:

- identify and fill the gaps where educational programs may be lacking;
- build the educational capacity in the central registries so there is a solid infrastructure to provide education and day-to-day support of data collectors;
- develop a comprehensive training program for NPCR-funded programs; and
- provide the necessary training to support a cadre of highly educated trainers in the NPCR-funded programs.

Training plans should be based on needs assessments such as review of registry data deficiencies, and should anticipate the educational support needed to introduce new coding structures to reporters. The training function must be goal-oriented, planned, carried out, and evaluated for contribution to the collection of quality cancer data. Training plans may:

- focus on new coding systems, such as the Multiple Primary/Histology rules implemented in 2007 (http://www.seer.cancer.gov/tools/mphrules/);
- address problems noted in nationwide data reliability studies, such as the 2006 assessment for the Collaborative Staging system (http://www.cancerstaging.org/cstage/index.html);
- include sessions on basic abstracting principles for new reporters and advanced abstracting for experienced registrars; such sessions are often

presented in the context of comprehensive coding instruction on all registry data elements for specific primary sites of cancer; and

- focus on particular issues within cancer registry abstracting, such as the application and resolution of edits, the review and revision of case finding activities to promote more complete and timely collection of data, or the resolution of quality issues identified by central registry and NPCR re-abstracting audits or patterns of care studies.

# 3.0 Program Standards for Data Collection

The NPCR communicates requirements for data collection to funded registries through Funding Opportunity Announcements and posted data submission requirements for the NPCR-Cancer Surveillance System. These standards include reportability or case definition, data item definitions and coding structures, data edits, and data transmission formats.

The NPCR collaborates with other national organizations in creating, identifying, and publishing data standards. In particular, the NPCR works through the procedures established by the North American Association of Central Cancer Registries (NAACCR) to define reportable cases, to request new data items, to identify NPCR-required data items in the NAACCR Data Dictionary, and to create and distribute data edits. NPCR specifies the use of NAACCR-defined data layouts for the electronic transmission of cancer information between central registries and from registries to NPCR.

## 3.1 Reportability

Reportability, within the context of a public health surveillance system, defines the disease entities whose occurrences within individual persons must be identified, and about which characteristic data elements must be collected and reported to the designated public health agency.

### Reference Date

The reference date is the effective date cancer registration starts in a specified at-risk population or in a specific facility. Each cancer registry establishes a reference date for reportable cases. According to the textbook *Central Cancer Registries: Design, Management and Use*, all reportable cases with a date of diagnosis on January 1st of the reference year and later are included in the registry database[1].

NPCR enhancement grants were initially used by funded registries in the collection of 1995 case data, with registries having the option to complete retrospective case ascertainment and data abstraction for previous diagnosis years. States applying for planning grants established reference dates as their registry programs became operational. The NPCR reference date for each central registry is January 1st of the first

[1] Menck H, Deapen D, Phillips JL, Tucker, T, eds. *Central Cancer Registries: Design, Management and Use. 2nd Edition.* Iowa: Kendall/Hunt, 2007.

year in which the registry received NPCR funding, which may be different from the registry's data collection reference date.

## Residency

A population-based registry includes all tumors occurring in the at-risk population, and rules must be in place for determining the members of that population. The goal of central registries is to include all cases of disease in state residents diagnosed and treated at facilities within state boundaries. Through data exchange agreements with other states, registries also collect data on state residents diagnosed and treated at facilities outside state boundaries.

Central registries use the same rules for patient address at diagnosis used by the Census Bureau in enumerating population. The rules guide registries in making residence decisions for part-year residents, institutionalized and homeless persons, military personnel, and students. The web link for the US Census Bureau is: http://www.census.gov

## Reportable Conditions

Public Law 102-515 and its amendments identify reportable conditions for the National Program of Cancer Registries. The *International Classification of Diseases for Oncology*, Third Edition (ICD-O-3) is the standard classification system used to determine reportability. NPCR requires reporting of:

- all diseases listed in the ICD-O-3 with a behavior code of "/2", in situ disease; or "/3", malignant disease; except:
- basal and squamous cell carcinomas of skin;
- carcinoma in situ of cervix uteri and cervical intraepithelial neoplasia; and
- prostatic intraepithelial neoplasia.
- all solid tumors of brain and central nervous system, including the meninges and intracranial endocrine structures, listed in the ICD-O-3 with behavior codes of:
- "/0" benign disease;
- "/1" disease of uncertain malignant potential;
- "/2", in situ disease; or
- "/3", malignant disease.

Note: North American standard setters have agreed juvenile astrocytoma, listed in the ICD-O-3 with a behavior code of "/1"; will be reportable with a behavior code of "/3".
See Appendix E: Reportable Conditions List 1992 – 2007

### Determining Number of Primary Cancers

Implemented for cancers diagnosed 1/1/2007 and later, the 2007 *Multiple Primary and Histology Coding Rules* contains site-specific standards for determining the number of primary cancers in an individual and for assigning ICD-O-3 histology codes to the diagnosed cancers. The rules are found at http://www.seer.cancer.gov/tools/mphrules/.

The *SEER Rules for Determining Multiple Primaries* are the standard accepted by central registries and by NPCR for the diagnosis years prior to 2007. These rules can be found within the appropriate editions of the *SEER Program Code Manual* available at: http://www.seer.cancer.gov/tools/codingmanuals/historical.html.

## 3.2 Reference Manuals

NPCR Required Manuals for cancers diagnosed 2007 and later are listed below.

| **DATA STANDARDS AND DATA DICTIONARY** |
|---|
| *NAACCR Standards for Cancer Registries, Volume II. Data Standards and Data Dictionary. Eleventh Edition, current.*<br>http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=133 |
| *2007 Multiple Primary and Histology Coding Rules*.<br>http://www.seer.cancer.gov/tools/mphrules/ |
| **DISEASE CLASSIFICATIONS** |
| *International Classification of Diseases for Oncology*. Third Edition. Geneva: World Health Organization, 2000. Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Parkin D, Whelan S, eds.<br><br>Available to order at: http://www.iacr.com.fr/icdo3.htm |
| **STAGE AND EXTENT OF DISEASE MANUALS** |
| *SEER Summary Staging Manual - 2000: Codes and Coding Instructions.*<br>http://www.seer.cancer.gov/tools/ssm |
| *Collaborative Staging Manual and Coding Instructions*. NIH Pub. No. 04-5496, 2006.<br>http://www.cancerstaging.org/cstage/manuals.html<br><br>*AJCC Cancer Staging Manual, Sixth Edition, 2002*<br>http://www.cancerstaging.org |

| CANCER TREATMENT – SEER DATABASES |
|---|
| *SEER*Rx Interactive Drug Database*<br>http://www.seer.cancer.gov/tools/seerrx/ |
| **CANCER TREATMENT – COMMISSION ON CANCER MANUALS** |
| *FORDS Facility Oncology Registry Data Standards. Revised for 2007*<br>http://www.facs.org/cancer/coc/fordsmanual.html |
| **ADDRESS CODING** |
| *Postal Addressing Standards. U.S.P.S. Pub 28, November 2000.*<br>http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf. |
| **OCCUPATION AND INDUSTRY CLASSIFICATION AND CODING** |
| *U.S. Census Bureau, Housing and Household Economic Statistics Division. Census 2000, "Alphabetical Indexes of Industries and Occupations."*<br>http://www.census.gov/hhes/www/ioindex/view.html. |

[Refer to Appendix F for Full Citations of Reference Manuals]

## 3.3 Required Data Items

| Program Standard Reference: | | |
|---|---|---|
| **IV.** | **Data Content and Format** | |
| | a. | For all NPCR required reportable cases, the central cancer registry collects or derives all required data items using standard codes as prescribed by NPCR (see III. a). |

Volume II in the NAACCR Data Standards for Cancer Registries series, *Data Standards and Data Dictionary,* lists all cancer items defined for data collection and reporting by the national standard setters: SEER, ACoS Commission on Cancer (CoC) and NPCR. Data items are defined with their coding structures or references to appropriate coding manuals. Tables show the placement of data items in the NAACCR record layout (the format used for electronic transmission of registry information), and requirements for data collection and transmission established by SEER, CoC, and NPCR. Revised editions of the data dictionary and corresponding record layout are released on an annual basis. Historic and current versions of the dictionary and record layout are maintained on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=133.

The following chart lists the standard data items required by NPCR by diagnosis year. The table provides the name of the data item and the specific reporting requirements established by NPCR. Bolded item names have been identified for collection by NPCR for all years of the program to date.

[See Appendix G for Required Status Data Item Table for Diagnosis Years 1997-2008–NPCR]

## 3.3.1 NPCR Data Items Required for Collection

| Requirements Legend | |
|---|---|
| R | Required |
| R* | Required when available |
| R^ | These text fields may be met by one or several text block fields |
| R+ | Required by diagnosis year |
| RH | Historically collected, transmitted |
| RH* | Historically collected, transmitted when available |
| RS | Required, site specific |
| D | Derived value |
| O | Optional |
| S | Supplementary/recommended |
| # | May code using SEER or CoC data item and associated rules |
| . | Not in data set |

**Table 3.3.1**
**NPCR Required Data Items**
**(NAACCR Record Layout)**

| DIAGNOSIS YEAR | | 2008 | 2007 | 2006 |
|---|---|---|---|---|
| Item # | Item Name | Collect | Collect | Collect |
| 70 | **Addr at DX--City** | R | R | R |
| 2330 | **Addr at DX--No & Street** | R | R | R |
| 100 | **Addr at DX--Postal Code** | R | R | R |
| 80 | **Addr at DX--State** | R | R | R |
| 2335 | Addr at DX--Supplemental | R | R | R |
| 230 | **Age at Diagnosis** | R | R | R |
| 430 | **Behavior (92-00) ICD-O-2** | RH | RH | RH |
| 523 | Behavior Code ICD-O-3 | R | R | R |
| 240 | **Birth Date** | R | R | R |
| 250 | **Birthplace** | R* | R* | R* |
| 1910 | **Cause of Death** | R | R | R |
| 120 | **Census Cod Sys 1970/80/90** | RH* | RH* | RH* |
| 364 | Census Tr Cert 1970/80/90 | RH* | RH* | RH* |
| 365 | Census Tr Certainty 2000 | R | R | R |
| 110 | **Census Tract 1970/80/90** | RH* | RH* | RH* |
| 130 | Census Tract 2000 | R | R | R |

| Table 3.3.1<br>NPCR Required Data Items<br>(NAACCR Record Layout) | | | | |
|---|---|---|---|---|
| **DIAGNOSIS YEAR** | | **2008** | **2007** | **2006** |
| **Item #** | **Item Name** | **Collect** | **Collect** | **Collect** |
| 610 | **Class of Case** | R | R | R |
| 200 | **Computed Ethnicity** | R | R | R |
| 210 | **Computed Ethnicity Source** | R | R | R |
| 90 | **County at DX** | R | R | R |
| 2810 | CS Tumor Size | R | . | . |
| 2810 | CS Extension | R | R | R |
| 2820 | CS Tumor Size Ext/Eval | R | . | . |
| 2830 | CS Lymph Nodes | R | R | R |
| 2850 | CS Mets at DX | R | R | R |
| 2880 | CS Site-Specific Factor 1 | RS | RS | RS |
| 2900 | CS Site-Specific Factor 3 | RS | RS | RS |
| 2935 | CS Version 1st | R | R | R |
| 2936 | CS Version Latest | R | R | R |
| 2110 | **Date Case Report Exported** | R | R | R |
| 2112 | **Date Case Report Loaded** | R | R | R |
| 2111 | **Date Case Report Received** | R | R | R |
| 580 | Date of 1st Contact | R | R | R |
| 1270 | **Date of 1st Crs RX--COC** | R# | R# | R# |
| 390 | **Date of Diagnosis** | R | R | R |
| 1260 | **Date of Initial RX--SEER** | R# | R# | R# |
| 1750 | **Date of Last Contact** | R | R | R |
| 2113 | **Date Tumor Record Availbl** | R | R | R |
| 2380 | **DC State File Number** | R | R | R |
| 3020 | Derived SS2000 | D | D | D |
| 3050 | Derived SS2000--Flag | D | D | D |
| 490 | **Diagnostic Confirmation** | R | R | R |
| 1790 | Follow-up Source | R* | R* | RH |
| 1791 | Follow-up Source Central | R | R | R |
| 366 | GIS Coordinate Quality | R* | R* | R* |
| 440 | **Grade** | R | R | R |
| 522 | Histologic Type ICD-O-3 | R | R | R |
| 420 | **Histology (92-00) ICD-O-2** | RH | RH | RH |
| 1920 | **ICD Revision Number** | R | R | R |
| 2116 | ICD-O-3 Conversion Flag | R | R | R |
| 192 | IHS Link | R* | R* | R* |
| 280 | **Industry Code--Census** | R* | R* | R* |
| 300 | **Industry Source** | R* | R* | R* |
| 410 | **Laterality** | R | R | R |
| 2352 | Latitude | R* | R* | R* |
| 2354 | Longitude | R* | R* | R* |
| 2300 | **Medical Record Number** | R | R | R |
| 470 | Morph Coding Sys--Current | R | R | R |

| Table 3.3.1<br>NPCR Required Data Items<br>(NAACCR Record Layout) | | | | |
|---|---|---|---|---|
| **DIAGNOSIS YEAR** | | **2008** | **2007** | **2006** |
| **Item #** | **Item Name** | **Collect** | **Collect** | **Collect** |
| 50 | **NAACCR Record Version** | . | . | . |
| 2280 | **Name--Alias** | R | R | R |
| 2240 | **Name--First** | R | R | R |
| 2230 | **Name--Last** | R | R | R |
| 2390 | **Name--Maiden** | R | R | R |
| 2250 | **Name--Middle** | R | R | R |
| 191 | NHIA Derived Hisp Origin | D | D | D |
| 45 | NPI--Registry ID | . | . | . |
| 545 | NPI--Reporting Facility | R* | R* | . |
| 330 | **Occup/Ind Coding System** | R* | R* | R* |
| 270 | **Occupation Code--Census** | R* | R* | R* |
| 290 | **Occupation Source** | R* | R* | R* |
| 1990 | **Over-ride Age/Site/Morph** | R | R | R |
| 2040 | **Over-ride Histology** | R | R | R |
| 2060 | **Over-ride Ill-define Site** | R | R | R |
| 2070 | **Over-ride Leuk, Lymphoma** | R | R | R |
| 2050 | **Over-ride Report Source** | R | R | R |
| 2000 | **Over-ride SeqNo/DxConf** | R | R | R |
| 2071 | **Over-ride Site/Behavior** | R | R | R |
| 2074 | **Over-ride Site/Lat/Morph** | R | R | R |
| 2010 | **Over-ride Site/Lat/SeqNo** | R | R | R |
| 2030 | **Over-ride Site/Type** | R | R | R |
| 2020 | **Over-ride Surg/DxConf** | R | R | R |
| 20 | **Patient ID Number** | R | R | R |
| 1940 | **Place of Death** | R | R | R |
| 630 | Primary Payer at DX | R* | R* | R |
| 400 | **Primary Site** | R | R | R |
| 160 | **Race 1** | R | R | R |
| 161 | Race 2 | R | R | R |
| 162 | Race 3 | R | R | R |
| 163 | Race 4 | R | R | R |
| 164 | Race 5 | R | R | R |
| 1570 | Rad--Regional RX Modality | R | R | R |
| 1340 | **Reason for No Surgery** | R | R | R |
| 10 | Record Type | R | R | R |
| 40 | **Registry ID** | R | R | R |
| 540 | **Reporting Facility** | R | R | R |
| 3300 | RuralUrban Continuum 1993 | D | D | D |
| 3310 | RuralUrban Continuum 2003 | D | D | D |
| 1460 | **RX Coding System--Current** | R | R | R |
| 1410 | **RX Summ--BRM** | R | R | R |
| 1390 | **RX Summ--Chemo** | R | R | R |

| Table 3.3.1<br>NPCR Required Data Items<br>(NAACCR Record Layout) | | | | |
|---|---|---|---|---|
| **DIAGNOSIS YEAR** | | **2008** | **2007** | **2006** |
| **Item #** | **Item Name** | **Collect** | **Collect** | **Collect** |
| 1400 | **RX Summ--Hormone** | R | R | R |
| 1420 | **RX Summ--Other** | R | R | R |
| 1292 | **RX Summ--Scope Reg LN Sur** | R | R | R |
| 1294 | **RX Summ--Surg Oth Reg/Dis** | R | R | R |
| 1290 | **RX Summ--Surg Prim Site** | R | R | R |
| 1380 | **RX Summ--Surg/Rad Seq** | R | R | R |
| 1639 | RX Summ--Systemic/Sur Seq | R | R | R |
| 3250 | RX Summ--TransplntEndocr | R | R | R |
| 2660 | **RX Text--BRM** | R^ | R^ | R^ |
| 2640 | **RX Text--Chemo** | R^ | R^ | R^ |
| 2650 | **RX Text--Hormone** | R^ | R^ | R^ |
| 2670 | **RX Text--Other** | R^ | R^ | R^ |
| 2620 | **RX Text--Radiation (Beam)** | R^ | R^ | R^ |
| 2630 | **RX Text--Radiation Other** | R^ | R^ | R^ |
| 2610 | **RX Text--Surgery** | R^ | R^ | R^ |
| 760 | **SEER Summary Stage 1977** | RH | RH | RH |
| 759 | SEER Summary Stage 2000 | RH | RH | RH |
| 380 | **Sequence Number--Central** | R | R | R |
| 220 | **Sex** | R | R | R |
| 450 | Site Coding Sys--Current | R | R | R |
| 2320 | **Social Security Number** | R | R | R |
| 190 | **Spanish/Hispanic Origin** | R | R | R |
| 2550 | **Text--DX Proc--Lab Tests** | R^ | R^ | R^ |
| 2560 | **Text--DX Proc--Op** | R^ | R^ | R^ |
| 2570 | **Text--DX Proc--Path** | R^ | R^ | R^ |
| 2520 | **Text--DX Proc--PE** | R^ | R^ | R^ |
| 2540 | **Text--DX Proc--Scopes** | R^ | R^ | R^ |
| 2530 | **Text--DX Proc--X-ray/Scan** | R^ | R^ | R^ |
| 2590 | **Text--Histology Title** | R^ | R^ | R^ |
| 2580 | **Text--Primary Site Title** | R^ | R^ | R^ |
| 2600 | **Text--Staging** | R^ | R^ | R^ |
| 320 | **Text--Usual Industry** | R* | R* | R* |
| 310 | **Text--Usual Occupation** | R* | R* | R* |
| 500 | **Type of Reporting Source** | R | R | R |
| 1760 | **Vital Status** | R | R | R |
| | | | | |
| **Bold - Items in data set for every diagnostic year** | | | | |

[Refer to Appendix G for a Timeline of Data Item Requirements: Diagnosis Years 1997-2008]

## 3.4 Unresolved Data Item Issues

For the following data items, NPCR has coding instructions that may differ from other standard setters. Chapter V in the NAACCR *Data Standards and Data Dictionary* discusses current inconsistencies among coding standards adopted by the standard setting organizations.

| | |
|---|---|
| Patient ID Number | NAACCR Item 20 |

NPCR requires the patient ID number remain the same regardless of diagnosis or data collection year, or software change. The registry must not re-use patient ID numbers when records are deleted from the registry database.

| | |
|---|---|
| County at DX | NAACCR Item 90 |

NPCR requires the use of Federal Information Processing Standards (FIPS) codes for cancers diagnosed January 1, 2002, and later, with the addition of code “999” for unknown.

| | |
|---|---|
| Spanish/Hispanic Origin | NAACCR Item 190 |
| Computed Ethnicity | NAACCR Item 200 |
| Computed Ethnicity Source | NAACCR Item 210 |
| NHIA Derived Hispanic Origin | NAACCR Item 191 |

NPCR requires collection and reporting of each of these data fields. Registries agree on the coding structure for Spanish/Hispanic Origin, but vary in how Spanish/Hispanic Origin is determined. Registries may collect ethnicity directly from the medical record, impute ethnicity based on other record information, derive ethnicity from matching surnames to a list of Spanish surnames, or derive ethnicity based on application of a computer algorithm to other available data items. The fields Computed Ethnicity, Computed Ethnicity Source, and NHIA Derived Hispanic Origin are included in an attempt to capture the methodology used in coding Spanish ethnicity.

| | |
|---|---|
| Occupation Code Census | NAACCR Item 270 |
| Industry Code Census | NAACCR Item 280 |
| Occupation Source | NAACCR Item 290 |
| Industry Source | NAACCR Item 300 |
| Text--Usual Occupation | NAACCR Item 310 |
| Text--Usual Industry | NAACCR Item 320 |
| Occup/Ind Coding System | NAACCR Item 330 |

PL 102-515 requires collection of “information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record.” NPCR requires reporting of the seven listed data fields *when they are available*, including text descriptions. U.S. Census Bureau codes from the 1990 Census

should be used for reportable cases diagnosed before 1/1/2003, and U.S. Census Bureau codes from the 2000 Census should be used for cases diagnosed 2004 and later. NPCR encourages states to update occupation and industry data items when performing death certificate linkage.

| | |
|---|---|
| Sequence Number—Central | NAACCR Item 380 |

Sequence Number--Central is defined as sequencing of all reportable neoplasms over the lifetime of a person.

| | |
|---|---|
| SEER Summary Stage 2000 | NAACCR Item 759 |
| SEER Summary Stage 1977 | NAACCR Item 760 |
| Derived SS2000 | NAACCR Item 3020 |

NPCR requires collection and reporting of seven of 15 Collaborative Stage data items, one derived stage field (Derived SS2000), one derived stage flag, and codes for the Collaborative Stage version used for data collection and stage derivation.

## Treatment Data Items

NPCR requires collection and reporting of summary treatment data items for the first course of definitive treatment when available. NPCR also requires the data item RX Coding System--Current, NAACCR 1460, which identifies the SEER and COC manuals used to code treatment.

| | |
|---|---|
| Date of Initial RX—SEER | NAACCR Item 1260 |
| Date of 1st Crs RX—COC | NAACCR Item 1270 |

NPCR allows use of either SEER's or CoC rules and definitions to code treatment. SEER includes all treatment occurring within one year of diagnosis in the first course of treatment when no other information is available to define first course. CoC includes all treatment occurring within four months of date of diagnosis in the absence of a specified treatment plan. SEER codes date of first course of treatment as zeroes when no treatment is given: CoC codes the date of decision for no treatment as the date of first course of treatment.

| | |
|---|---|
| RX Summ—Surg/Rad Seq | NAACCR Item 1380 |

NPCR requires registries to follow the CoC FORDS definition (FORDS page 164) for code "9". SEER and NAACCR code "9" as sequence unknown, but both surgery and radiation were given. CoC code "9" is defined as unknown if radiation or surgery given.

| | |
|---|---|
| Vital Status | NAACCR Item 1760 |

NPCR requires code "0" to indicate the patient is dead.

## 3.5 Data Exchange Format

**Program Standard Reference:**

**IV. Data Content and Format**

b. The central cancer registry uses a standardized, NPCR-recommended data exchange format to transmit data to other central cancer registries and NPCR (see III. a.).

**III. Electronic Data Exchange**

a. The central cancer registry uses and requires a standardized, NPCR-recommended data exchange record layout for the electronic exchange of cancer data. NPCR-recommended data exchange layouts include:
   i. For abstract reports: The NAACCR record layout version specified *in year-appropriate Standards for Cancer Registries Volume II: Data Standards and Data Dictionary*
   ii. For pathology reports: *NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting*
   iii. In an electronic format (where the medical records are owned by the hospital)

b. At a minimum, 85% of reports from non-hospital reporting sources are submitted to the central cancer registry in an electronic format (e.g. radiation therapy centers, ambulatory surgery centers, and in-state and out-of-state pathology laboratories where medical records are owned by the reporting source).

c. At a minimum, 75% of reports from physician offices, identified as required to submit cancer cases to the central cancer registry, do so in an electronic format (where the medical records are owned by the physician). This includes responses from physicians to central cancer registry inquiries.

d. The central cancer registry primarily uses a secure Internet-based, FTP, or encrypted email mechanism to receive data from all reporting sources.

NPCR requires registries use NAACCR's standardized data exchange record layout for the electronic exchange of cancer data. NAACCR has approved two record layout types for use:

- ASCII-delimited layout for registry abstract data; and
- HL7 message standard for pathology report data.

Note: An ASCII-delimited layout for pathology report data is available for laboratories and/or registries unable to use HL7. More information can be found at: http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=501

### 3.5.1 Record Layout Format for Registry Data

The ASCII-delimited layout for registry abstract data is updated on an annual basis and released by NAACCR in April for implementation with cases diagnosed January 1st of the following year. NAACCR publishes technical descriptions of the record layouts in *Standards for Cancer Registries, Volume I: Data Exchange Standards and Records Descriptions*. NAACCR publishes detailed specifications and codes for each data item in the data exchange record layout in *Standards for Cancer Registries, Volume II: Data Standards and Data Dictionary*.

Historic and current versions of Volume I are maintained on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=125.

Historic and current versions of Volume II are maintained on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=133.

### 3.5.2 Record Layout Format for Pathology Data

NPCR recommends use of *NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting. Version 2.0* contains specifications for electronically transmitting pathology reports based on Health Level 7 (HL7) Version 2.3.1, as well as an alternative ASCII delimited layout.

Historic and current versions of Volume V and the *Electronic Pathology Reporting Guidelines* are maintained on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=122

# 4.0 Completeness, Quality and Timeliness Requirements

NPCR Program Standards specify the requirements for data completeness, timeliness, and quality by which data submissions will be evaluated. The data evaluation results are used as a component in NPCR's overall evaluation of central registry program performance. Data evaluation results are also used to determine registry data eligibility for inclusion in national cancer data publications.

**Program Standard Reference:**

V. **Data Completeness/Timeliness/Quality**

a. Within 24 months of the close of the diagnosis year, at least 75% of physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients submit all reportable cases to the central cancer registry, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities (based on PL 102-515).

b. Within 12 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following two data quality criteria:
   1. Data are 90% complete based on observed-to-expected cases as computed by NPCR.
   2. 97% pass an NPCR-prescribed set of standard edits.

c. Within 24 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following five data quality criteria:
   1. Data are 95% complete based on observed-to-expected cases as computed by NPCR.
   2. There are 3% or fewer death-certificate-only cases.
   3. There is a 1 per 1,000 or fewer unresolved duplicate rate.
      1. The percent missing for critical data elements are:
         i. 2% or fewer age
         ii. 2% or fewer sex
         iii. 3% or fewer race
         iv. 2% or fewer county
      2. 99% pass an NPCR-prescribed set of standard edits.

## 4.1 Data Evaluation

The following methodologies are used to determine whether the registry's data submission meets the requirements for NPCR standards of completeness and quality:

## COMPLETENESS OF CASE ASCERTAINMENT

**Standard**: **Data completeness/Timeliness/Quality:** V.a, V.b.1, V.c.1

Method: NAACCR method for estimating completeness of case ascertainment.

The rate is adjusted for duplicates if the duplicate rate is derived from a sample of the incidence file, but is not adjusted if the duplicates are identified and corrected on the entire database.

Documentation for the NAACCR method is available on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=447

## RECORDS FAILING EDITS

**Standard:** **Data Completeness/Timeliness/Quality:** V.b.2, V.c.5.

Method: Calculating the number of records failing any core edit divided by the total number of records reported, converted to a percentage.

$$\text{Rate} = \frac{\text{number of records failing any core edit} * 100}{\text{total number of records}}$$

## PERCENTAGE OF DEATH CERTIFICATE ONLY CASES

**Standard:** **Data Completeness/Timeliness/Quality:** V.c.2

Method: Calculating the number of death-certificate-only cases divided by the total number of records, converted to a percentage.

$$\text{Rate} = \frac{\text{number of death-certificate-only cases} * 100}{\text{total number of records}}$$

**UNRESOLVED DUPLICATE RATE**

**Standard:** **Data Completeness/Timeliness/Quality:** V.c.3

Method: NAACCR Duplicate protocol: evaluate the number of duplicate records in the registry that have not been identified or corrected using regular matching, linkages, or other registry protocols.

Forms are available in the NPCR-CSS Submission Packet at https://www.npcrcss.org/docserver/

**UNKNOWN AGE; SEX; RACE; COUNTY RATE**

**Standard:** **Data Completeness/Timeliness/Quality:** V.c.4

Method: Determined separately for each of four listed data items (age, sex, race and county).
Calculating the number of records with unknown values for each of the items divided by the total number of records, converted to a percentage.

$$\text{Rate} = \frac{\text{number of records with unknown value} * 100}{\text{total number of records}}$$

## 4.2 Data Completeness

NPCR program requirements support the attainment of standards for data completeness in the following data collection activities:

- health care facilities and physician offices reporting;
- death clearance;
- data exchange among central registries in bordering states;
- case finding audits of reporting sources; and
- data linkages with other federally funded programs identifying cancers.

### 4.2.1 Reporting Sources

Standard V.a., Completeness/Timeliness/Quality, describes reporting requirements for physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, as well as for hospitals or other facilities providing

screening, diagnostic, or therapeutic services to patients. The standard reiterates the language of Public Law 102-515.

## 4.2.2 Interstate Data Exchange

**Program Standard Reference:**

**V. Data Completeness/Timeliness/Quality**

b. Within 12 months of the close of the diagnosis year, the central cancer registry exchanges data with other central cancer registries where a data-exchange agreement is in place. The data file must also include all cases not previously exchanged.

1. Regardless of residency, the central cancer registry collects data on all patients diagnosed and/or receiving first course of treatment in the registry's state/territory.
2. The recommended frequency for data exchange is, at a minimum, two times a year.
3. Exchanged data must meet the following minimum criteria:
   - i. Exchange agreements are in place with all bordering central cancer registries.
   - ii. Exchanged data include a dataset that consists of NPCR core data items.
   - iii. 99% of data pass an NPCR-prescribed set of standard edits.
   - iv. The dataset is transmitted via secure encrypted Internet-based, FTP, or encrypted email mechanism.
   - v. A standardized, NPCR-recommended data exchange format is used to transmit data (see III. a.).

Standard V.b., in the box above, describes the requirements for data exchange among central registries of bordering states. Implementation of this standard may require enabling legislation or formal agreements between states to allow the release of patient-identifiable information from one state registry to another state registry.

## 4.2.3 Death Clearance Activities

Death clearance is defined as the process of matching registered deaths in a population against reportable conditions in the central cancer registry database for two purposes: 1) ascertainment of vital status for persons in the registry (death clearance match); 2) identification of all deaths with a reportable condition mentioned as a cause of death which are not found in the central cancer registry (death clearance followback). A Death Certificate Only (DCO) case is a reportable case for which the Death Certificate is the only source of information. By Standard V.c.2, "Death certificate only" cases must represent 3% or fewer of total cases in the registry database.

NPCR will adopt the minimum requirements for conducting death clearance as established by the *Death Clearance Manual* to be published by NAACCR June 2008.

The Funding Opportunity Announcement requires the central registry perform a data linkage with the state's death records at least annually to enhance the completeness

and quality of central registry data. Following this linkage, the central registry, at a minimum, must update the NAACCR fields Date of Last Contact (Item 1750), Vital Status (Item 1760), and Cause of Death (Item 1910).

### 4.2.4 Data Completeness Audits

Data completeness audits assess the central registry's activities for identifying and collecting all reportable cancers. Routine case finding may be organized as a collaborative activity between reporting agencies and the central registry. For example, pathology laboratories may submit electronic data files of pathology reports, and the central registry may identify the reportable cancer diagnoses from these electronic data streams. On a periodic basis the central registry staff may conduct formal case finding audits, through review of original sources of information used by the reporting facilities, to assure all eligible cases are identified and reported. The audits require central registry staff have access to primary data sources, such as disease indexes, pathology reports, and treatment logs. Central registries must have an appropriate mechanism for tracking reported versus non-reported cancers and cancers not eligible for inclusion in the registry. Mechanisms must also be in place to request new cancer reports for eligible cases which have not been submitted.

Standard VI.a.3, Data Quality Assurance, requires a case finding and/or re-abstracting audit based on a sampling of source documents be conducted for each hospital-based reporting facility at least once every five years. These audits may include manual review of source documents, as well as data linkages of electronic files from submitting facilities with the central cancer registry database. NPCR program requirements specify registries participate in an NPCR-sponsored independent Data Completeness and Quality Audit, which is conducted by a CDC-approved organization/entity on a five-year cycle.

### 4.2.5 Data Linkages

The NPCR requires central registries perform data linkage with state programs funded by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). This linkage may identify cancer cases missing in the registry database or discrepancies in diagnostic and treatment information between the NBCCEDP and the central registry database. The NBCCEDP programs are required to collect and report a set of minimal data elements for all client participants.

The NPCR encourages central registries to perform other data linkages as identified to enhance the completeness of central registry data. Examples of partners for such linkages may be:

- a tertiary care facility;
- a regional health care system; or
- a health statistics agency within the Health Department.

## 4.3 Data Quality

The NPCR program has established requirements to help ensure data quality. These requirements include:

- electronic reporting format;
- standardized record layout;
- standardized data elements;
- standardized data edits;
- consolidation of multiple records into a single tumor record using best practices;
- geocoding to specify geographic locations of address at diagnosis;
- data linkages and algorithms to assign race and ethnicity; and
- data audits.

### 4.3.1 Electronic Reporting Format (Standards III.a-III.d and IV. b.)

Electronic reporting reduces the opportunities to introduce variability or errors into data through manual procedures. Electronic reporting depends on the specification of uniform transmission formats for data, so that senders and receivers correctly identify the same data items and values. The use of a standard transmission format facilitates the communication of cancer surveillance data between reporting facilities and the central registries, and between the central registries and the NPCR.

### 4.3.2 Standardized Data Elements (Standards III.a, IV.a)

NPCR references the NAACCR year-appropriate *Standards for Cancer Registries Volume II: Data Standards and Data Dictionary* as the source of information for the prescribed data transmission layouts. The *Data Dictionary* specifies code structures and provides field descriptions for all data elements. Individual data items and reportability requirements for each standard setter, including the NPCR, are displayed in the "Required Status Table" in Volume II. Current and previous versions of the NAACCR Data Dictionary are available at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=133.

### 4.3.3 Standardized Data Edits (Standards V.b.2 and V.c.5)

The Funding Opportunity Announcement requires programs use computerized standardized edits, and at a minimum, run the NPCR edits on a quarterly basis. The NPCR edits are collected in an edit set, labeled as "Central: Vs [current version] NPCR Req-Consol-All Edits", in the current version of the Edits metafile. NPCR also publishes core and advanced edits requirements in the submission specifications for the annual call for data for the NPCR-Cancer Surveillance System. The Edits metafiles are maintained and published by NAACCR at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=136.

### 4.3.4 Record Consolidation

NPCR requires registries perform consolidation of reported data following best practices or standards as they become available. The NPCR has adopted the definition of consolidation as stated in the *NAACCR Standards for Cancer Registries, Volume III, Standards for Completeness, Quality, Analysis, and Management of Data*: "The process of reconciling or compiling data obtained from more than one source on the same person or tumor" or the preparation of "a composite set of values for each patient and tumor, incorporating information from a variety of sources". Case consolidation is a major activity of central registries, and the balance between computerized and manual practices varies widely among registries. This variation in practice makes it extremely important for each registry to establish and follow consistent procedures.

### 4.3.5 Geocoding

Geocoding is the process of assigning geographic identifiers to patient address at diagnosis. Identifiers include geographic coordinates expressed as latitude and longitude, and census tract, which can be determined from the coordinates. NPCR requires reporting of census tract, and census tract certainty for each cancer diagnosis; latitude and longitude are required as available. Reviewing and updating address at diagnosis coding on individual records in preparation for geocoding improves information in existing data fields. Latitude and longitude information facilitates spatial analysis of cancer data in geographic information systems. Census tract identification facilitates analysis of cancer diagnosis and treatment using socioeconomic variables. The NPCR identifies GIS (Geographic Information System) analysis and/or mapping as an advanced activity registries are encouraged to undertake when they consistently meet or exceed the NPCR program standards. A NAACCR document on *Using Geographic Information Systems Technology in the Collection, Analysis, and Presentation of Cancer Registry Data: A Handbook of Basic Practices* is available at http://www.naaccr.org/filesystem/pdf/GIS%20handbook%206-3-03.pdf.

### 4.3.6 Data Linkages/Coding Algorithms

Linkages conducted by the central cancer registry improve the quality of data within the registry database.

The NPCR-required data linkage with the NBCCEDP database may reveal data differences between the registry and the program data set which must be reconciled.

The NPCR may require central registries perform data linkages between the Indian Health Service (IHS) patient registration database and the registry databases in order to improve the identification and classification of American Indians and Alaska Natives by the cancer registries. The IHS website http://www.ihs.gov/MedicalPrograms/EPI provides further information on cooperative agreements with the CDC.

The NPCR requires registries to process data using the NAACCR Hispanic Identification Algorithm (NHIA) to improve the coding of ethnicity data. Information on NHIA is available at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=73.

Other data linkages which may provide useful information to the registry include:

- local tribal registration lists;
- hospital discharge data systems;
- healthcare facility billing systems;
- driver license and voter registration lists; and
- vital statistics.

### 4.3.7 Data Quality Audits (Standard VI.a.3)

NPCR program requirements specify registries perform case-finding and/or re-abstracting audits of hospital-based reporting facilities at least once every 5 years. These external audits assure the quality and completeness of central registry data.

Re-abstracting and recoding studies are audit procedures whose purposes are to:

- standardize interpretation and abstracting of the medical record;
- estimate rates of agreement; and
- identify problems in data collection and interpretation.

Registry options for conducting external audits of reporting sources include:

- reliability studies developed by the CCR for reporting entities;
- visual review of all reports from new abstractors with follow-back on data quality issues;
- sampling of cases from facilities with visual review of coded data and text;
- selection of certain sites/histologies for annual review, such as all unknown primaries; and

- reconciliation of conflicting data between registries reporting the same case.

Registries have many options for conducting internal audits, such as:

- periodic random review of coding of pathology reports sent directly to the CCR;
- systematic random review of case consolidation performed by CCR staff;
- quality checks of data collected and processed by central registry staff;
- participation in national quality assurance studies; and
- systematic random review of case information collected by CCR staff.

Registry staff members have opportunities to audit and improve their own abstracting skills by participating in reliability studies offered by the standard setters for new or revised coding systems, such as the Collaborative Staging Assessment and the Multiple Primary/Histology Rules Reliability Study offered by SEER.

## 4.4 Data Timeliness

The NPCR program has established standards to help ensure cancer data are available for use in a timely manner. Standards include completeness requirements by diagnosis year, and reporting in electronic format.

### 4.4.1 Reporting from Close of Diagnosis Year (Standards V.b, and V.c.)

Data should be 90% complete within 12 months of end of diagnosis year. Data should be 95% complete within 24 months of end of diagnosis year.

Completeness of data is based on the calculation of observed to expected cases by NPCR. NPCR uses the NAACCR method of estimating case completeness. The NAACCR method is described in Appendix G of *NAACCR Standards for Cancer Registries, Volume III, Standards for Completeness, Quality, Analysis, and Management of Data,* at http://www.naaccr.org/filesystem/pdf/NAACCR%20Volume%20III%20Final%20PDF%20File%2011-29-04.pdf.

### 4.4.2 Reporting in Electronic Format (Standards III.a-III.d and IV.b)

NPCR program standards place emphasis on electronic reporting to increase the efficiency of registry operations. Increased efficiency of operations and the use of computerized technology to create, format, transmit, and process cancer registry data files, in turn, facilitate the timeliness of reporting.

# 5.0 NPCR-CSS Data Submission

**Program Standard Reference:**

**VII. Data Submission**

*c.* The central cancer registry annually submits a data file to the NPCR-Cancer Surveillance System (CSS) that meets the reporting requirements outlined in the NPCR-CSS Submission Specifications document and meets criteria for publication in *United States Cancer Statistics.*

The National Program of Cancer Registries-Cancer Surveillance System (NPCR-CSS) began collecting data from central cancer registries in 2001. The rationale and approach for this national surveillance system are described in a document available on the NPCR website at http://www.cdc.gov/cancer/npcr/training/css.htm.

The goal of NPCR-CSS is to allow the analysis of aggregated data from NPCR-funded states on a regional or national level, as a statistical basis for the planning and implementation of cancer prevention and control initiatives. Analysis of aggregated data provides more accurate and stable estimates of cancer incidence for population groups including racial and ethnic minorities, medically underserved groups, and other subpopulations. Analysis of aggregated data also reveals geographic variability in cancer treatment practices, use of state-of-the-art cancer treatment, and deviations from standards of cancer care. The public-use data files from the CSS provide greater access to cancer data for the public, scientists, and policy makers.

## 5.1 Submission Information

Submission requirements, Data Release Policy, and Utilities to aid in the preparation of the submission are available on the Utilities page of the CSS website, at https://www.npcrcss.org/docserver/. A login and password is required to access this site.

### 5.1.1 NPCR-CSS Submission Packet

The NPCR-CSS Submission Packet includes submission specifications, data items, data edits, all submission forms, confidentiality, data security, data set participation information, and frequently asked questions.

The NPCR-CCS submission specifications address these areas:

Reportable cases and data elements:

- diagnosis years to be reported;
- reportable diagnoses based on ICD-O codes, with any exclusions noted;
- data items to be reported by diagnosis year, with coding standards noted;

- conversion of county codes if release of county designations prohibited by state law;
- required algorithmic processing for indicated data fields, such as the NHIA algorithm for deriving Hispanic origin; and
- required data linkages, for example linkage with the Indian Health Service database for determining Native American origin.

Editing standards:

- core edits to be applied to data to assess compliance with NPCR program standards;
- advanced edits to be applied to data to assist in improving overall data quality;
- inter-record edits to be applied to data; and
- identification of duplicate records using NAACCR protocol.

Report Format:

- electronic record layout.

Submission administration:

- submission dates;
- preparation of submission;
- file transfer instructions;
- data security;
- transmittal forms;
- questions; and
- references.

Data Evaluation:

- data standards to be applied in evaluation of submissions, by sets of criteria; and
- measurement error by criteria.

### 5.1.2 NPCR-CSS Data Release Policy

The NPCR-CSS Data Release Policy describes the planned release of data submitted to CDC as part of the annual NPCR-CSS data submission. This policy, which originally took effect October 2003, is updated annually. NPCR grantees are asked to complete and return the NPCR-CSS Data Set Participation Agreement as part of their annual CSS data submission.

## 5.2 Utilities

As a service to participating central cancer registries, NPCR offers the following utilities specific to the submission year. The website can be found at: https://www.npcrcss.org/docserver/. A login and password is required to access this site.

### ICD-O-2 to ICD-O-3 Conversion Program

NPCR requires the conversion of histology codes from ICD-O-2 to ICD-O-3 for all cancers diagnosed before 2001.

### NHIA V2 SAS Program

All NPCR registries are required to use Version 2 of the NAACCR Hispanic Identification Algorithm (NHIA) SAS program or equivalent and record the NHIA variable in the NPCR-CSS data submission. NAACCR has combined the NHIA program with the NAACCR Asian Pacific Islander Identification Algorithm (NAPIIA), into a single NAACCR Hispanic and Asian Pacific Islander Identification Algorithm (NHAPIIA). A copy of the SAS program and the associated files required to run the program are available from the NAACCR Web site under the heading "Cancer Research, Data Analysis Tools." A SAS license is required to run the SAS program.

### GenEDITS Plus with the NPCR Core and Advanced Edits Metafile

GenEDITS Plus is a Windows-based stand-alone program packaged with the EDITS metafiles to run the NPCR core and advanced, single field and inter-field edits on a NAACCR record layout file. The program produces summary and detailed reports of core and advanced edit errors. The README.TXT file contains installation and usage information.

### NPCR-CSS Edits Metafiles

The runtime EDITS metafiles for the NPCR core and advanced single field and inter-field edits are provided for use by registries which have implemented the EDITS engine outside of the GenEdits Plus program.

### NPCR-CSS Call for Data Edits Online Help

The Online Help program installs a Windows help file containing information that may be useful to registries when preparing their NPCR-CSS submission. Installation instructions are included in the zip file.

### Inter-Record Edits Standalone Program (ICD-O-2/ICD-O-3)

The Inter-Record Edits Standalone Program validates the consistency of data between multiple records for a patient. The program produces summary and detailed reports of inter-record errors. After program installation, a help file is available describing its use. The Inter-Records Edits program should be run after the NPCR core and advanced edits have been run and errors have been corrected. The program can also be configured and used during preparations for the NAACCR submission.

### Data Extraction Utility

The utility is an executable file containing the NPCR Data Extraction Utility for the submission. The program will read the current NAACCR record layout and write a new file containing only data items requested for the submission. After program installation, a help file is provided describing its use.

### Northcon11 Record Conversion Program

For those registries with data files in a NAACCR version lower than v11 format, a free-standing Windows program is available to convert files of cancer registry records in NAACCR data formats. Input files may contain NAACCR version 6, 7, 8, 9, 10, or 11. Converted output files can be NAACCR version 7, 8, 9, 10.2, or 11.

# 6.0 NPCR Program Evaluation

The NPCR evaluates program participants to ensure that their data meets the standards for completeness, quality and timeliness. The NPCR also assesses each cancer registry's operations to monitor that its long term goals are met.

## 6.1 NPCR-CSS Data Evaluation Reports

Following each data submission, registries receive the NPCR-CSS Data Evaluation Reports (DERs) detailing the completeness, accuracy and timeliness of the five-year period under evaluation. The DERs show the program's progress in meeting the following standards:

- Percent Completeness Adjusted for Duplicates: The percentage of observed to expected, unduplicated cases where the expected cases are estimated using methods developed by the North American Association of Central Cancer Registries (NAACCR) (http://www.naaccr.org/). Annual case completeness evaluation is based on the current NAACCR method.
- Unresolved Duplicate Rate: Because some cancer patients receive diagnostic or treatment services at more than one reporting facility, cancer registries perform a procedure to identify and resolve duplicate case reporting to ensure each cancer case is counted only once. Prior to the NPCR-CSS data submission, each registry performs a protocol developed by NAACCR for assessing duplicate cases. This information is reported to NPCR with the data submission.
- Percent Death Certificate Only Cases: Another measure of completeness of case ascertainment is the proportion of cases ascertained solely on the basis of a death certificate, with no other information on the case available after the registry has completed a routine procedure known as "death clearance and follow back".
- Percent Missing Critical Data Elements (Age, Sex, Race and County): The proportion of cases missing information deemed critical for the reporting of population-based cancer incidence data.

- Percent Passing Edits: Edits test the validity and logic of data components. Edits are applied to single field variables, inter-field variables and to multiple records (each record denotes a case of cancer in a patient) in those instances where a patient has multiple cancer diagnoses. Inter-record (IR) edits are run on the entire data submission from the reference year through the most current 24-month data. There are two types of edits: core edits applied to variables deemed necessary for reporting incidence data; and advanced edits applied to variables used for advanced surveillance activities such as survival analyses. At this time, it should be noted there are no standards for advanced edits.

## 6.2 NPCR Program Evaluation Instrument (PEI)

The NPCR PEI assesses central cancer registry system attributes, including:

- simplicity (the structure and ease of operation);
- program flexibility;
- data quality activities;
- acceptability;
- activities affecting surveillance sensitivity;
- representativeness;
- timeliness; and
- program stability.

The instrument consists of a series of questions designed to provide a consistent approach to evaluating programs across NPCR, and is administered through a secure web-based system. For both funded programs and NPCR, the PEI assesses whether the program's design and purpose are clear and defensible, and whether valid long-term goals are met. The PEI focuses on how well the system operates to meet its purpose and objectives.

Formalization of program evaluation using the PEI is intended to develop defensible and consistent progress toward funded programs meeting NPCR Program Standards and toward NPCR meeting program goals. The PEI provides NPCR the information needed to focus attention on:

- strategic planning;
- meaningful performance measures for funded programs and NPCR;
- program results; and
- appropriate technical assistance that can improve data quality and program efficiency and usefulness.

When states complete the PEI, immediate access to a PDF of state information is provided. The information should be used for self-assessment of program goals and operations. PEI results may be reviewed by both central registry and NPCR staff in preparation for site visits.

An example of the PEI can be found in Appendix H.

## 6.3 Data Completeness and Quality Audits

Discrepancies in the completeness and quality of cancer data among states have made analysis of cancer patterns by state and by geographic region difficult. As a consequence, there is an on-going need to assess the completeness and quality of cancer reporting, case finding, and data abstracting.

### NPCR Data Completeness and Quality Audit (DCQA)

NPCR conducts a continuous program of data assessment through the DCQA process, with the following characteristics:

- programs are audited once every five years;
- completeness and data accuracy of all sites are reviewed;
- treatment data are evaluated;
- focus is on reporting hospitals; and
- auditors conduct a post-audit debriefing with the central registry.

### Special Audits

NPCR conducts special audits to assess registry performance in response to significant changes in cancer data standards, or to investigate registry operations of special concern.

The Reportable Hematopoietic Diseases audit in 2004:

- included three states for the 2002 diagnosis year;
- reviewed malignant conditions originating in the bone marrow, blood, spleen, and reticuloendothelial or hematopoietic systems;
- focused on hospitals and specialty physicians (hematologists, oncologists); and
- identified common coding mistakes and training needs.

The Targeted Casefinding Audit in September 2005 through March 2006 was:

- conducted in eight states;
- directed to impact their CSS submission to meet NPCR standards for 24 month data;
- identified barriers and problems affecting case completeness; and

- focused on both hospital and non-hospital facilities.

# 7.0 Data Use

A primary NPCR goal is to provide data to public health planners and others monitoring the burden of disease and planning effective cancer prevention and control programs. NPCR has received data annually from funded programs, from their NPCR reference year forward.

## 7.1 National Data Use – Electronic Data Release Activities

Currently, NPCR has four products for electronic data release. These products are updated annually to include the most recent year of data. All data represented in these products must meet NPCR quality standards and their use must be authorized in writing by participating states. The data products described in subsections 7.1.1 – 7.1.5 have been created with the assistance of the NPCR Scientific Working Group and the Small Data Release Group.

### 7.1.1 Creation of Datasets

Prior to inclusion in a public data set, data files submitted by each participating registry are checked for data format, record layout, data consistency (reasonableness), and confidentiality in a Pre-Edit Verification. If any records in a file contain discrepant or confidential data, the whole file is rejected and the State notified.

Records in the retained data files are next checked for reportability criteria. Records are flagged for non-reportability if they show:

- State of diagnosis differing from submission State;
- diagnosis year earlier than State reference year;
- benign or borderline histology, except for CNS tumors diagnosed in 2004 and later and borderline ovarian histology diagnosed from 1992 through 2000 (coded using ICD-O-2 criteria);
- basal or squamous cell carcinoma of skin;
- carcinoma in situ of cervix, AIN III, CIN III, VIN III, VAIN III; or
- PIN III diagnosed 2001 and later.

Reportable records are processed through the EDITS program, using NPCR core and advanced edit sets, and edit set results are flagged for each record.

The Analytic File is created using the cases flagged as reportable. For this file, in situ bladder cancers are recoded to malignant cancers. Pilocytic astrocytomas (coded as 9421/1 in ICD-O-3) are re-coded during abstraction and reported by central registries as malignant (9421/3). Based on EDITS results, records are excluded from the file for:

- invalid, missing, or unknown age;
- coding errors in single fields: primary site, race, and sex;
- inter-field edit errors:
  - age/birth date/diagnosis date;
  - age/site/morphology;
  - birth date/diagnosis date; or
  - sex/primary site;
- cases submitted less than 24 months from date of diagnosis.

### 7.1.2 United States Cancer Statistics (USCS)

Since 2002, CDC and NCI, in collaboration with NAACCR, have combined their data sources to publish the official annual federal cancer statistics in the *United States Cancer Statistics (USCS): Incidence and Mortality* report. This publication is available at http://www.cdc.gov/cancer/npcr/uscs/. The report includes cancer incidence from registries with high-quality data with the latest report representing 98% of the U.S. population. Cancer mortality statistics in the USCS publication are based on information from all death certificates filed in the 50 states and the District of Columbia and processed at the National Center for Health Statistics (NCHS). For consistency with the cancer incidence data in USCS, cancer sites in mortality data were grouped according to the revised SEER recodes dated January 27, 2003. Because NCHS uses different groupings for some sites, the death rates in the USCS publication may differ slightly from those published by NCHS. Online access to the USCS is available at http://apps.nccd.cdc.gov/uscs and additional information on NCHS is available at http://www.cdc.gov/nchs.

### 7.1.3 U.S. County Cancer Incidence Dataset

This dataset consists of aggregate cancer incidence rates and case counts for major cancer sites for selected counties in the United States. The purpose of this release is to provide aggregated county-level data for cancer control planning, policy-making, and monitoring. Examples of current users include state cancer control planners, state legislators and policy-makers, and the American Cancer Society (ACS). The dataset can be accessed at the State Cancer Profiles website, http://www.statecancerprofiles.cancer.gov/. This website is maintained by the National Cancer Institute, and provides data from both the SEER and the NPCR cancer databases.

### 7.1.4 CDC WONDER: Online Data-Reporting System

CDC has collaborated with NPCR-funded programs to define, test, and release NPCR data in CDC WONDER, an online reporting system hosted at CDC. Launched in early 2006, CDC WONDER allows greater access to NPCR data than is available through the County Cancer Incidence Dataset. Users can obtain reports containing age-adjusted rates, crude rates, and case counts, requested by state, large metropolitan statistical

areas, year of diagnosis, sex, race, and age for both adult and childhood classifications of cancer. This system provides easy access to critical data that can help guide and evaluate interventions focused on cancer prevention and control. The CDC Wonder web address is http://wonder.cdc.gov/cancer.html.

### 7.1.5 Restricted Access File

Since 2004, NPCR and the NPCR Small Data Release Group (SDRG) have collaborated to define procedures for release of NPCR data at the individual record level as a Restricted Access File (RAF). Great care has been taken to balance data release procedures and data items with the need to maintain confidentiality. The data included in the RAF have met or exceeded the NPCR's data quality standards. In addition, cancer registries have authorized the release of their data in these files.

There are currently two RAFs. The state-level RAF (SRAF) is a file with state as the smallest identified geographic unit. To protect confidentiality, significant review of proposals is required before this file will be released. More recently, the Regional RAF (RRAF), defined by the United States Census regions (Northeast, South, Midwest, and West) as the smallest identified geographic unit, was developed. Because the broader level of geographic specificity in the RRAF effectively reduces the potential of identifying an individual, the review process is abbreviated. In most other respects, the two files are identical and the RRAF is a good resource for many analyses that do not utilize state-level data. By the fall of 2006, SRAF application was available to all NPCR registries, the ACS, and SEER. SRAF and RRAF application availability is planned for all researchers with an approved proposal and a signed data release agreement.

Documentation for the RAF contents and applications for SRAF and RRAF data releases are available at the NPCR web site: https://www.npcrcss.org/docserver/. A login and password is required to access this site.

## 7.2 National and International Data Use - Publications

NPCR data are included in national and international compilations of cancer information in addition to *United States Cancer Statistics (USCS)* (http://apps.nccd.cdc.gov/uscs/). NPCR data are also included in national compilations of healthcare information in which cancer care is one of many healthcare issues addressed.

### 7.2.1 The Annual Report to the Nation on the Status of Cancer

CDC, NPCR and the National Center for Health Statistics (NCHS) collaborate with ACS, NAACCR, and SEER to produce the *Annual Report to the Nation on the Status of Cancer,* first published in 1998. The published volumes are:

- Annual Report to the Nation on the Status of Cancer, 1973-1996, with a Special Section on Lung Cancer and Tobacco Smoking.
- Annual Report to the Nation on the Status of Cancer, 1973-1997, with a Special Section on Colorectal Cancer.

- Annual Report to the Nation on the Status of Cancer, 1973-1998, Featuring Cancers with Recent Increasing Trends.
- Annual Report to the Nation on the Status of Cancer, 1973-1999, Featuring Implications of Age and Aging on U.S. Cancer Burden.
- Annual Report to the Nation on the Status of Cancer, 1975-2000, Featuring the Uses of Surveillance Data for Cancer Prevention and Control.
- Annual Report to the Nation on the Status of Cancer, 1975-2001, with a Special Feature Regarding Survival.
- Annual Report to the Nation on the Status of Cancer, 1975-2002, Featuring Population-Based Trends in Cancer Treatment.
- Annual Report to the Nation on the Status of Cancer, 1975-2003, Featuring Cancer among U.S. Hispanic/Latino Populations.

The current report is available at http://seer.cancer.gov/report_to_nation/. Previous reports are available at http://seer.cancer.gov/report_to_nation/archive.html.

### 7.2.2 National Healthcare Quality Report

Since 2003 the Agency for Healthcare Research and Quality (AHRQ) has published a National Healthcare Quality Report (NHQR). This report is published on behalf of the U.S. Department of Health and Human Services (DHHS) in collaboration with an HHS-wide Interagency Work Group. The NHQR examines and tracks the quality of health care in the United States, using the most scientifically credible measures and data sources available. Measures of healthcare quality address the extent to which providers and hospitals deliver evidence-based care for specific services, as well as the outcomes of care provided. The NPCR is a contributing source of data for the reports, which are listed at http://www.qualitytools.ahrq.gov.

### 7.2.3 National Healthcare Disparities Report

A companion report to the NHQR, the National Healthcare Disparities Report is a comprehensive national overview of disparities in access to and quality of healthcare among racial, ethnic, and socioeconomic groups, as well as among subpopulations such as children and the elderly. The NPCR is a contributing source of data for these reports. The web link is http://www.qualitytools.ahrq.gov.

### 7.2.4 Cancer Incidence in Five Continents

*Cancer in Five Continents* presents comprehensive data, published every five years, on cancer incidence for over 200 populations worldwide. For each population, age-specific, standardized and cumulative incidence rates are given by sex, for different types of cancer. NPCR registries meeting the following criteria may have their data represented in *Cancer in Five Continents:*

- IACR member;
- data meet *United States Cancer Statistics* publication criteria; and
- permission granted for publication.

The IACR website is http://www.iacr.com.fr.

### 7.2.5 Cancer Incidence in North America

NPCR registries that submit data to NAACCR and meet the criteria for silver or gold certification are eligible to have their data included in the annual publication, *Cancer Incidence in North America (CINA)*. The monographs present cancer incidence and death rates by race and ethnicity, gender, and geographic areas. The information can be used by national, state, provincial, and local health professionals for policy development, hypothesis generation, and as a resource for the cancer registry or the general public. The publication is accessed at: http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=50.

## 7.3 Special Studies

NPCR and central registry staff participate in active research and publication in the cancer registry field. NPCR registries meeting established criteria may apply for NPCR funding of special studies. These studies may encompass the collection and analysis of additional cancer case data, with publication of findings to the larger registry community.

### 7.3.1 Articles and Monographs

The NPCR webpage, “Scientific Articles by the National Program of Cancer Registries”, provides a complete list of scientific articles by NPCR authors with links to PubMed citations. The web link is**:** http://www.cdc.gov/cancer/dcpc/library/articles/npcr.htm.

Included in the list of publications are citations for a series of twelve articles which appeared as a monograph on colorectal cancer, published in the journal *Cancer*, 2006; 107 (S5). The monograph, developed in coordination with NCI, central cancer registries, academic institutions, and the ACS, was designed to highlight the magnitude of the national burden of colorectal cancer and to guide cancer control and prevention activities for this disease.

### 7.3.2 Patterns of Care (POC) Studies

NPCR has funded central registries to conduct studies examining the care provided to cancer patients. Two studies were initiated in June, 2001, and a third study in May, 2005:

- Breast, Colon, Prostate Cancer Data Quality and Patterns of Care Study,
- Ovarian Cancer Patterns of Care Study; and
- Breast and Prostate Cancer Data Quality and Patterns of Care Study.

The Breast, Colon, Prostate Cancer Data Quality and Patterns of Care Study was designed to assess the quality and completeness of stage at diagnosis, and the treatment data collected by the participating registries. The study goal was to determine the extent to which patients received guidelines-based, stage-specific treatments for localized breast and prostate cancers and stage III colon cancer. The study design also included participation in the CONCORD Study, a multi-national project. The CONCORD Study purpose was to identify international differences in survival, and to enable direct comparison of cancer survival within and between countries using standardized data collection protocols, quality control procedures, and central analysis of individual cancer records. As a separately funded activity, NPCR recipients could also conduct an optional linkage with the state Breast and Cervical Cancer Early Detection Program data to validate the accuracy of comparable information within the two databases. Several manuscripts have been published, with several presentations made at conferences. See Appendix B for an inventory of publications and professional presentations on CDC-NPCR's Pattern of Care Studies. Further information about the Breast/Colorectal/Prostate POC Study is available at http://www.cdc.gov/cancer/npcr/publications/pocstudy.htm.

The Ovarian Patterns of Care study was designed to evaluate medical record information on ovarian cancer and the stage and treatment data reported to the registry. Findings of the study were presented at the American Society of Clinical Oncology (ASCO) annual meeting in 2006. The published article is available in *Journal of Clinical Oncology*, 2006 ASCO Annual Meeting Proceedings Part I. Vol 24, No. 18S (June 20 Supplement), 2006: 15031

The Breast and Prostate Cancer Data Quality and Patterns of Care Study supports enhanced surveillance and operations research to improve the completeness, timeliness, quality, and use of first course of treatment and stage data. The study is expected to describe treatment patterns and determinants of receipt of guideline-concordant treatments for breast cancer and appropriate therapy for prostate cancer. There will be a particular focus on whether disparities in care exist among racial/ethnic and age groups, geographic areas, or socio-economic levels. The study will evaluate the quality and availability of existing data from a variety of sources, including cancer registries, medical records, and insurance claims, to support such analyses, and will identify ways to strengthen the data infrastructure for cancer care assessment. A long term goal of this study is to strengthen the use of data among NPCR-funded state cancer registries for the improvement of cancer care.

### 7.3.3 Data Quality Studies

The Oral/Pharyngeal Data Quality study, initiated in 2001, was designed to identify and provide solutions for a range of quality issues related to information collected for these cancers, including strategies for obtaining stable incidence rates.

### 7.3.4 Reporting Pathology Protocols

NPCR has funded a series of Reporting Pathology Protocols (RRP) projects to implement a new means of collecting and transmitting pathology information using the SNOMED CT-encoded College of American Pathologists (CAP) cancer checklists and HL7 messages. The CAP checklists enable pathologists to provide needed information in a clear and consistent manner, ensuring that cancer diagnoses will be recorded and coded using a fixed set of data items at the pathology laboratory.

An initial pilot project was initiated in 2001, focusing on colon and rectum cancers. Participating pathology laboratories in two states used an electronic version of the checklists, and the information was formatted into a project standard HL7 message using Logical Observation Identifiers Names and Codes (LOINC) as the questions and SNOMED CT codes as the answers. The "Report on the Reporting Pathology Protocols for Colon and Rectum Cancers" is available at http://www.cdc.gov/cancer/npcr/npcrpdfs/rpp_report_121605.pdf.

The second project, focusing on cancers of the breast, prostate, and melanoma, started in 2003 with the participation of three state registries. Project participants include representatives from NPCR and hospital registries, hospital anatomic pathology laboratories, laboratory information system vendors, SNOMED International, and HL7 messaging consultants. The participants' Messaging Work Group is tasked with defining the common HL7 message data items and associated structure of the CAP checklist data. The Evaluation Work Group will establish evaluation measures for the validity and reliability of this method of electronically capturing cancer data.

Related to the RRP projects, NPCR has funded the Veterans Administration Medical Center of Atlanta to implement SNOMED-encoded cancer checklists in the VA pathology laboratory. The project provides the opportunity to see the benefits and challenges of using the checklists in a busy laboratory, and to compare the completeness and quality of traditional reports with the information obtained from the checklists.

### 7.3.5 Economic Analysis

NPCR is conducting a multi-year economic analysis of program activities to compare operating costs for registries that have achieved standards for high-quality data with costs for registries that have not. The study will examine:

- the cost of performing core surveillance activities;
- the cost of enhancing the infrastructure and operation of NPCR registries; and
- the cost of performing advanced surveillance activities.

Researchers will determine factors and variables influencing costs, and will develop a resource-allocation model based on cost-effectiveness. The first report from this study, "The National Program of Cancer Registries: Explaining State Variations in Average

Cost per Case Reported", published in Preventing Chronic Disease, online serial, Vol. 2, No. 3, July 2005, is available at http://www.cdc.gov/pcd/issues/2005/jul/04_0124.htm

The second report from this study, "Economic Assessment of Central Cancer Registry Operations, Part I: Methods and Conceptual Framework" was published in the Journal of Registry Management, Fall, 2007; Volume 34, Number 3. A copy of this report can be obtained at http://www.ncra-usa.org/i4a/pages/index.cfm?pageid=3307.

### 7.3.6 Central Registry Workload Management Study

NPCR is conducting a workload and time management study to assess the current practices of central cancer registries. The study purpose is to document the staffing requirements, task by task−case finding, abstracting, follow-up, quality assurance, data usage and reporting, conference/committee activity, management and administration, training, other activities−required of central registries. These staffing requirements will then be studied as a function of co-variables.

The study will include:

- Workload Current Practices Survey
- Workload Guidelines/Time Standards
- Workload Standards Brochure

The guide will be a self-help manual on Workload and Time Management and will be customized to the registries' tasks and circumstances. The brochure will be suitable for explaining the registry workload to interested parties.

### 7.3.7 State Cancer Profiles Web site

NPCR contributes in the development of the State Cancer Profiles Web site, which provides a system to characterize the cancer burden in a standardized manner in order to motivate action, integrate surveillance into cancer control planning, characterize areas and demographic groups, and expose health disparities. The focus is on cancer sites for which there are evidence based control interventions. Interactive graphics and maps provide visual support for deciding where to focus cancer control efforts. The State Cancer Profiles can be found at: http://statecancerprofiles.cancer.gov/.

### 7.3.8 American Cancer Society (ACS) Cancer Facts & Figures

NPCR participates in the development of the American Cancer Society Cancer Facts and Figures which presents data on cancer incidence, mortality, survival, cancer risk factors, and annual estimates of expected new cases and deaths. Findings for the US population as a whole, along with detailed state-by-state data on cancer cases and deaths are included. The ACS Cancer Facts and Figures can be found at: http://www.cancer.org/docroot/STT/STT_0.asp.

## 7.4 State Data Use

| VII . DATA USE |
|---|
| c. The central cancer registry, state health department, or its designee annually uses registry data for planning and evaluation of cancer control objectives in at least three of the following ways:<br>1. Comprehensive cancer control<br>2. Detailed incidence/mortality estimates<br>3. Linkage with a statewide cancer screening program to improve follow-up of screened patients<br>4. Health event investigation(s)<br>5. Needs assessment/program planning<br>6. Program evaluation<br>7. Epidemiologic studies |

| IX . COLLABORATIVE RELATIONSHIPS |
|---|
| a. The central cancer registry actively collaborates in the state's comprehensive cancer control planning efforts.<br><br>b. The central cancer registry establishes a working relationship with all components of the National Cancer Prevention and Control program to ensure the use of registry data to assess and implement cancer control activities. |

Standard VII.c, Data Use, enumerates required data uses by participating program registries. The Funding Opportunity Announcement for the funding cycle commencing in 2007 specifies registries describe their efforts to promote the use of registry data for planning and evaluation of cancer control activities. In addition, Standard IX, Collaborative Relationships, specifies that funded registries must establish and maintain collaborative relationships with Comprehensive Cancer Control Programs and National Breast and Cervical Cancer Early Detection Programs, if funded.

Data collected by state cancer registries enable public health professionals to better understand and address the cancer burden. Registry data are critical for programs focused on risk-related behaviors or on environmental risk factors. Such information is also essential for identifying when and where cancer screening efforts should be enhanced, and for monitoring the treatment provided to cancer patients. In addition, reliable registry data are fundamental to a variety of research efforts, including those aimed at evaluating the effectiveness of cancer prevention, control or treatment programs.

The NPCR report, “Data for Cancer Control Planning and Evaluation: Partners’ Meeting”, March 2002, provides a blueprint for the integration of cancer registry data into cancer control activities. The report is available at http://www.cdc.gov/cancer/npcr/partners.htm.

### State Registry Contacts

Each central registry may use its website to present its own information, activities, and publications featuring data quality, data use, and other studies. NPCR provides links to each central registry website at http://apps.nccd.cdc.gov/cancercontacts/npcr/contactlist.asp. The NPCR contact list also provides an important link to the individual cancer registry programs supported by NPCR.

## 8.0 Collaborative Relationships

NPCR works with national organizations, state registries, and other key groups to develop, implement, and promote effective cancer surveillance practices and activities. The NPCR website at http://www.cdc.gov/cancer/npcr/partners.htm lists DCPC partners and highlights collaborative activities focusing on cancer surveillance issues.

NPCR collaboration occurs in many forms:

- providing funding and technical support for studies performed by collaborating agencies;
- recruiting program states for collaborative studies;
- requiring the collection of data items or data linkages to support other agency goals;
- providing technical advice on surveillance issues;
- working with many agencies to effect a major change in surveillance models, coding systems, or rules;
- sponsoring and participating in national organizations;
- publishing data cooperatively with other organizations; and
- co-sponsoring conferences to define directions for cancer surveillance policies and activities.

### 8.1 NPCR Work Groups

**Collaborators:** NPCR and state program representatives

NPCR formed two workgroups, the NPCR Central Cancer Registry Council (NCCRC) and the Scientific Workgroup (SWG). Each workgroup provides a forum for information sharing and discussion. The NCCRC focuses on issues related to the implementation of new or changed data item collection and/or submission requirements, program

standards, and quality control activities as they relate to NPCR data. The NCCRC, co-chaired by members of NPCR's ORTAT and SRT, consists of representatives from NPCR-funded programs. State representatives serve rotating two-year terms to provide an opportunity for participation from all funded programs. The SWG is led by a member of the SRT and focuses on issues related to data use, analysis, and linkage to other data sets.

## 8.2 Indian Health Service

**Collaborators:** NPCR and Indian Health Service (IHS)

"Nationally, American Indian and Alaskan Native (AI/AN) communities have lower rates of cancer. However, in certain regions such as Alaska and the Northern Plains states, AI/AN cancer incidence and mortality rates exceed those for the US general populations. As a response to these disparities, the CDC supports numerous cancer surveillance, prevention and control projects in Indian Country through an Inter-agency agreement between the Indian Health Service (IHS) and the CDC's Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Control." http://www.ihs.gov/MedicalPrograms/EPI [click on Cancer].

Data for Native Americans are included in *United States Cancer Statistics* (USCS) (http://apps.nccd.cdc.gov/uscs/). NPCR may require programs to conduct data linkages between the IHS patient registration database and the central registry databases to improve identification and classification of American Indians and Alaska Natives in the cancer registries.

## 8.3 Multi-Agency Projects

NPCR collaborates with other national and international organizations on several projects to develop standards and rules to ensure consistent data collection.

### 8.3.1 TNM Staging Classification

**Collaborators:** CDC, International Union against Cancer (UICC) (http://www.uicc.org/), and the American Joint Committee on Cancer (AJCC) (http://www.cancerstaging.org/). This collaborative effort has multiple goals:

- develop and maintain a standardized staging classification suitable for cancer registries and screening programs compatible with Tumor Node Metastasis (TNM) and capable of ensuring stability of criteria over time;
- monitor the utilization of the TNM classification to detect problems in interpretation and application of TNM standards;
- expand the TNM classification to include more anatomic sites and tumor types;
- continue to evaluate existing classifications for their relevance in view of new developments in imaging, diagnosis, and management;

- disseminate updated information through appropriate publications; and
- assess prognostic factors' information and develop a system to serve as a prognostic index.

### 8.3.2 Collaborative Staging System

**Collaborators**: NPCR, AJCC, the National Cancer Registrars Association (NCRA), SEER, NAACCR, the National Cancer Institute of Canada (NCIC), CoC

The goal of this collaborative effort is to develop, produce, and maintain the Collaborative Staging (CS) system, an innovative approach to collecting stage data uniformly in cancer registries throughout the United States and Canada. This system has replaced separate stage data collection by the AJCC's Tumor, Node, Metastasis (TNM) system, the SEER Extent of Disease (EOD) coding scheme, and two versions of a summary staging system used by many state central cancer registries. The CS system collects several discrete data elements related to extent of disease and their determination by clinical or pathologic criteria; these elements are then evaluated by a computer algorithm to derive stage classifications needed for data analysis. The Collaborative Staging system was implemented for cancers diagnosed as of January 1, 2004. Information on Collaborative Staging is available on the AJCC website at http://www.cancerstaging.org/cstage/index.html.

### 8.3.3 Multiple Primary and Histology Coding Rules

**Collaborators**: NPCR, SEER, CoC, AJCC, NCRA, NAACCR, and Statistics Canada

The goal of this collaborative effort is to develop, produce, and maintain Multiple Primary and Histology (MP/H) coding rules. These rules represent a revised system for determining the number of primary cancers occurring in an individual over the course of a lifetime and applying the appropriate ICD-O-3 topography and morphology codes to each primary.

The system replaces generic rules for all cancer sites with a new series of both generic and site-specific rules, and addresses the appropriate application of ICD-O-3 codes for complex morphologies. The rules are designed to be translatable into computerized algorithms applied to cancer database records. The Multiple Primary and Histology Coding Rules system was implemented for cancers diagnosed beginning January 1, 2007. Information on the MP/H rules is available on the SEER website at http://www.seer.cancer.gov/tools/mphrules/.

NPCR provided additional support for nationwide training of cancer registrars in the application of the new rules by funding attendance at "train the trainer" sessions for NPCR-funded central registry personnel. The designated trainers, in turn, provide training for registrars reporting to the central registries.

## 8.4 Modeling Electronic Reporting Project (MERP)

**Collaborators**: NPCR, NCI-SEER, CoC, NAACCR, SNOMED, software vendors, hospital cancer registries, and central cancer registries

The purpose of this project is to advance the cancer surveillance community's efforts to capture electronically available data from the electronic health record and other data sources. Project objectives are to:

- create robust, scalable and transportable models for electronic case ascertainment in hospitals;
- create Public Health Information Network (PHIN)-compliant data exchange messages using standard vocabularies between hospital and central cancer registries;
- contribute toward a national plan and model that will provide an infrastructure for electronic data exchange among cancer registries; and
- assess the feasibility and utility of the model through an implementation pilot.

Information on the MERP project is available on the NPCR website at http://www.cdc.gov/cancer/npcr/tools/merp/.

## 8.5 North American Association of Central Cancer Registries (NAACCR)

"NAACCR is a professional organization that develops and promotes uniform data standards for cancer registration; provides education and training; certifies population-based registries; aggregates and publishes data from central cancer registries; and promotes the use of cancer surveillance data and systems for cancer control and epidemiologic research, public health programs, and patient care to reduce the burden of cancer in North America."

NPCR currently funds NAACCR under CDC's Standards Development and Maintenance for Cancer Surveillance cooperative agreement to provide resources for standard-setting activities related to the operation of population-based cancer registries. The stated purposes of the cooperative agreement are to:

- improve the quality of population-based central cancer registry data and operations through data item and transmittal standards;
- facilitate coordination and communication from health care facilities to (and among) central cancer registries; and
- promote the use of cancer incidence data for cancer control such as health care interventions planning, resource allocation, program evaluation, and research.

NPCR contributes to the definition of data standards maintained and published by NAACCR, and in turn uses protocols and methodologies published by NAACCR for the evaluation of data submitted to the NPCR-CSS. NPCR staff members actively participate on NAACCR committees and workgroups to develop consensus standards for the cancer registry community. NAACCR also collaborates in the publication of the annual *United States Cancer Statistics* (USCS) report (http://apps.nccd.cdc.gov/uscs/).

The NAACCR website is http://www.naaccr.org.

## 8.6 National Cancer Registrars Association (NCRA)

"NCRA is a not-for-profit association representing cancer registry professionals and Certified Tumor Registrars (CTR). NCRA's primary focus is education and certification with the goal to ensure all Cancer Registry professionals have the required knowledge to be superior in their field. Worldwide, there are over 4,200 NCRA members and over 4,000 CTRs. Cancer Registrars capture a complete summary of the history, diagnosis, treatment, and disease status for every cancer patient. Registrars' work leads to better information that is used in the management of cancer, and ultimately, cures."

CDC provides funds to support the NCRA annual conference. This conference advances professional development of cancer registrars by providing an educational opportunity for registrars in hospitals and central registries to increase their knowledge and expand their professional expertise.

The website for NCRA is http://www.ncra-usa.org.

## 8.7 International Association of Cancer Registries (IACR)

"The International Association of Cancer Registries (IACR) was founded in 1966, as a professional society dedicated to fostering the aims and activities of cancer registries worldwide. It is primarily for population-based registries, which collect information on the occurrence and outcome of cancer in defined population groups (usually the inhabitants of a city, region, or country). To ensure that cases are properly recorded, and that the statistical data gathered are complete and can be used to make valid comparisons, cancer registries must conform to accepted working practices and standards. The Association was created to foster the exchange of information between cancer registries internationally, so improving quality of data and comparability between registries. The Association is a non-governmental organization which has been in official relations with the World Health Organization since January 1979."

CDC provides funds to support the IACR annual conference. This conference advances professional development by providing an educational opportunity for cancer registrars from international cancer registries to increase their knowledge and expand their professional expertise. Support of this conference is consistent with CDC's mission to support population-based cancer registries worldwide. The IACR is headquartered in Lyon, France.

The IACR website address is http://www.iacr.com.fr/.

## 8.8 International Union Against Cancer (UICC)

"The UICC is the leading international non-governmental organization dedicated exclusively to the global control of cancer. Its vision is of a world where cancer is eliminated as a major life-threatening disease for future generations. UICC's mission is to build and lead the global cancer control community engaged in sharing and exchanging knowledge and competence; transferring scientific findings to clinical, patient and public settings; systematically reducing and eliminating disparities in prevention, early detection and treatment; and delivering the best possible care to people living with cancer in every part of the world."

The CDC played an active role in planning a conference track addressing public health, cancer prevention, and early cancer detection during the 2006 UICC Quadrennial Congress and Cancer Organizations Combined Conference. This conference, held in Washington D.C., brought together leading clinicians, practitioners, organization leaders, patient care experts, and public health experts from around the world to discuss current strategies to translate what is known and proven about cancer control into action for diverse economic communities worldwide. The UICC is headquartered in Geneva, Switzerland.

The UICC website address is http://www.uicc.org.

## 8.9 National Coordinating Council for Cancer Surveillance

"The mission of the National Coordinating Council for Cancer Surveillance (NCCCS) is to coordinate cancer surveillance activities within the United States through communication and collaboration among major national cancer organizations, ensuring that the needs of cancer patients and the communities in which they live are fully served; that scarce resources are maximally used; and that the burden of cancer in the United States is adequately measured and ultimately reduced. The NCCCS was created to provide a forum for examining the current state of cancer surveillance operations, identify the broad issues involved, and recommend practical approaches that will facilitate the work of registries and contribute to the goal of coordinating data collection and improving data quality across the nation. The council enables these organizations to collaborate on cancer monitoring and registry operations."

NPCR participates with the ACS, CoC, SEER, NCRA, and NAACCR on the NCCCS.

## 8.10 State Collaborative Relationships

| Program Standard Reference | | |
|---|---|---|
| **IX.** | **Collaborative Relationships** | |
| | c. | The central cancer registry establishes and regularly convenes an advisory committee to assist in building consensus, cooperation, and planning for the registry. Representation should include key organizations and individuals both within (such as representatives from all cancer prevention and control components) and outside the program (such as hospital cancer registrars, the American Cancer Society, clinical-laboratory personnel, pathologists, and clinicians). Advisory committees may be structured to meet the needs of the state/territory such as the Comprehensive Cancer Control Program committee structure, an advocacy group, or a focus group. |

NPCR Standard IX.c, listed in the box above, requires the central cancer registry to establish a committee to advise the registry and assist in building consensus and planning. This committee, composed of community members, medical professionals, and registry professionals, serves as a resource for the central registry in gaining community and legislative support for its programs; the committee also assists the registry in developing long-range priorities and in monitoring progress toward attainment of goals. The registry may consult its advisory committee for:

- assistance in responding to citizen concerns about data privacy;
- assistance in lobbying for state funding; or
- guidance in selecting among competing priorities for use of scarce resources.

Through collaboration with committee members, the registry gains access to a diversity of viewpoints reflecting community needs, develops advocates, and widens opportunities for promoting data use.

# 9.0 Resources

Public Law 102-515 states in Sec. 399J, Technical Assistance in Operations of Statewide Cancer Registries: "The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system."

NPCR's responsibilities are defined in the current Funding Opportunity Announcement. NPCR is responsible for the following activities:

- Technical assistance to central cancer registries for effective program management including, but not limited to: registry operations, data management, and budget management.
- Development of publicly available software programs for collecting and processing cancer registry data.
- Convene a meeting of the Program Directors, at least annually, for information sharing and updates, to provide the participants a forum to discuss issues of relevance, share successes and challenges, and to identify common solutions to problems.
- Convene an annual train-the-trainer meeting to provide education and training to central cancer registry trainers with the goal of building capacity within the central cancer registry to provide education and training to central cancer registry staff and reporters.

## 9.1 Technical Assistance for Program Management

NPCR provides general technical assistance to all program registries through:

- participating in standard-setting activities;
- publishing program requirements in grant applications;
- developing software programs to support registry activities;
- hosting conferences addressing public health surveillance issues;
- participating in research; and
- publishing materials focused on registry operations and procedures.

In addition to these general programmatic activities, NPCR program consultants are available to consult directly with registry management staff to resolve issues which may be affecting the registry's ability to attain or to adhere to program standards. NPCR monitors performance of participating programs by routine reports and by on-site and reverse-site visits.

## 9.2 Software Programs for Cancer Registry Data

NPCR supports the development of software to aid central registries in the collection and processing of cancer data. The software is distributed free to the public health community.

### 9.2.1 Registry Plus Software

Registry Plus is a suite of publicly available, free-of-charge Windows-based software programs used for collecting and processing cancer registry data. Registry Plus currently includes nine applications (see Table below), plus various utility programs. All programs are compliant with national standards and can be used separately or together

for both routine and special data collection. In addition, the applications are fully customizable for user/registry-specific needs.

A CDC security assessment of the Web Plus component was completed in September 2007. Web Plus met all NIST SP 800-37 Guide for Security Certification and Accreditation of Federal Information Systems and FIPS 200 Minimum Security Requirements for Federal Information and Information Systems. Security scans were run that tested the program code and ensured no vulnerabilities exist in the code itself. It is the responsibility of installing organizations to secure their own infrastructure.

## REGISTRY PLUS SUITE OF SOFTWARE PROGRAMS

| PRODUCT | FUNCTION AND USE |
|---|---|
| **Abstract Plus** | • Used to abstract and code cancer cases using standard data items and codes<br>• Customized by central registries for distribution to and use by hospitals and other reporting sources to abstract reports of cancer, as well as for abstraction at the central registry<br>• Also used for special projects and start-up registries |
| **Web Plus** | • Used to abstract, code, and collect cancer data securely over the Internet<br>• Customized by central registries for abstracting and reporting cancer by physician's offices, low-volume facilities, and for follow-back efforts aimed at increased cancer reporting<br>• Supports upload of files of abstracts in NAACCR format; used by hospitals and non-hospital reporting sources for submission of files of cancer reports to central registries<br>• Eliminates need to distribute and maintain software at reporting facilities |
| **Prep Plus** | • Used to receive and apply data quality and completeness edits to batches of abstracts<br>• Customized by central registries for processing, reviewing, and editing reported abstracts |
| **CRS* Plus (including TLC* Plus)** | • Used to link and consolidate edited abstracts in the central registry<br>• Customized by central registries for creating consolidated patient and tumor tables for the same person and tumor with the best values from multiple sources<br>• Provides for automatic determination of multiple primary tumors and consolidation of data items from multiple case reports into incidence records<br>• Produces extracts for NPCR and NAACCR call-for-data submissions<br>• Provides standard management reports |
| **Link Plus** | • Uses probabilistic methods to link records<br>• Configured by central registries for:<br>- Detecting duplicates within the registry to reduce over-counting of cancers<br>- Linking cancer registry files to external files for follow-back and research purposes |

| PRODUCT | FUNCTION AND USE |
|---|---|
| **Registry Plus Online Help** | • Used to look-up abstraction and coding information<br>• Contains current versions of all standard abstracting and coding manuals (NAACCR, FORDS, CS, ICD-O-3, SEER, ROADS)<br>• Facilitates abstraction by centralizing information into one easy-to-use resource<br>• Eliminates need to purchase and maintain manuals in hardcopy form |
| **HL7 Mapper Plus** | • Used to view and work with HL7 files and messages<br>• Imports HL7 files manually/directly from PHIN MS queue<br>• Tests messages for required data items; searches cancer terms to mark potential cases<br>• Parses HL7 messages and maps HL7 data elements to NAACCR data elements<br>• Builds a pathology lab database (MS Access, SQL Server, or Oracle)<br>• Will include abstracting module |
| **EditWriter3** | • Used to define data items and record layouts, specify editing algorithms, logic, and documentation, and generate metafiles |
| **GenEDITS Plus** | • Used to apply data quality edits to data files using metafiles and to generate error reports for error resolution |
| **Registry Plus Online Help** | • Single, integrated, user-friendly online help system for Windows<br>• Includes standard coding manuals that are cross-referenced, indexed, and context-linked<br>• Embedded in Registry Plus applications and is also available as a free-standing product |
| **Utility Programs** | • Small programs performing variety of useful functions for Registry Plus programs<br>• File Identifier (Recnizer) – identifies files in NAACCR-prescribed formats<br>• Record Converter (Northcon 11) – converts files between NAACCR layout versions |

*CRS: Central Registry System, TLC: Tumor Linkage and Consolidation

## Registry Plus Training Manuals

Training manuals are available for Abstract Plus and Web Plus (for both users and administrators). Manuals for Prep Plus, CRS Plus, and Link Plus are under development. The training manuals are available from the NPCR website, and can be downloaded for each application.

## Obtaining Registry Plus Programs

More information about the various Registry Plus programs, as well as installation files for Abstract Plus, Link Plus, Registry Plus Online Help, EDITS Tools, and Utility Programs can be downloaded from the Registry Plus section of the NPCR website: http://www.cdc.gov/cancer/npcr/tools/registryplus/.

Registries interested in obtaining other Registry Plus programs, or having questions about any Registry Plus programs, may contact NPCR at: cancerinfo@cdc.gov.

### 9.2.2 EDITS

EDITS software programs provide tools to improve data quality by standardizing the way data items are checked for validity. These tools can be built into interactive data collection systems to achieve real-time field-by-field editing during data entry. They can also be used in batch-editing processes for data already collected. EDITS provides software to support three types of data activities: defining standards for data quality, creating data collection processes, and analyzing data. The EDITS programs include EditWriter, the EDITS Application Program Interface, and GenEditsPlus.

EditWriter is a versatile and complete development environment for defining, testing, documenting, and distributing data standards and maintaining standard data definitions. EditWriter produces metafiles (a compiled database which contains all the logic, tables, and values needed to check data fields for validity) that can be used on many operating systems and hardware platforms. Single-item, cross-field, and inter-record checks can be included in metafiles. Standard metafiles are distributed to the registry community through postings on the NAACCR website at http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=136. A new metafile is released to accompany every new NAACCR layout, containing all the edits approved by the standard setters. Central registries may also develop and distribute customized metafiles to support state data requirements.

The EDITS Application Program Interface (API), a library of C language functions, can be incorporated into programs of many descriptions, including programs for interactive data entry, after-the-fact verification of data, recoding, reformatting, and vertical or horizontal subsetting. GenEditsPlus, the generic EDITS driver program, is a batch application for editing any data file with any Metafile. Records gathered under different circumstances using different programs can be interpreted in a uniform way when validated with the same metafile.

Additional information about the EDITS programs, and software downloads, are found at http://www.cdc.gov/cancer/npcr/tools/edits/. Originally written as MS-DOS programs, EDITS modules have been converted to the Windows operating environment.

An EDITS Online Help, which will link into the Registry Online Help, is under development. The EDITS Online Help will provide the edit logic to assist users in understanding why edits failures occur and how to resolve them.

## 9.3 Annual Program Directors Meeting

NPCR convenes a meeting of Program Directors at least annually for information sharing and updates. The meeting provides the participants a forum to discuss issues of relevance, to share successes and challenges, and to identify common solutions to problems. Participation of appropriate staff is a required recipient activity, and NPCR funds travel for up to two persons from each participating program for this meeting.

## 9.4 NPCR Education and Training

NPCR emphasizes the critical importance of training for cancer registrars to support the collection of reliable, consistent, high-quality data needed for cancer prevention and control activities. NPCR develops and produces training materials using multiple communication technologies to reach the training audience. The NPCR Training web page is at http://www.cdc.gov/cancer/npcr/training.

NPCR embraces these education core values:

- Education is an essential element in achieving data quality, completeness, and timeliness.
- Content of education programs and products must respond to issues identified in quality assurance activities.
- Educational opportunities must be offered continuously in diverse formats and methods of access.

Education objectives include:

- providing resources through sponsoring training opportunities, developing materials, and funding registries to participate in educational sessions;
- building the capacity of NPCR registries to provide education within their community of reporting facilities;
- monitoring the educational infrastructure for gaps in access to education; and
- searching for methods and technology to improve access to education for the entire cancer surveillance community.

NPCR supports in-person meetings and training for participating states, including:

- required trainer attendance at an annual Train-the-Trainer meeting in Atlanta;
- recommended attendance of at least one program registry representative at the annual NAACCR meeting;
- recommended attendance of at least one program registry representative at the annual NCRA meeting; and
- recommended attendance at training sessions for application of new or revised coding and data collection rules.

NPCR supports web-conferencing and/or teleconferencing for trainer meetings, and has also adopted the use of webcasts for training sessions. All training materials are accessible at the NPCR training web page, and provided at no cost.

### 9.4.1 NPCR Education and Training Series (NETS)

The NETS modules are a series of educational tools for state trainers to support central cancer registries in their role of providing education to staff and reporters. Each module provides specific instructions for the presenter(s), a comprehensive overview with Power Point slides, complete speaker's notes, case scenarios, and exercises with answer sheets that include the rationale for each answer. The modules cover the entire spectrum of education, from basic incidence reporting to advanced abstracting, and include topics of special interest for central registry staff. As each module is completed, it will be posted to: http://www.cdc.gov/cancer/npcr/training/ .

#### Training for the Trainer

"Building a Quality Presentation" provides information on identifying what training is needed, training methods, building Power Point presentations, and developing exercises.

#### Abstracting for the Beginner

"Beginner Module for Reporters" includes what registries do, why cancer data is collected, information flow from facility to the national level, confidentiality of health data, casefinding, reportable cases, coding, how cancers grows and spreads, and how to complete the electronic cancer reporting form.

#### Training for Central Registry Staff

"Quality Control of Data in the Central Cancer Registry" provides an overview of the principles of quality, use of data management reports, and various audit methods. "Validating Data with Text" includes the importance of text, how to record text, and what text to record.

#### Advanced Abstracting

Modules are available for head and neck, colorectal, lung, breast, gynecologic, and genitourinary. Each module includes anatomy and cancer characteristics, determining and coding primary site, stage and treatment, and multiple primaries. The modules also address such areas as interpreting diagnostic tests, determining metastases, and identifying first course of treatment versus secondary treatment. Modules are available at http://www.cdc.gov/cancer/npcr/training/abstracting/.

#### Data Use

"Uses of Cancer Registry Data" includes examples of data use for cancer control monitoring, health event investigations, geographic information, legislation and funding documentation, public health initiatives, interacting with the media, data linkages, statistics, data management reports, marketing the central cancer registry, and marketing data reporter and facility services.

### 9.4.2 Educational Materials for Cancer Registrars

NPCR has published additional materials to support registrar training, focusing on basic information for new registrars and coding for benign tumors of the central nervous system, which became reportable in 2004.

#### Fundamentals of Registry Operations

Available at: http://www.cdc.gov/cancer/npcr/training/training-sessions.htm, this series of downloadable tutorials is intended to be used as a training resource for new employees and as reference materials for experienced central registry or hospital registry professionals. The tutorials address various cancer registry functions and the necessary procedures for each. Subjects covered include:

- Case Ascertainment
- Principles of Abstracting
- Data Editing and EDITS
- Coding and Visual Editing
- Follow-up: Active and Passive
- Casefinding and Reabstracting
- Data Collection and Coding: Race and Ethnicity
- Basic Cancer Epidemiology and Biostatistics

#### Brain Tumor Registry Reporting Training Materials

NPCR developed training materials covering data collection for benign, borderline, and malignant central nervous system tumors, and is available at http://www.cdc.gov/cancer/npcr/training/btr/. All cancer registry standard-setting organizations have agreed to use these training materials to promote consistency in training. In addition to NPCR, these materials have been approved by the CoC, SEER, and NAACCR.

The slide presentation available at http://www.cdc.gov/cancer/npcr/training/btr/ppt/ was developed through a contract with NAACCR and reviewed by a NAACCR Registry Operations Committee's Brain Tumor subcommittee, which included representation from all cancer registry standard-setting organizations.

## 9.5 Recruitment Materials

Recognizing the implications of a cancer registrar shortage, NPCR developed a cancer registrar recruitment project with NCRA. "Quality Cancer Data Saves Lives: The Vital Role of Cancer Registrars in the Fight Against Cancer", is a set of three Power Point presentations of various length designed to describe the cancer registry career option to Health Information Management students and other allied health professionals. These presentations are available at: http://www.cdc.gov/cancer/npcr/registry/QualityData.

# 10.0 Guidance Documents

NPCR provides guidance documents to further assist the central registries in meeting the standards for participation. They are a more comprehensive discussion of the standard and include specific instructions for implementation.

## 10.1 Advisory Committee Guidance

### I. Background and Purpose

In 2007, with the new Program Announcement, the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) will implement new standards that require central cancer registries (CCRs) to have an advisory committee. NPCR has always recognized the important role an advisory committee can play in supporting the CCR, and NPCR program announcements have consistently stated that funded programs (Recipient Activities) are responsible for establishing or enhancing, and regularly convening, an advisory committee. However, this activity has not been included in previous NPCR program standards.

NPCR offers the following suggestions to CCRs who do not have procedures in place to meet this standard. CCRS that have an advisory committee may find these suggestions helpful in making the committee more useful. NPCR is not requiring a specific structure for Advisory Committees. The purpose of this document is to provide ideas so that states can maximize the usefulness of their Advisory Committee.

### II. Program Standards: Collaborative Relationships

The central cancer registry establishes and regularly convenes an advisory committee to assist in building consensus, cooperation, and planning for the registry. Representation should include key organizations and individuals both within (such as representatives from all cancer prevention and control components) and outside the program (such as hospital cancer registrars, the American Cancer Society, clinical-laboratory personnel, pathologists, and clinicians). Advisory committees may be structured to meet the needs of the state or territory, such as the Comprehensive Cancer Control Program committee structure, an advocacy group, or a focus group.

### III. General Committee Structure

Examples of possible structures include:

**Official state government advisory committee**

- Structure: Committee follows state regulations for advisory committees. (These usually require legislative representation.)
- Advantages:

- The requirements of the state may stipulate participation of representation from the legislature, therefore ensuring their participation.
- Legislative participation may facilitate direct communication to local and national legislators regarding CCR issues.
- Legislators can report on other pending legislation that may affect the CCR.

o Disadvantages:

- Getting committee approval may be cumbersome, and representation may be limited.
- Committee member appointment may also be cumbersome and not done in a timely manner.
- Committee cannot lobby Congress; however, individual members can.
- Legislating committee members from various state agencies does not ensure interest in the program, and input may be minimal.

**Part of the Comprehensive Cancer Control (CCC) Program**

o Structure: One of the Comprehensive Cancer Control Program committees may form a subcommittee to advise the CCR.

o Advantages: Members of the CCR advisory committee may be on other CCCP committees, and meeting can be scheduled in conjunction with other committee meetings to improve attendance and decrease expenses.

o Disadvantages: None identified at this time.

**Independent public committee**

o Structure: Advisory committee is established as a public advocacy committee.

o Advantages:

- The committee is more independent.
- CCR may have greater in-put on committee membership.
- Committee members may lobby local and national legislators.

o Disadvantages:

- Expenses must be provided by the CCR or another supporting organization such as the American Cancer Society.

**Hybrid**

o The committee may incorporate aspects of several of the models mentioned.

## IV. Purposes of a CCR Advisory Committee

- Assist in building consensus, cooperation, and planning for the CCR.
- Assist the CCR in setting goals and evaluating the efficiency and effectiveness of the CCR.
- Advocate for needed legislative changes.
- Serve as a CCR data request review committee.
- Recommend policies on data use.
- Address problem-reporting issues and advocate solutions to identified problems. For example, a hospital administrator might address the problem of a hospital's non-compliance, and a physician might address physician reporting through direct contact with individual physicians or physician groups.
- Provide spokespersons for the CCR to make presentations at state medical association and other professional meetings.

## V. Suggestions for Establishing an Advisory Committee

- Establish the responsibility, accountability, and multidisciplinary membership using a method appropriate to the CCR's organizational structure.
- Identify appropriate committee representatives, such as
    - All components of the state's cancer prevention and control programs.
    - Other state programs that may have relevant interaction with the CCR, such as the Tobacco Control Program.
    - Cancer surveillance partners, such as hospital cancer registrars, the American Cancer Society, clinical and laboratory personnel, pathologists, and clinicians. These partners may serve as subject matter experts.
    - Legislators.
    - Legal counsel (from CCR agency).
    - Other members as required by state legislation or regulations.
- Determine the meeting format (face-to-face meetings or conference calls) and frequency.
- Determine the advisory committee's mission. Example mission statements may be:
    - The mission of the (CCR) advisory committee is to coordinate cancer surveillance activities within the state

through communication and collaboration among major cancer organizations. In so doing, the (CCR) seeks to ensure the needs of cancer patients and the communities in which they live are fully served, scarce resources are used maximally, and the burden of cancer in the state is adequately measured and ultimately reduced.

- The (CCR) advisory committee was created to provide a forum for examining the current state of cancer surveillance operations and identifying the broad issues involved, to recommend practical approaches to facilitate the work of the (CCR), and to contribute to the goal of coordinating data collection and improving data quality across the state. The (CCR) advisory committee enables these organizations to collaborate on cancer monitoring and registry operations.

- Determine the naming format and structure for the committee. The standard was designed to provide programs with the flexibility to structure and name their advisory committee in a way that meets the needs of the program.
- Establish the funding mechanism.
  - Will committee member travel be reimbursed? By whom?
  - Who will provide meeting space?
  - Will refreshments or meals be provided? If so, who will provide funding?
  - What is required by state legislation or regulations?

### VI. Monitoring Compliance

- Compliance with this standard will be monitored through self-assessment on the NPCR Program Evaluation Instrument.

**Note:** This document has been reviewed and edited by the NPCR Cancer Registry Council (formerly known as the NPCR Logistics Workgroup).

## 10.2 Attribution Guidelines-Partners

### I. Background

In 1992, Congress responded to the need for local, state, regional and national cancer incidence data by passing the Cancer Registries Amendment Act, Public Law 102-515. The act authorized the Centers for Disease Control and Prevention (CDC) to establish the National Program of Central Registries (NPCR). Funds are provided through Congressional appropriation to the Division of Cancer Prevention and Control (DCPC), Cancer Surveillance Branch (CSB). CDC's NPCR supports central registries and promotes the use of registry data in 45 states, the District of Columbia, Puerto Rico and the Pacific Islands Jurisdictions.

CDC-NPCR funds are used to support activities of partners within the cancer surveillance community. Support of these partnerships is essential to NPCR accomplishing its mission.

In order to demonstrate the effectiveness of the use of program funds and to assure continued Congressional financial support, proper acknowledgment of products and activities supported through NPCR funding is critical. This document provides guidance, developed by DCPC, CSB, for partners to follow in providing appropriate acknowledgment of CDC-NPCR support.

## II. General Guidelines

The guidelines outlined in this document are to be used by CDC-NPCR partners when CDC-NPCR funds are applied to cancer surveillance activities:

- Conducting an educational meeting or national conference
- Developing Web site content (e.g., central registry or state health department Web sites)
- Developing, producing and/or distributing articles, reports, publications and other products (e.g., Journal articles, annual reports)

## III. Specific Guidelines

**Contracts**

- All contract deliverables must comply with U.S. Department of Health and Human Services (DHHS) and CDC logo requirements. In general, the DHHS and CDC logos must appear on products, publications, announcements, and Web site postings.
- All documents and presentations developed and delivered under contract for CDC's use should contain no brand or marking of contractors who developed the material. Materials of this type should be marked with CDC logos and information only.
- All contract deliverables must comply with funding attribution verbiage as listed within the notice of contract award (e.g., "This project was supported by contract number xxx-xxxx-xxxxx from Centers for Disease Control and Prevention.)".
- The title, content and attribution of the products, publications, announcements and Web site postings are expected to reflect that it is a CDC-NPCR funded product or activity.

**Cooperative Agreements**

All cooperative agreement activities and products (e.g., publication of annual reports, CCR program manual) must comply with funding attribution verbiage as listed within the notice of grant award (e.g., "We acknowledge the Centers for Disease Control and Prevention, for its support of the xxxxxxxx, and the printing and distribution of the xxxxxxxx under cooperative agreement xxx/xxxxxx-xx awarded to xxxxxxx. The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention").

**Data Use in Research Activities and Publications**

CDC-NPCR provides funding and technical support to states, territories and numerous national partners. Support for cancer registries is a line item in the budget from Congress, and these dollars are used to promote the collection of complete, timely, and high quality population-based cancer data for CDC-NPCR. When the data, that are collected and reported through support from CDC-NPCR, are used for research and publication, acknowledgment of CDC-NPCR in the text is critical. Text similar to the following sentence should be included: "These data were collected by xxxxxxx Cancer Registry participating in the National Program of Cancer Registries (NPCR) of the Centers for Disease Control and Prevention (CDC)." (e.g., CDC-NPCR should be described in the Technical Notes).

## 10.3 Data Security Guidance

### I. Background and Purpose

In 2007, the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) implemented new standards that include requirements for data security procedures. This document is provided to help Central Cancer Registries (CCRs) meet the NPCR standards and help CCRs transmit cancer data more securely.

### II. Standards for Data Security

The central cancer registry primarily uses a secure Internet-based, FTP, or encrypted e-mail mechanism to receive data from all reporting sources.

### III. Data Security Issues

Confidential medical information that may contain patient names, addresses, birthdates, and social security numbers is transmitted frequently to and from the CCR via the postal system. This presents a large risk to the CCR that confidential medical records may be intercepted and used for identity theft, or confidential medical information may be revealed. Submission of non-encrypted electronic registry data on disks or CDs via the postal system presents the same risks as submitting paper records.

- NPCR strongly recommends these alternatives to sending medical information via the postal system:
  - WebPlus provides secure electronic data submission for reporters with Internet access.
  - CCR can provide a secure Internet-based FTP or Web site where data can be posted.
  - Encrypted files can be attached to an email message.
  - CCRs can encourage reporters to use the encryption options provided by their software vendors.
  - CCR can provide an encryption program for all electronic reporters.
  - Encrypted data can be submitted via disk or CD if Internet access is not available.
- All states have small-volume reporters that may send paper copies of patient information through the mail to the CCR to be abstracted by CCR staff. In addition, paper copies of pathology reports are frequently sent to the CCR through the mail. Pathology report and death clearance follow-back letters are also sent and returned to the CCR via the postal system.
  - Alternatives to sending medical information via the postal system:
    - WebPlus provides secure electronic data submission. If the CCR prefers, reporters can complete the demographic information and place other cancer information in the text fields for coding by CCR staff.
    - In some instances the installation and training required for WebPlus for facilities with very few cases a year may not be appropriate. Also, some reporters may not have internet access. If WebPlus is not an option, Abstract Plus can be used in the same way, but data must be encrypted and submitted as either an e-mail attachment or on disk or CD. NPCR considers this electronic reporting even when the CCR staff does the coding.

- A PDF file can be attached to an e-mail message if medical records are being sent to the CCR from hospitals or physician offices. This may also be an option for receiving pathology reports. This method is more secure than the postal system, but is not considered electronic transmission because the information must be keyed in to the CCR registry system.
- Follow-back letters can be sent and received via an e-mail attachment. Forms can be completed electronically (such as in a Microsoft® Word document) and returned to the CCR as an e-mail attachment.
- The use of a secure fax is another option. This can be via a standard or encrypted fax (which is fairly expensive). The fax machine must be located in a secure area. Medical records can be faxed to the CCR and the CCR can fax follow-back forms to reporters. The standard fax is not very secure, but it is better than the postal system.

## 10.4 Electronic Reporting Guidance

### I. Background and Purpose

In 2007, the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) implemented new standards that require electronic reporting. This document is provided to help Central Cancer Registries (CCRs) meet the NPCR standard.

### II. Standards for Electronic Reporting

- At a minimum, 95% of reports from hospitals are submitted to the central cancer registry in an electronic format (where the medical records are owned by the hospital).
- At a minimum, 85% of reports from non-hospital reporting sources are submitted to the central cancer registry in an electronic format. (E.g., radiation therapy centers, ambulatory surgery centers, and in-state and out-of-state pathology laboratories where medical records are owned by the reporting source.)
- At a minimum, 75% of reports from physician offices, identified as required to submit cancer cases to the central cancer registry, do so in an electronic format (where the medical records are owned by the physician). This includes responses from physicians to central cancer registry inquiries.

### III. Clarifications for Electronic Reporting Requirements

Electronic data exchange is a broad term used to describe methods of transferring data that do not require manual data entry to create an abstracted record.

- Electronic reporting standards apply to all data submitted to the CCR regardless of whether it is proactive (data routinely submitted) or reactive (response to follow-up for pathology reporting or death certificate clearance).
- Examples of electronic reporting:
    - Encrypted NAACCR-formatted cancer data submitted on a disk or CD-ROM.
    - Data entered using Web-Plus or another CCR online reporting program.
    - Data submitted (preferably to a secure fax machine) from a facility or physician's office on a data form that can be scanned and uses forms recognition software to create an electronic data file.
    - Data CCR staff abstracted from a source document (either at the facility or from mailed copies of records) on a laptop or directly into a CCR database. In this case, the CCR has "an agreement with the facility to do their reporting" similar to other abstracting arrangements. NPCR has issued guidance on when CCRs can use NPCR funds to support this type of arrangement on a limited basis; see *Guidance on Direct Data Collection.*
    - Pathology reports submitted in HL7 or other electronic media requiring conversion to NAACCR or another CCR software file format.
- Methods of electronic data exchange that do not meet the electronic reporting standard:
    - A facility sends in a paper abstract form.
    - A pathology laboratory sends paper copies of pathology reports.
    - A physician's office or facility sends a standard paper form with patient information that must be manually keyed in to a CCR database.
    - CCR personnel call a facility or physician for primary patient information (not just for clarification of conflicting data).

## IV. Challenges to Electronic Reporting

Many CCRs use printed forms to collect some information. These forms may be an abstract form completed by a small-volume hospital or physician's office to report cases, or a form sent by the CCR to obtain follow-back information for pathology reports or death certificate clearance. These forms are not considered electronic reporting because the information received must be keyed in to the CCR registry software.

- Alternatives to non-electronic reporting:
    - NPCR's Web Plus online abstracting capability is ideal for complying with electronic reporting requirements for reporting from physicians'
    - If WebPlus is not a suitable option (the facility does not have Internet access, or the case load is too small to justify training), the use of forms recognition software allows the CCR to receive a faxed or e-mailed form that can be written to the database automatically. The information is considered electronic reporting and is much more efficient, saving the time needed to key in the information.
- Electronic forms (such as in Microsoft® Word) distributed via the Internet provide the highest efficiency. The CCR can e-mail a form containing known information to the reporter, who can then complete their portion electronically, eliminating the problems of handwriting recognition. As an option to Internet transmission, the reporter can be mailed a blank electronic form on CD or disk), which they can complete on their computer and fax to the CCR.
    - NPCR is providing this analysis of forms recognition software. The report identifies potential forms recognition products in the market, compares their strengths and weaknesses, and provides cost estimates. When using forms recognition software, the following tips will increase accuracy:
        - Use check boxes when possible.
        - Understand that every character may not be interpreted accurately; visual comparison of the original and the electronic form will be necessary.
        - Use a word processor instead of handwriting to complete forms. Handwritten responses present significant problems in interpretation.
        - A program to convert the forms recognition output into a NAACCR or CCR software format will be needed.
        - NPCR is happy to provide you with a forms recognition software report prepared by Northrop Grumman. The recommendations included in the report are those of the Northrop Grumman Web

Applications Team. NPCR does not recommend or endorse any software.

Additional information on DCPC Forms Recognition Software Analysis can be found in Appendix I.

## 10.5 Guidance for Use of NPCR Funding for Data Collection

As a general rule, NPCR dollars should not be used for data collection (abstracting) from reporting facilities.

Exceptions can be made by specific request with adequate justification.

Unobligated funds can be used on a one-time basis to catch up on delinquent cases.

Justification must be provided on a site-by-site basis for why it is more efficient and cost effective for CCR staff to do data collection.

Acceptable justification includes:

- All other means of obtaining the cases have been exhausted.
- Reporting facility has a very small number of reportable cases.
- Frequent turn over in non-cancer registry reporting facility requires repeated on-site training.

## 10.6 Physician Reporting Guidance

### I. Background and Purpose

In 2007 the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) implemented new standards that emphasize non-hospital reporting, including specific physician reporting requirements. NPCR legislation requires funded states to have "A means to assure the **complete reporting** of cancer cases to the statewide cancer registry **by physicians, surgeons, and all other health care practitioners** diagnosing or providing treatment for cancer patients, **except** for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities". The 2007 NPCR standards require **at least 75 percent of physicians, surgeons, and all other health care practitioners** to report required cases **within 24 months of the close of the diagnosis year**.

For CDC to monitor compliance with this standard, each central cancer registry (CCR) must provide an accurate count of these reporters to use as a denominator, and to monitor reporting compliance and timeliness.

Complete implementation will vary by state. NPCR offers the following suggestions to states that do not have procedures in place to meet this standard.

## II. Suggestions for Implementing Physician Reporting

- Implement physician reporting gradually to make the process more manageable.
    - Start the reporting with one specialty physician or group and then move on to the second, etc.
    - Train office staff to report one site at a time and then add more sites?
- Determine the **physician specialties** that represent the greatest number of missed cases by evaluating
    - Follow-back requirements for pathology reports.
    - Follow-back requirements for death certificates.
    - Rates for individual cancers compared to national rates to identify physician specialties where cases may be missing, such as urology (prostate) or dermatology (melanoma).
- Target the physician specialty with the highest number of missed cases first, and add additional specialties in an ongoing process.
- CCRs may want to require larger physician practices to report proactively, and other small-volume reporters to report in response to inquiries from the CCR. Regardless of their reporting requirements, they will be counted in the denominator for determining NPCR standard compliance.
- Develop physician reporting procedures.
    - Develop a data and software manual for physician office staff.
- Send new physician reporters a letter of introduction explaining the CCR law that requires that physicians report all cases not reported by other facilities, procedures for how and when to report, and a copy of the reportable list. Include a copy of the law, HIPAA information, and any state-specific documents, or copies of the HIPAA legislation information available on the NAACCR Web site.
    - Have letters sent to physicians from state officials outlining reporting requirements.
    - Have CCR administrator send letters to potential reporters.
    - Send letters with information on the CCR and direct letters to Medical Director or Office Manager.

- Arrange to make presentations on the importance of physician reporting to various physician association meetings. Include example of how data are used. Possible meetings include:
  - State AMA meeting
  - State or local Urology meeting
  - State or local Dermatology meeting
  - State or local Oncology Association meeting
- Follow up with a personal contact with the physician or practice manager. Focus on the impact of physician reporting on cancer surveillance and the importance of population-based cancer data for cancer control efforts, and list the reports that are available as a result of reporting.

- Use NPCR software Web Plus for physician reporting when possible. This program uses the Internet for reporting, and all software and case information are maintained on a CCR server providing data security. Provide demonstrations of available tools.
- Use NPCR software Abstract Plus for physician reporting if the physician office does not have access to the Internet.
- Link with ICD-9 or CPT billing codes to generate CCR casefinding list
- Provide training with targeted, clear, and concise educational materials and provide ongoing support.
  - Offer to provide training for the physician office staff learning how to abstract reportable information.
- Provide on-going communication
  - Keep lines of communication open even if e-reporting is in place.
  - Send letters of recognition for good reporters
- Try to achieve links to licensure based on reporting compliance in states that require licensure. (i.e., Licensing is contingent on meeting all state reporting rules.) CCR sends a list of noncompliant physicians to the state licensing board.
- Communicate with other central registries about physician reporting to exchange tips, ideas for success, etc.
- See NPCR website http://www.cdc.gov/cancer/npcr/ for additional information on all CDC products including Web Plus and Abstract Plus.

## III. Methods for Identifying Physicians

- Use follow-back for pathology reports and death clearance to identify new physician sources
- Use your state's physician licensing agency list, which may be available electronically to identify new physicians and update mailing information. This database may be available within the Health Department. Each state should review the physician license list to ascertain its usability for identifying physicians and their contact information.
    - Set up a continual process to include newly practicing physicians, and exclude physicians who no longer practice in that State.
- Look for other state programs/associations/societies which may already have physician directories that can be shared.
- Obtain hospital staff physician lists that may be updated annually.
- Investigate the use of physician address services.
- Use M.D.s on the advisory committee to advocate for physician reporting. Physicians could also offer counseling to the CCR on how to achieve compliance, or offer to make presentations to specialty organizations.

## IV. How to Count Physicians for PEI and NPCR Standards Compliance

- **Multiple physicians that practice in a clinic or other practice:** The entity responsible for reporting is the clinic or practice, even if it is owned by a physician or multiple physicians. The clinic or practice owns the records, not each individual physician. The clinic is also counted as one reporting source, like an ambulatory surgery center that may have multiple surgeons.
- **Physicians with more than one office or practice address:** Reporting depends on ownership of the records. If an individual physician has multiple offices, reporting requirements are determined by the CCR. It may be the responsibility of each office (because that's where the records are located), or the physician if all records are maintained in a single record-keeping system. It is possible for a single physician to be counted multiple times if reporting comes from several offices.

## V. How to Establish a Data Reporter's Database

- Determine if the physician database is to be separate, or part of a database that includes other reporters such as ambulatory surgery centers and radiation oncology centers.
- Find out if any other department maintains a physician database that could be used (such as departments responsible for physician licensing or for emergency medical services).
- Develop a new database if necessary using Microsoft® Access®, Microsoft® Excel, or similar software products.
    - CCR software may allow the generation and incorporation of a single Doctor file which provides information on the central registry's reporting physicians; this information is then available within the applications for reports, etc.
- Update the database on an ongoing basis (as responses are returned) and at least annually.
- Include information required to complete the NPCR Program Evaluation Instrument (PEI). Suggestions for other information include:
    - Physician or facility identification number
    - Contact information, including the entire address and the name of the person responsible for responses
    - Reporting source, which can be an individual physician, clinic, or physician group; one physician can be listed with multiple clinics or practices
    - Physician specialty

- Reporting status (proactive, response to inquiries, does not respond)
- Method of reporting (Web Plus, electronic form, or other)
- Date last updated
- Initials of person updating
- Source of update
- Use follow-back for information to complete missing fields.

## VI. How to Improve Reporting Compliance – Suggestions from the 2007 Program Directors' Meeting

- If state laws prohibit sending information electronically, work to change laws. If non-hospital sources are prohibited from sending via internet, offer alternative methods that would enable centers to do electronic reporting (use of disks, Web Plus, etc.)
- Levy fines for non compliance
- Urge the DOH to give law some teeth
- Involve the advisory committee
- Find vocal professional groups supportive of the CCR
- Standardize text
- Address issues of data release
- Invite reporters to annual workshops and training
- Define the benefits for non-hospital sources
- Offer feedback for non-hospital sources – running data reports, creating report cards
- Build a rapport
- Develop a newsletter

# Appendix A: Reference List for Chapter 1: Introduction, Overview and Accomplishments


(1) U.S. Cancer Statistics Working Group. United States cancer statistics: 2004 Incidence and mortality web-based report version. *Centers for Disease Control and Prevention, and National Cancer Institute* 2007; Available at: URL: http://www.cdc.gov/cancer/npcr/uscs. Accessed April, 2008.

(2) Parkin DM. The evolution of the population-based cancer registry. *Nat Rev Cancer* 2006 August;6(8):603-12.

(3) Black BL, Cowens-Alvarado R, Gershman S, Weir HK. Using data to motivate action: the need for high quality, an effective presentation, and an action context for decision-making. *Cancer Causes Control* 2005 October;16 Suppl 1:15-25.

(4) U.S. Department of Health and Human Services. Healthy People 2010 (2 vols), 2nd ed. Washington, DC: U.S. Government Printing Office;2000.

(5) Wingo PA, Jamison PM, Hiatt RA et al. Building the infrastructure for nationwide cancer surveillance and control--a comparison between the National Program of Cancer Registries (NPCR) and the Surveillance, Epidemiology, and End Results (SEER) Program (United States). *Cancer Causes Control* 2003 March;14(2):175-93.

(6) Frey CM, McMillen MM, Cowan CD, Horm JW, Kessler LG. Representativeness of the surveillance, epidemiology, and end results program data: recent trends in cancer mortality rates. *J Natl Cancer Inst* 1992 June 3;84(11):872-7.

(7) Nattinger AB, McAuliffe TL, Schapira MM. Generalizability of the surveillance, epidemiology, and end results registry population: factors relevant to epidemiologic and health care research. *J Clin Epidemiol* 1997 August;50(8):939-45.

(8) Merrill RM, Dearden KA. How representative are the surveillance, epidemiology, and end results (SEER) program cancer data of the United States? *Cancer Causes Control* 2004 December;15(10):1027-34.

(9) Public Law 102-515. *Cancer Registries Amendment Act* 1992;Available at: URL: http://www.cdc.gov/cancer/npcr/npcrpdfs/publaw.pdf.

(10) State cancer registries: status of authorizing legislation and enabling regulations--United States, October 1993. *MMWR Morb Mortal Wkly Rep* 1994 February 4;43(4):71, 74-1, 75.

(11) Public Law 107-260. *Benign Brain Tumor Cancer Registries Amendment Act* 2002; Available at URL: http://www.cdc.gov/cancer/npcr/training/pdfs/Amendment_Act.pdf

(12) Swan J, Wingo P, Clive R et al. Cancer surveillance in the U.S.: can we have a national system? *Cancer* 1998 October 1;83(7):1282-91.

(13) Wingo PA, Howe HL, Thun MJ et al. A national framework for cancer surveillance in the United States. *Cancer Causes Control* 2005 March;16(2):151-70.

(14) Wingo PA, Ries LA, Rosenberg HM, Miller DS, Edwards BK. Cancer incidence and mortality, 1973-1995: a report card for the U.S. *Cancer* 1998 March 15;82(6):1197-207.

(15) Edwards BK, Brown ML, Wingo PA et al. Annual report to the nation on the status of cancer, 1975-2002, featuring population-based trends in cancer treatment. *J Natl Cancer Inst* 2005 October 5;97(19):1407-27.

(16) Jemal A, Clegg LX, Ward E et al. Annual report to the nation on the status of cancer, 1975-2001, with a special feature regarding survival. *Cancer* 2004 July 1;101(1):3-27.

(17) Edwards BK, Howe HL, Ries LA et al. Annual report to the nation on the status of cancer, 1973-1999, featuring implications of age and aging on U.S. cancer burden. *Cancer* 2002 May 15;94(10):2766-92.

(18) Howe HL, Wingo PA, Thun MJ et al. Annual report to the nation on the status of cancer (1973 through 1998), featuring cancers with recent increasing trends. *J Natl Cancer Inst* 2001 June 6;93(11):824-42.

(19) Ries LA, Wingo PA, Miller DS et al. The annual report to the nation on the status of cancer, 1973-1997, with a special section on colorectal cancer. *Cancer* 2000 May 15;88(10):2398-424.

(20) Wingo PA, Ries LA, Giovino GA et al. Annual report to the nation on the status of cancer, 1973-1996, with a special section on lung cancer and tobacco smoking. *J Natl Cancer Inst* 1999 April 21;91(8):675-90.

(21) Howe HL, Wu X, Ries LA et al. Annual report to the nation on the status of cancer, 1975-2003, featuring cancer among U.S. Hispanic/Latino populations. *Cancer* 2006 September 6.

(22) Weir HK, Thun MJ, Hankey BF et al. Annual report to the nation on the status of cancer, 1975-2000, featuring the uses of surveillance data for cancer prevention and control. *J Natl Cancer Inst* 2003 September 3;95(17):1276-99.

(23) Perkins CI, Hotes J, Kohler BA, Howe HL. Association between breast cancer laterality and tumor location, United States, 1994-1998. *Cancer Causes Control* 2004 September;15(7):637-45.

(24) Wingo PA, Jamison PM, Young JL, Gargiullo P. Population-based statistics for women diagnosed with inflammatory breast cancer (United States). *Cancer Causes Control* 2004 April;15(3):321-8.

(25) Hotes JL, Ellison LF, Howe HL, Friesen I, Kohler B. Variation in breast cancer counts using SEER and IARC multiple primary coding rules. *Cancer Causes Control* 2004 March;15(2):185-91.

(26) Young JL, Jr., Ward KC, Wingo PA, Howe HL. The incidence of malignant non-carcinomas of the female breast. *Cancer Causes Control* 2004 April;15(3):313-9.

(27) Joslyn SA, Foote ML, Nasseri K, Coughlin SS, Howe HL. Racial and ethnic disparities in breast cancer rates by age: NAACCR Breast Cancer Project. *Breast Cancer Res Treat* 2005 July;92(2):97-105.

(28) Howe HL, Weinstein R, Alvi R, Kohler B, Ellison JH. Women with multiple primary breast cancers diagnosed within a five year period, 1994-1998. *Breast Cancer Res Treat* 2005 April;90(3):223-32.

(29) Goodman MT, Howe HL, Tung KH et al. Incidence of ovarian cancer by race and ethnicity in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2676-85.

(30) Howe HL, Weinstein R, Hotes J, Kohler B, Roffers SD, Goodman MT. Multiple primary cancers of the ovary in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2660-75.

(31) Goodman MT, Correa CN, Tung KH et al. Stage at diagnosis of ovarian cancer in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2648-59.

(32) Goodman MT, Howe HL. Descriptive epidemiology of ovarian cancer in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2615-30.

(33) Howe HL, Tung KH, Coughlin S, Jean-Baptiste R, Hotes J. Race/ethnic variations in ovarian cancer mortality in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2686-93.

(34) Hall HI, Tung KH, Hotes J, Logan P. Regional variations in ovarian cancer incidence in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2701-6.

(35) Young JL, Jr., Cheng W, X, Roffers SD, Howe HL, Correa C, Weinstein R. Ovarian cancer in children and young adults in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2694-700.

(36) Roffers SD, Wu XC, Johnson CH, Correa CN. Incidence of extraovarian primary cancers in the United States, 1992-1997. *Cancer* 2003 May 15;97(10 Suppl):2643-7.

(37) Chen VW, Ruiz B, Killeen JL, Cote TR, Wu XC, Correa CN. Pathology and classification of ovarian tumors. *Cancer* 2003 May 15;97(10 Suppl):2631-42.

(38) Reed E, Ahmed F, Jackson-Thompson J et al. Foreword: Promoting the use of registry-based national cancer surveillance data for colorectal cancer prevention and control. *Cancer* 2006 September 1;107(5 Suppl):1101-2.

(39) Jackson-Thompson J, Ahmed F, German RR, Lai SM, Friedman C. Descriptive epidemiology of colorectal cancer in the United States, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1103-11.

(40) Ahmed F, Goodman MT, Kosary C et al. Excess risk of subsequent primary cancers among colorectal carcinoma survivors, 1975-2001. *Cancer* 2006 September 1;107(5 Suppl):1162-71.

(41) Matanoski G, Tao XG, Almon L, Adade AA, vies-Cole JO. Demographics and tumor characteristics of colorectal cancers in the United States, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1112-20.

(42) Wu X, Cokkinides V, Chen VW et al. Associations of subsite-specific colorectal cancer incidence rates and stage of disease at diagnosis with county-level poverty, by race and sex. *Cancer* 2006 September 1;107(5 Suppl):1121-7.

(43) Stewart SL, Wike JM, Kato I, Lewis DR, Michaud F. A population-based study of colorectal cancer histology in the United States, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1128-41.

(44) Cress RD, Morris C, Ellison GL, Goodman MT. Secular changes in colorectal cancer incidence by subsite, stage at diagnosis, and race/ethnicity, 1992-2001. *Cancer* 2006 September 1;107(5 Suppl):1142-52.

(45) Coughlin SS, Richards TB, Thompson T et al. Rural/nonrural differences in colorectal cancer incidence in the United States, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1181-8.

(46) Fairley TL, Cardinez CJ, Martin J et al. Colorectal cancer in U.S. adults younger than 50 years of age, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1153-61.

(47) Lai SM, Zhang KB, Uhler RJ, Harrison JN, Clutter GG, Williams MA. Geographic variation in the incidence of colorectal cancer in the United States, 1998-2001. *Cancer* 2006 September 1;107(5 Suppl):1172-80.

(48) Parikh-Patel A, Bates JH, Campleman S. Colorectal cancer stage at diagnosis by socioeconomic and urban/rural status in California, 1988-2000. *Cancer* 2006 September 1;107(5 Suppl):1189-95.

(49) Coughlin SS, Costanza ME, Fernandez ME et al. CDC-funded intervention research aimed at promoting colorectal cancer screening in communities. *Cancer* 2006 September 1;107(5 Suppl):1196-204.

(50) McDavid K, Schymura MJ, Armstrong L et al. Rationale and design of the National Program of Cancer Registries' Breast, Colon, and Prostate Cancer Patterns of Care Study. *Cancer Causes Control* 2004 December;15(10):1057-66.

(51) Alley LG, Chen VW, Wilke JM, Schymura M, Rycroft RK, Shen T, Bolick-Aldrich S, Roshala W, Fulton J. CDC-NPCR's Breast, Colon, and Prostate Cancer Data Quality and Patterns of Care Study: Overview and Methodology. *Journal of Registry Management,* 34(4):148-157, 2007.

(52) Alley LG, Fulton JP, Wike JM, Kahn A, Roshala W, Chen VW, Rycroft RK, Bolick-Aldrich S, German RR, Snodgrass J. Studying Patterns of Care: An Evaluation of a Project Using CDC-NPCR Data. *Journal of Registry Management*, 35(1):27-33, 2008.

(53) Wu X, Richardson LC, Kahn A, Fulton JP, Cress RD, Shen T, Wolf HJ, Bolick-Aldrich S, Chen VW. Survival Differences between Non-Hispanic Black and Non-Hispanic White Women with Localized Breast Cancer: The Impact of Guideline-Concordant Therapy. *Journal of the National Medical Association,* 100(5):490-498, 2008.

(54) Byers TE, Wolf HJ, Bauer KR, Bolick-Aldrich S, Chen VW, Finch JL, Fulton JP, Schymura MJ, Shen T, Van Heest S, Yin X. The Impact of Socioeconomic Status on Survival After Cancer in the United States: Findings from the National Program of Cancer Registries Patterns of Care Study. *Cancer,* 113(3): 582-91, 2008.

(55) German RR, Wike JM, Wolf HJ, Schymura MJ, Roshala W, Shen T, Schmidt B, Stuckart E. Quality of Cancer Registry Data: Findings From CDC-NPCR's Breast, Colon, and Prostate Cancer Data Quality and Patterns of Care Study. *Journal of Registry Management,* 35(2): 67-74, 2008.

# Appendix B: Inventory of Publications and Professional Presentations on CDC-NPCR's Patterns of Care Studies

## Publications

Alley LG, Chen VW, Wike JM, Schymura M, Rycroft RK, Shen T, Bolick-Aldrich S, Roshala W, Fulton J. CDC-NPCR's Breast, Colon, and Prostate Cancer Data Quality and Patterns of Care Study: Overview and Methodology. *Journal of Registry Management*, 34(4): 148-157, 2007.

Stewart SL, Wike JM, Cress R, O'Malley C, Neloms S, Kahn AR, Schymura MJ. Ovarian cancer treatment patterns and outcomes in the United States: A National Program of Cancer Registries (NPCR) study. *Journal of Clinical Oncology*, 24(No. 18S): 15031, 2006 (ASCO Annual Meeting Proceedings Part I).

McDavid K, Schymura MJ, Armstrong L, Santilli L, Schmidt B, Byers T, Steele CB, O'Connor L, Schlag NC, Roshala W, Darcy D, Matanoski G, Shen T, Bolick-Aldrich S, and The Breast, Colon, and Prostate Cancer Data Quality and Patterns of Care Study Group. Rationale and design of the National Program of Cancer Registries' breast, colon, and prostate cancer patterns of care study. *Cancer Causes and Control*, 15: 1057-1066, 2004.

## Oral Presentations

Kahn AR. "Patient and Provider Factors Associated with Treatment for Ovarian Cancer." NAACCR annual meeting, June 5, 2007.

German RR, Wu X, Cress RD, Schymura MJ, Stewart SL, Chen VW. "Using Cancer Registry Data to Describe Treatment Patterns for Breast, Prostate, Colon, and Ovarian Cancers." CDC Cancer Partners Summit, July 13, 2006.

Cress RD. "Adjuvant Chemotherapy for Patients with Stage III Colon Cancer: Preliminary Results from the NPCR Patterns of Care Study." NAACCR annual meeting, June 15, 2006.

Chen VW. "Enhancing Populations-based Registry Data to Assess Cancer Care: Strengths and Challenges." NAACCR annual meeting, June 13, 2006.

Wu XC. "Dissemination of Guideline Therapy for Localized Breast Cancer Patients: (Preliminary) Results from a NPCR's Patterns of Care Study." NAACCR annual meeting, June 13, 2006.

Schymura MJ. "Factors Associated with Initial Treatment for Clinically Localized Prostate Cancer: Preliminary Results from the NPCR Patterns of Care Study (PoC1)." NAACCR annual meeting, June 13, 2006.

German RR. "The Quality of Cancer Registry Data: Preliminary Results from the CDC-NPCR's PoC Study." NAACCR annual meeting, June 13, 2006.

Alley LG. "Using NPCR Data to Describe Patterns of Care for Three Cancers." NAACCR annual meeting, June 2005.

Alley LG. "The Importance of Conducting Population-Based Patterns of Care (PoC) Studies: Improving Cancer Patient Care." Federal Special Interest Group (SIG) of the NCRA Annual Educational Conference, April 2005.

Alley LG. "Overview of CDC's Patterns of Care Cancer Studies". CDC-NPCR Program Directors' Meeting, March 2004.

Posters

Alley AG, Chen VW, Fulton J, Kahn AR, Roshala W, Rycroft RK, Shen T, Wike JM, German RR, Bolick-Aldrich S. *CDC/NPCR Patterns of Care (POC) Study For Breast, Prostate, and Colon Cancers: Challenges and Lessons Learned*. NAACCR annual meeting, June 2007.

Alley AG, German RR, Wike J, Stewart SL, Richardson LC, Wilson R, Van Heest S, Chen VW, Cress R, Sabatino S, Schymura MJ. *National Program of Cancer Registries (NPCR) Patterns of Care Study for Breast, Prostate, and Colon Cancers: An Overview.* American Public Health Association annual meeting, November 2006.

Stewart SL, Wike JM, Cress R, O'Malley C, Neloms S, Kahn AR, Schymura MJ. *Treatment Patterns and Outcomes of Ovarian Cancer Patients By Histology: Data from the NPCR Patterns of Care Study*. NAACCR annual meeting, June 2006.

Kahn AR, Schymura MJ, Solghan SM, and the NPCR Ovarian Cancer Treatment Patterns and Outcomes Study Group. *Ovarian Cancer Treatment in New York*. NAACCR annual meeting, June 2006.

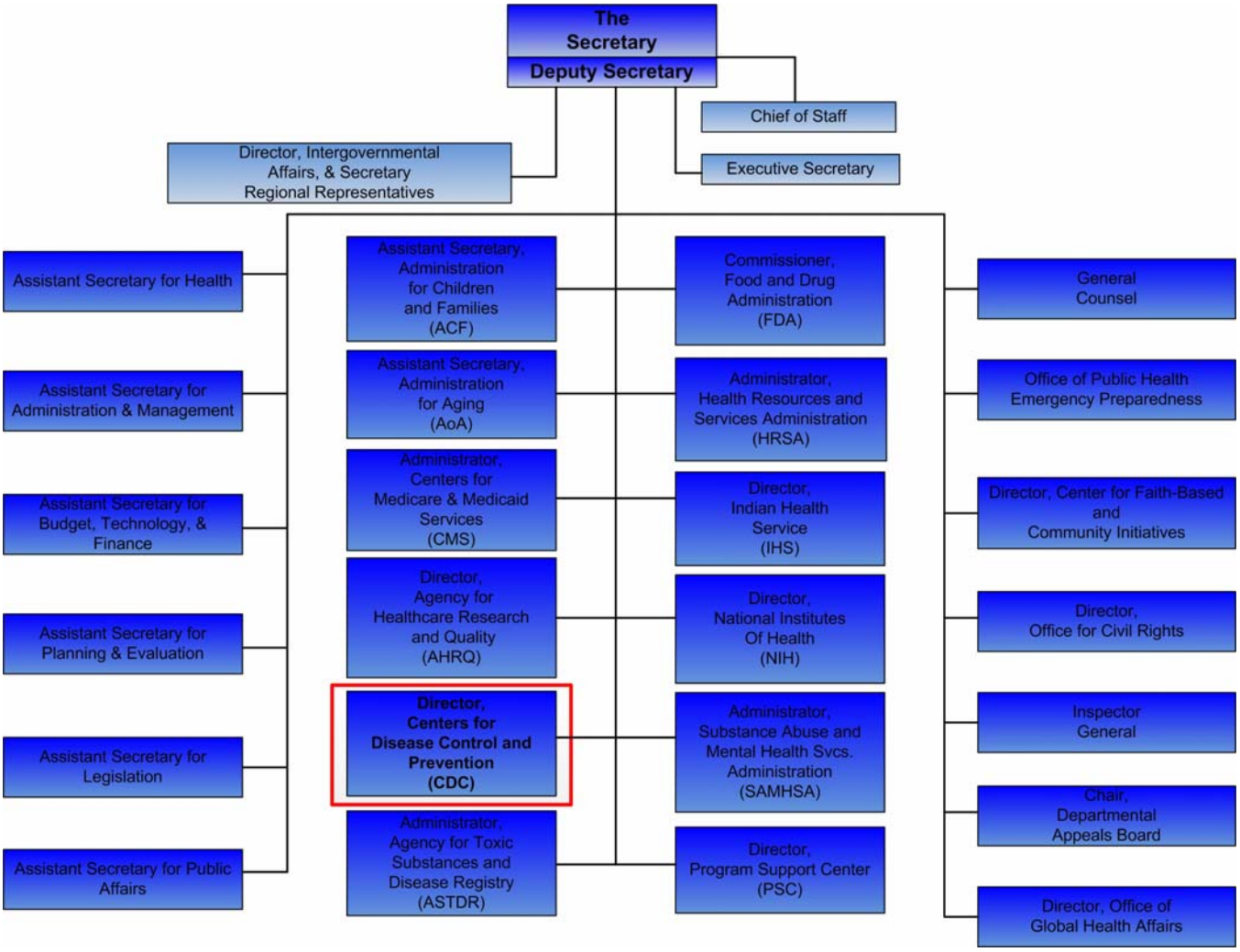
German RR, Byers T, Wolf H, Wike J, Alley LG, Almon L, Stewart SL. *The Quality of Cancer Registry Data: Design and Interim Findings from the CDC-NPCR's PoC Study*. NAACR annual meeting, June 2005.

Alley LG, Wike J, Stewart SL, German RR, Ahmed F, Almon L, Wingo P, Friedman C. *Using NPCR Data to Describe Patterns of Care for Three Cancers*. CDC-NPCR Program Directors' Meeting, May 2005.

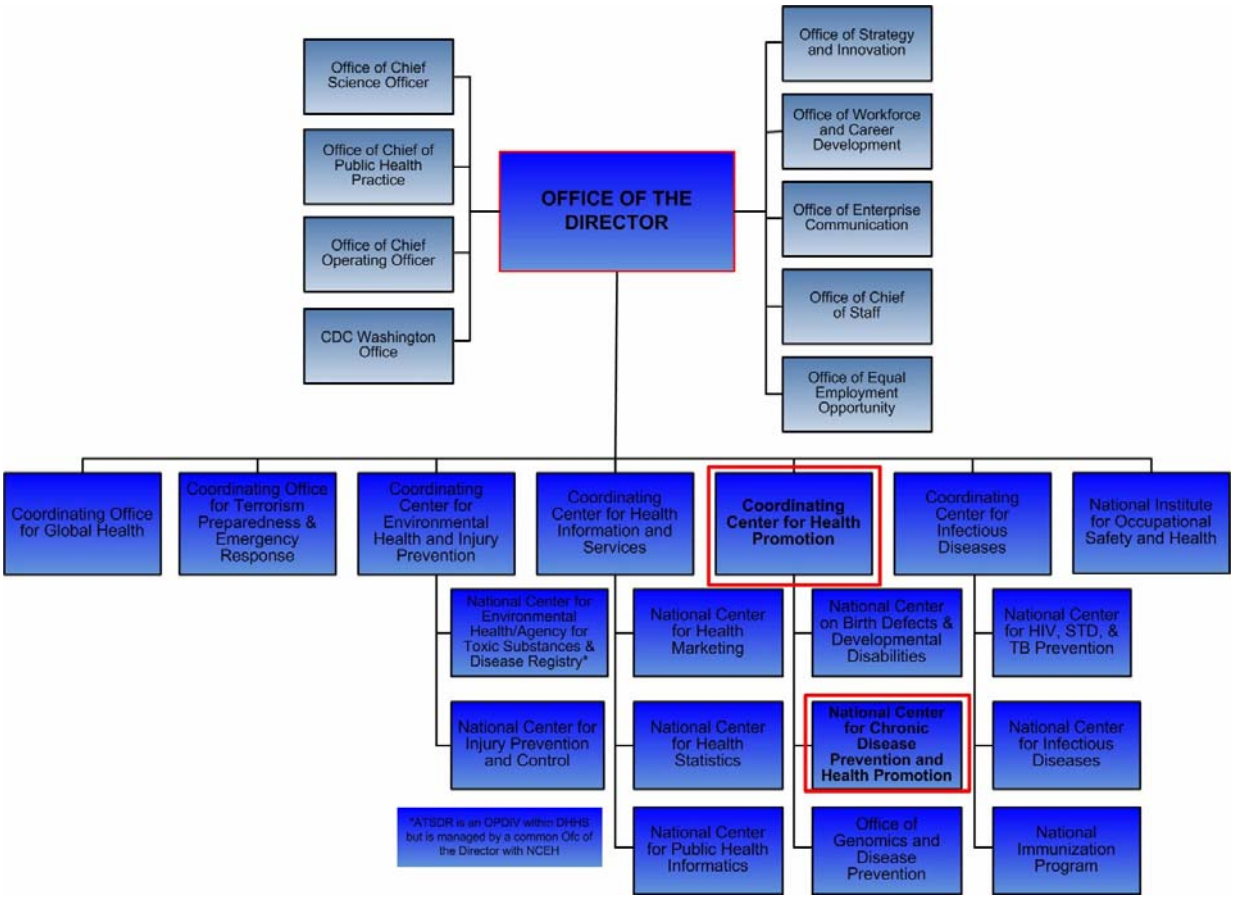
Alley LG, Wike J, Stewart S, Friedman C. *Using Cancer Registry Data to Describe Disparities in Patterns of Care for Breast, Colon, and Prostate Cancers*. National Conference on Chronic Disease Prevention and Control, February 2005.

# Appendix C:
# Organizational Charts

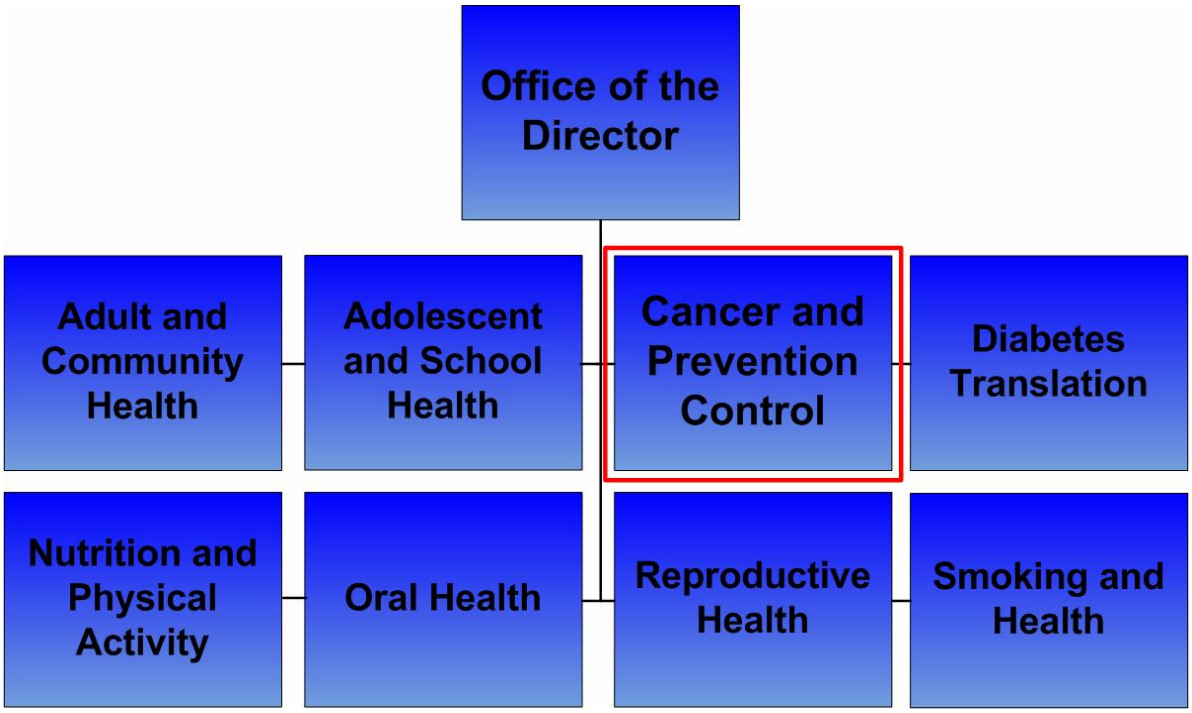
U.S. Department of Health and Human Services (DHHS) Organization Chart



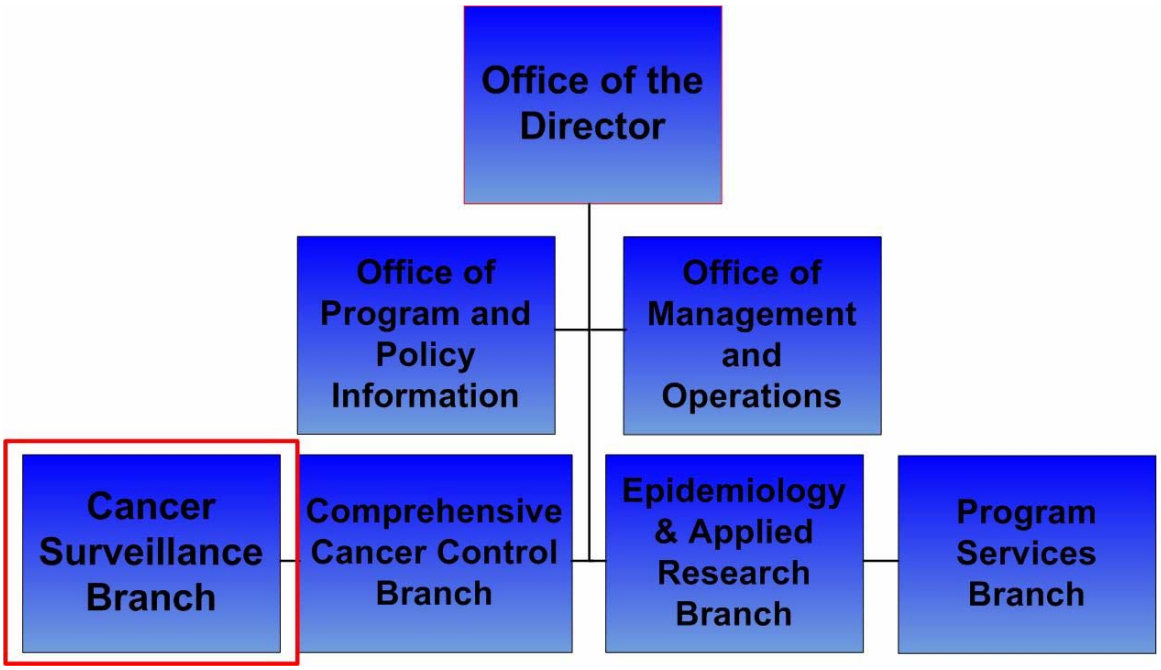
Centers for Disease Control and Prevention (CDC) Organizational Chart



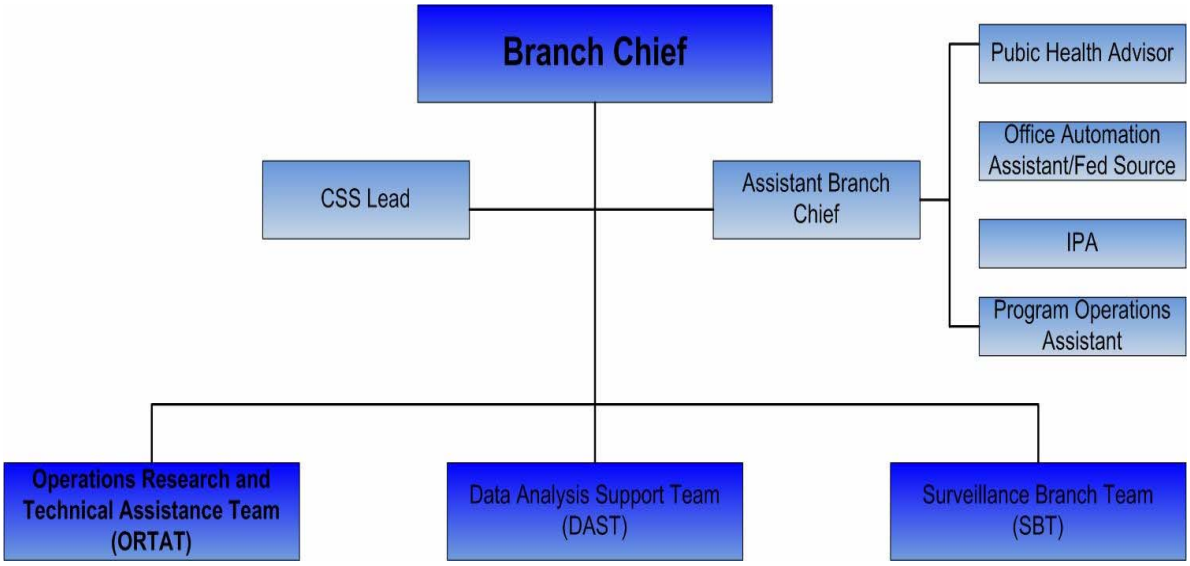
CDC's National Center for Chronic Disease Prevention and Health Promotion Organization Chart




CDC's Division of Cancer Prevention and Control Organization Chart



Cancer Surveillance Branch Organization Chart



# Appendix D: Guidelines for Defining Public Health Research and Public Health Non-Research

Revised October 4, 1999

**Purpose**

The Centers for Disease Control and Prevention (CDC) is committed to preventing disease and injury and improving health for all Americans. CDC is also committed to protecting individuals who participate in all public health activities. In the conduct of public health research, CDC follows the Code of Federal Regulations, Title 45, Part 46, The Public Health Service Act as amended by the Health Research Extension Act of 1985, Public Law 99-158, which sets forth regulations for the protection of human subjects.

This document, *Defining Public Health Research and Public Health Non-Research*, sets forth CDC guidelines on the definition of public health research conducted by CDC staff irrespective of the funding source (i.e., provided by CDC or by another entity). Under Federal regulations (45 CFR 46), the final determination of what is research and whether the Federal regulations are applicable lies with CDC and, ultimately, with the Office for Protection from Research Risks (OPRR). Thus, this document is intended to provide guidance to state and local health departments and other institutions that conduct collaborative research with CDC staff or that are recipients of CDC funds. The guidelines are intended to ensure both the protection of human subjects and the effective practice of public health.

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**Background**

In 1974, the Department of Health and Human Services (formerly the Department of Health, Education and Welfare) developed regulations to assure the protection of human subjects from research risks. These regulations were developed to address ethical issues raised in connection with biomedical or behavioral research involving human subjects. Because most biomedical research is funded by the National Institutes of Health (NIH), the regulations were developed to deal specifically with the types of research funded by NIH. The regulations have been revised several times; currently the Department is operating under Title 45 Code of Federal Regulations Part 46, 1991 revision. The regulations will be referred to as 45 CFR 46.

The practice of public health poses several challenges in implementing 45 CFR 46. Although some public health activities can unambiguously be classified as either research or non-research, for other activities the classification is more difficult. The difficulty in classifying some public health activities as research or non-research stems either from traditionally held views about what constitutes public health practice or from the fact that 45 CFR 46 does not directly address many public health activities. In addition, the statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers is not recognized in the regulations. Human subject protections applicable for activities occurring at the

boundary between public health non-research and public health research are not readily interpretable from the regulations.

The regulations state that "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Obtaining and analyzing data are essential to the usual practice of public health. For many public health activities, data are systematically collected and analyzed, blurring the distinction between research and non-research. Scientific methodology is used both in non-research and research activities that comprise the practice of public health. Because scientific principles and methodology are applied to both non-research and research activities, knowledge is generated in both cases. Furthermore, at times the extent to which that knowledge is generalizable may not differ greatly in research and non-research. Thus, non-research and research activities cannot be easily defined by the methods they employ. Three public health activities - surveillance, emergency responses, and evaluation - are particularly susceptible to the quandary over whether the activity is research or non-research.

The key word in the regulations' definition of research for the purpose of classifying public health activities as either research or non-research is "designed." The major difference between research and non-research lies in the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge may be gained in any public health endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered.

Classifying an activity as research does not automatically lead to review by an institutional review board (IRB) for the protection of human subjects. Once an activity is classified as research, two additional determinations must be made: (1) does the research involve human subjects and, if so, (2) does the research meet the criteria for exemption from IRB review. This policy deals only with the first determination of whether a public health activity is research or non-research.

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**Definitions**

Research - As defined in 45 CFR 46, research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Human Subjects - As defined in 45 CFR 46, a human subject means "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context

in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

Surveillance - The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988).

Emergency Response - A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).

Program Evaluation – An essential organizational practice in public health using a systematic approach to improve and account for public health actions (Centers for Disease Control and Prevention, 1999)

Evaluation - The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).

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**Policy**

CDC is required to and has an ethical obligation to ensure that individuals are protected in all public health research activities it conducts. All CDC activities must be reviewed to determine whether they are research involving human subjects. When an activity is classified as research involving human subjects, CDC and its collaborators will comply with 45 CFR 46 in protecting human research subjects.

Some surveillance projects, emergency responses, and evaluations are research involving human subjects; others are not. Each project must be reviewed on a case-by-case basis. Although general guidance can be given to assist in classifying these activities as either research or non-research, no one criterion can be applied universally. The ultimate decision regarding classification lies in the intent of the project. If the primary intent is to generate generalizable knowledge, the project is research. If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research. If the primary intent changes to generating generalizable knowledge, then the project becomes research.

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## Guidance for Compliance

### I. General

The Human Subjects Contact (HSC) in each Center, Institute, or Office (CIO) determines whether the project constitutes research. If the HSC is unclear about classifying a project, the HSC should consult with the CDC's Deputy Associate Director for Science. This determination is made by examining the intent of the project. What is the primary purpose for which the project was designed?

General Attributes of Public Health Research - Intent of the project is to generate generalizable knowledge to improve public health practice; intended benefits of the project may or may not include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected. Generalizable, for purposes of defining research, does not refer to the statistical concept of population estimation or to the traditional public health method of collecting information from a sample to understand health in the population from which the sample came. Holding public health activities to a standard of studying every case in order to classify an activity as non-research is not practical or reasonable.

General Attributes of Non-Research - Intent of the project is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess and/or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Other attributes, such as publication of findings, statutory authority (see discussion in next section), methodological design, selection of subjects, and hypothesis testing/generating, do not necessarily differentiate research from non-research because these types of attributes can be shared by both research and non-research projects.

A non-research project may generate generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original, primary intent. In this case, since the primary intent was not to generate or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken to generate or contribute to generalizable knowledge, the analysis constitutes human subjects research that requires IRB review.

If a project includes multiple components and at least one of those components is designed to generate generalizable knowledge, then the entire project is classified as research unless the components are separable.

## II. Specific

A. Surveillance - Surveillance is a term describing a method for public health data collection. Surveillance systems may be either research or non-research. Surveillance systems are likely to be non-research when they involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population. Data generated by these systems are used to manage public health programs. They have in place the ability to invoke public health mechanisms to prevent or control disease or injury in response to an event. Thus, the primary intent of these surveillance systems is to prevent or control disease or injury in a defined population by producing information about the population from whom the data were collected. These attributes of surveillance that is non-research are generally found in state statute or regulation where the intent of the activity, its purposes, and uses of the data are specified. Surveillance systems that most easily fit into this category are ones in which the data are limited to describing the occurrence of a health-related problem (disease reporting) and systems in which no analytic (etiologic) analyses can be conducted. Subjects are rarely selected according to a design; rather, all cases are entered into the surveillance system because they are passive reporting systems. Hypothesis testing is not part of the system.

Surveillance systems are likely to be research when they involve the collection and analysis of health-related data conducted either to generate knowledge that is applicable to other populations and settings than the ones from which the data were collected or to contribute to new knowledge about the health condition. The information gained from the data collection system may or may not be used to invoke public health mechanisms to prevent or control disease or injury, but this is not a primary intent of the project. Thus, the primary intent of these surveillance systems is to generate generalizable knowledge. Characteristics of surveillance systems that most easily fit into this category are: longitudinal data collection systems (e.g., follow-up surveys and registries) that allow for hypothesis testing; the scope of the data is broad and includes more information than occurrence of a health-related problem; analytic analyses can be conducted; and cases may be identified to be included in subsequent studies.

In general, lawful state disease reporting, monitoring requirements and other data collection activities conducted under state statute or under recognized public health authority are non-research. Disease reporting activities are not research. Disease reporting, for these purposes, is defined narrowly to include the reporting of the specific health condition or disease, demographic information; and accepted, known risk factors as specified in state statutes or regulations. When reporting systems collect data beyond standard reporting information, the reporting activity is not automatically considered to be non-research. Collection of data that would allow etiologic analysis is likely to be research.

If other activities are added to a surveillance project with the specific intent of generating new or generalizable knowledge, these additional activities are considered to be research. It becomes important to distinguish between disease reporting activities that

are non-research and uses of the reported data that may be either non-research or research.

Sometimes, CDC funds state and local health departments to establish surveillance systems with dual intentions on the part of CDC: to build state capacity in disease reporting and for CDC to generate new knowledge. Disease reporting activities conducted at the state level are generally non-research. However, if CDC uses the data collected through such reporting to generate new knowledge, CDC would be engaged in research. CDC may consider state health departments to be engaged in the research depending upon their role. If state health departments are participating beyond merely providing the data, they may be considered as engaged in the research. Institutions providing information to state health departments would not be considered engaged in the research (see OPRR memorandum dated 1/26/99).

Some surveillance projects do not fit easily into the categories described above. For these projects, the primary intent and elements of the project must be examined carefully.

B. Emergency Responses - Most emergency responses tend to be non-research because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. However, an emergency response may have a research component if: 1) samples are stored for future use intended to generate generalizable knowledge or 2) additional analyses are conducted beyond those needed to solve the immediate health problem. When investigational new drugs are used or drugs are used off-label, the emergency response is almost always research. The same applies to medical devices. For emergency responses, whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

C. Evaluation – The terms "evaluation" and "program evaluation" are used interchangeably. Yet, there are subtle differences between the two terms (see definitions and reference provided above). Evaluation is a term, broad in meaning, that refers to the systematic use of scientific methods to measure efficacy, implementation, utility, and so on of a program in its entirety or its components. Evaluations may or may not be research. Program evaluations are a subset of evaluations. As defined here program evaluations are almost never research.

When the purpose of an evaluation is to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective, the evaluation is research. The systematic comparison of standard or non-standard interventions in an experimental-type design is research. In these cases, the knowledge gained is applicable beyond the individual, specific program. Thus, the primary intent is to generate new knowledge or contribute to the knowledge in the scientific literature. Further, it is intended to apply the knowledge to other sites or populations.

When the purpose is to assess the success of an established program in achieving its objectives in a specific population and the information gained from the evaluation will be

used to provide feedback to that program, the evaluation, referred to as program evaluation, is non-research. In the non-research scenario, the evaluation is used as a management tool to monitor and improve the program. The evaluation activity is often a component of the regular, ongoing program. Information learned from the evaluation has immediate benefit for the program and/or the clients receiving the services or interventions. The information is often not generalizable beyond the individual program. Interventions and services that are evaluated are never experimental or new; they are known (either from empirical data or through consensus) to be effective.

Sometimes, the term "formative evaluation" is used to describe data collection activities that occur prior to the implementation of an intervention, service, or program. Whether the "formative evaluation" is research or non-research depends upon its intent. If the evaluation is conducted prior to implementing a new, modified, or previously untested intervention, the evaluation is part of the overall research project. If the evaluation is conducted to provide information on how to tailor a proven-effective intervention, service, or program in a specific setting or context, the evaluation is not research.

Evaluations of CDC's national programs, i.e., programs that CDC funds to all state health departments and in which evaluation is one component, are not research. These evaluation activities are on-going and involve generally the collection of minimal, standard data elements across all sites. The data are generally used at the local level as a management tool as well as at the national level for the same purpose. Sometimes, data from these evaluation activities will be aggregated at CDC and used for other purposes. When this occurs, subsequent use of the data may be research.

In some cases, program activities and evaluation activities are separable. For example, interventions or services are being provided; they have a history of being provided and there is an intention to continue to provide them. An evaluation is conducted to determine the efficacy of these program activities. In another example, a public health department, under its public health authority, may provide an untested intervention in an outbreak situation. An evaluation component is added. In both of these examples, because the intervention and evaluation activities are undertaken with different intentions and are separable, the intervention activities are not research but the evaluation activities are research.

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**Appendix**

Examples of CDC surveillance, emergency responses, and evaluation activities that are non-research and research.

**Surveillance:**

**Non-research** -

**National Notifiable Diseases Surveillance System (NNDSS)** - States and territories have asked CDC to act as a common data collection point for data on nationally notifiable diseases. A notifiable disease is considered by the Council of State and Territorial Epidemiologists to be a condition for which regular, frequent, and timely information about individual cases is necessary at the national level for the prevention and control of disease. NNDSS data are collected and published weekly in the

Morbidity and Mortality Weekly Report and annually in the Summary of Notifiable Diseases, United States. The NNDSS is essential to the day to day practice of public health. The primary intent of the surveillance system is to provide CDC and state and local health officials with information to detect and control outbreaks of disease. The NNDSS is also used to measure the impact of programs such as immunization. The intended benefits resulting from the NNDSS are for the residents of the states and local areas who contribute data to the system.

**Diabetes Surveillance Report** - Using public use data from several national surveys, a national diabetes surveillance system is produced. Data from the surveillance system are used to describe the burden of diabetes and its complications on a national and state level. The primary intent of the surveillance system is to provide information for the development of national and state public health priorities and policies regarding the prevention and control of diabetes. The intended benefits are for those who have diabetes or those who are at risk of developing diabetes.

**Research** -

**A Sentinel Surveillance System for Lassa Fever in the Republic of Guinea** - Four study sites were selected to identify and describe cases of Lassa fever. Cases were identified from hospital and outpatient admissions. The purpose of the project was to generate baseline information on the Lassa virus and human clinical Lassa fever in the Republic of Guinea. No public health interventions were planned as part of this project; there was no direct benefit for study participants. Thus, the primary intent was to contribute to the knowledge of Lassa fever.

**Developmental Disabilities in Very Low Birthweight Children: Linkage of the Georgia Very Low Birthweight Study and the Metropolitan Atlanta Developmental Disabilities Surveillance Program** - The Metropolitan Atlanta Developmental Disabilities Surveillance Program, an ongoing CDC surveillance program to monitor trends in the occurrence of selected developmental disabilities in children living in the metropolitan Atlanta area, and the Georgia Very Low Birthweight Study, conducted in the 1980s to investigate the environmental and other risk factors for very low birthweight were linked for specific investigations of adverse developmental outcomes. Linkage of these primary files provides a unique opportunity to assist efforts to assess the occurrence of selected developmental disabilities in metropolitan Atlanta children and to identify causes of these conditions without the additional time and resource expenditure of additional field data collection. For these investigations involving secondary analyses of the linked primary data sets, no individuals were contacted; only information available from the linkage were used. The purpose of the project was to estimate the prevalence of cerebral palsy, mental retardation, and hearing and visual impairments and to identify pre- and perinatal medical and sociodemographic risk factors for these disabilities in a population-based cohort of very low birthweight children in Atlanta. The primary intent was to generate generalizable knowledge about developmental disabilities.

**Emergency Responses:**

**Non-research** -

**Outbreak of Gastroenteritis** - Three days after a cruise ship left Los Angeles, California for several ports in Mexico, CDC was notified that 24 of 1,899 passengers

and 6 of 670 crew had presented to the ship=s infirmary with gastrointestinal illness. The purpose of the investigation was to determine the cause and extent of the outbreak and to prevent and control gastrointestinal illness among the ships passengers and crew. Although this type of investigation is often undertaken after the outbreak has occurred and therefore information gained is likely to benefit the ship=s next set of cruise passengers and crew, the primary intent of the investigation is to assist in controlling the current disease outbreak.

**Recall of Six Lots of Influenza Vaccine** - One of the pharmaceutical companies who manufactures influenza vaccine instituted a voluntary recall of six lots of influenza vaccine. The lots were recalled due to decreased potency of the A/Nanchang/933/95 (H3N2) component of the vaccine. CDC was notified by a state health department that a nursing home had vaccinated its residents with the recalled vaccine. The purpose of the investigation was to determine whether residents of this nursing home who received the vaccine had a suboptimal immune response and required revaccination. The primary intent of this investigation was to prevent the occurrence of influenza among the participants if they demonstrated a suboptimal immune response; there was a potential for participants to receive a direct benefit in the form of revaccination if they participated.

**Research** -

**Childhood Exposure to Nicotine-Containing Products in Rhode Island** - Between January 1, 1995 and June 30, 1996, 90 cases of nicotine-containing products were reported to the Rhode Island Poison Control Center. No known population-based investigation has been conducted to determine risk factors associated with nicotine-containing products poisoning. The purpose of the Epi-Aid was to determine risk factors associated with childhood exposure to nicotine-containing products, and to develop appropriate control measures. Although there may be some benefit to the 90 children exposed in Rhode Island, the benefits from this study extend beyond the study participants to the population of children who are at risk of exposure to nicotine-containing products. In addition, there was no immediate health problem to be controlled. Thus, the primary intent of the investigation was to generate generalizable knowledge about the risk factors associated with childhood exposure to nicotine-containing products.

**Azithromycin Used as Prophylaxis Against the Spread of Illness Due to Mycoplasma Pneumoniae in the Setting of an Outbreak** - During the first week of freshman entering a post high school academic institution, a cluster of respiratory illness was recognized by the infirmary staff. Early serologic testing suggest Mycoplasma pneumoniae as the etiologic agent. About four weeks later 42% of the freshman and 17% of the upperclassmen reported a respiratory illness; 50% of those tested had serologic evidence of Mycoplasma pneumoniae infection. The lower attack rate among upperclassmen was likely a consequence of them returning to campus 15 days after the freshmen arrived. A trial of chemoprophylaxis with azithromycin was proposed. Highly effective control measures in the setting of an outbreak have not been described. There is limited information about the role of antimicrobials in controlling an epidemic of Mycoplasma pneumoniae. Thus, the primary intent of the investigation was to generate generalizable knowledge about the efficacy of azithromycin to prevent the spread of Mycoplasma pneumoniae in an outbreak situation.

**Program Evaluation:**

**Non-research** -

**Evaluation of School-based HIV Prevention Program** - As part of the evaluation of the school-based HIV prevention program in Denver public schools, principals, teachers, student contact staff, students, and parents were interviewed. HIV program efforts in policy awareness, staff development, curriculum implementation, and status of students receiving HIV prevention education were assessed.

The purpose (primary intent) of the program evaluation was to provide information to Denver public schools that will be used to improve their school-based HIV prevention programs. The results from the evaluation were used to assess the success of the interventions in a specific population (Denver public school children) and to refine the interventions in that population.

**IMPACT Progress Reports** - The Office on Smoking and Health awarded 32 states and the District of Columbia health departments cooperative agreements to build capacity to conduct tobacco use prevention and control programs. These cooperative agreements are part of CDC=s Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT), which is a nationwide effort to establish comprehensive, coordinated tobacco use prevention programs. Evaluation of IMPACT is comprised of awardees submitting semi-annual progress reports. Information in the evaluation includes staffing, coalition composition and efforts, status of a state tobacco control plan, development of a resource center, training efforts, community outreach and mobilization, and participation in CDC national campaigns.

The primary intent of these state tobacco control program evaluations is to assess the success of the intervention activities within each state. The information gained from the evaluation is used to refine the interventions in that state. In addition, the information is used nationally to evaluate the success of the IMPACT program.

**Research** -

**Evaluation of Community Based Organization Intervention to Reduce Sexually Transmitted Disease (STD) Rates Among STD Patients in Miami -** Male STD Patients were randomized to either the standard HIV prevention counseling or intensive counseling comprised of four sessions of HIV counseling from a community based organization. STD clinic records were reviewed to determine whether there was a difference in return rates with new STDs between the groups. The objective of intervention and evaluation is to determine whether intensive counseling reduces the acquisition of new STDs among high risk people attending a STD clinic. The purpose of the project was to evaluate a new intervention for reducing the transmission of STDs. Knowledge gained from this evaluation would be used to generalize to other sites.

**A Comprehensive Evaluation for Project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together)** - Project DIRECT is a community diabetes demonstration project targeting African American adults residing in Raleigh, North Carolina. The project is three-tiered and addresses diabetes care, community screening for persons at high risk for developing diabetes, and population based approaches to increase physical activity and reduce dietary fat intake (two risk factors for diabetes). The goals of the community project are to reduce preventable

complications of diabetes via a health systems approach, increase the proportion of persons at risk for diabetes who are screened, and increase the proportion who participate in regular vigorous physical activity and eat a reduced fat diet. Baseline and follow-up population-based surveys are planned to evaluate the community intervention. The purpose of this project is to evaluate new and innovative interventions to prevent diabetes and its complications. Knowledge gained from this project will be used to develop similar intervention projects in other communities.

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## References


Fink, A. Evaluation fundamentals. Newberg Park: California: Sage Publication, Inc., 1993

Centers for Disease Control and Prevention. Framework for program evaluation in public health. MMWR 1999;48(No. RR-11):1-40.

Langmuir, AD. The Epidemic Intelligence Service of the Center for Disease Control. Public Health Reports 1980;95:470-7.

OPRR Memorandum. Engagement of Institutions in Research, January 26, 1999

Rossi, PH and Freeman, HE. Evaluation: A systematic approach. Newberg Park, California: Sage Publications, Inc., 1993.

Thacker, SB and Berkelman, RL. Public health surveillance in the United States. Epidemiologic Review, 1988;10:164-190.



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# Appendix E: Reportable Conditions List 1992 – 2007

| DIAGNOSIS YEARS | REPORTABLE CONDITIONS |
|---|---|
| For cases diagnosed between January 1, 1992 through December 31, 1993 | **all diseases** listed in ICD-O-2 with a behavior code of:<br>• "/2", in situ disease, or<br>• "/3", malignant disease<br>• **Except for:**<br>o basal and squamous cell carcinomas of the skin |

**Program Announcement 426 in 1994** excluded "carcinoma in situ of the cervix uteri" from the reportable list "because it has been well documented that routine collection of such data is incomplete due to inconsistent collection of other High Grade Neoplasia. In addition, these data are not comparable over time because of changing terminology and diagnostic criteria."

| DIAGNOSIS YEARS | REPORTABLE CONDITIONS |
|---|---|
| For cases diagnosed between January 1, 1994 through December 31, 2000 | **all diseases** listed in ICD-O-2 with a behavior code of:<br>• "/2", in situ disease, or<br>• "/3", malignant disease<br>• **Except for:**<br>o basal and squamous cell carcinomas of the skin<br>o carcinoma in situ of the cervix uteri |

**NAACCR 2001 Implementation Guide** introduced ICD-O-3 as the standard for coding primary site and morphology.

| DIAGNOSIS YEARS | REPORTABLE CONDITIONS |
|---|---|
| For cases diagnosed January 1, 2001 and later | **all diseases** listed in the ICD-O-3 with a behavior code of<br>• "/2", in situ disease, or<br>• "/3", malignant disease<br>• **Except for:**<br>o basal and squamous cell carcinomas of the skin<br>o carcinoma in situ of the cervix uteri and cervical intraepithelial neoplasia |

| | |
|---|---|
| | o prostatic intraepithelial neoplasia |

**Public Law 107-260 in 2002** expanded the reportable definition to include "malignant brain-related tumors" and "benign brain-related tumors", [brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any other part of the central nervous system", "pituitary gland, pineal gland, or craniopharyngeal duct]."

| DIAGNOSIS YEARS | REPORTABLE CONDITIONS |
|---|---|
| For cases diagnosed January 1, 2004 - present | **all diseases** listed in the ICD-O-3 with a behavior code of<br>• "/2", in situ disease, or<br>• "/3", malignant disease<br>• **Except for:**<br>o basal and squamous cell carcinomas of the skin<br>o carcinoma in situ of the cervix uteri and cervical intraepithelial neoplasia<br>o prostatic intraepithelial neoplasia<br>**all solid tumors of the brain and central nervous system**, including the meninges and intracranial endocrine structures, listed in the ICD-O-3 with behavior codes of<br>• "/0" benign disease,<br>• "/1" uncertain malignant potential of the disease<br>• "/2", in situ disease, or<br>o "/3", malignant disease |
| | **Note:** [U.S. standard setters have agreed that Juvenile astrocytoma, listed in the ICD-O-3 with a behavior code of "/1", will be reportable with behavior code of "/3".] |

# Appendix F: Full Citation for Reference Manuals

| DISEASE CLASSIFICATIONS | DATE RANGE FOR USE |
|---|---|
| Surveillance, Epidemiology, and End Results Program. *Multiple Primary and Histology Coding Rules.* Bethesda, MD: National Cancer Institute, January 2007. | 2007-current |
| Surveillance, Epidemiology, and End Results Program. "Coding Complex Morphologies", 2001. | 2001-2006 |
| Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Parkin D, Whelan S, eds. *International Classification of Diseases for Oncology*. Third Edition. Geneva: World Health Organization, 2000. | 2001-current |
| Percy C, VanHolten V, Muir C, eds. *International Classification of Diseases for Oncology*. Second Edition. Geneva: World Health Organization, 1990. | 1992-2000 |
| **STAGE AND EXTENT OF DISEASE MANUALS** | |
| Collaborative Staging Task Force of the American Joint Committee on Cancer. *Collaborative Staging Manual and Coding Instructions*. NIH Pub. No. 04-5496, 2006. http://www.cancerstaging.org/cstage/manuals.html | 2004-current |
| Collaborative Stage Task Force of the American Joint Committee on Cancer. *Collaborative Staging Manual and Coding Instructions*. NIH Pub. No. 04-5496, 2004. http://www.cancerstaging.org/cstage/manuals.html | 2004-2006 |
| Surveillance, Epidemiology, and End Results Program. Young J Jr, Roffers S, Ries L, Fritz A, Hurlbut A, eds. *SEER Summary Staging Manual - 2000: Codes and Coding Instructions*. Bethesda, MD: National Institutes of Health, National Cancer Institute, NIH Pub. No. 01-4969, 2001. http://www.seer.cancer.gov/tools/codingmanuals/historical.html | 2001-2003 |
| Surveillance, Epidemiology, and End Results Program. Shambaugh E, Weiss M, Axtell L, eds. *Summary Staging Guide.* Bethesda, MD: National Institutes of Health, National Cancer Institute, April 1977. NIH Pub. No. 86-2313. (Reprinted July 1986.). SEER Program, National Institutes of Health, April 1977. http://www.seer.cancer.gov/tools/codingmanuals/historical.html | 1977-2000 |

| CANCER TREATMENT – SEER MANUALS | |
|---|---|
| Surveillance, Epidemiology, and End Results Program. SEER*Rx - Interactive Antineoplastic Drugs Database. http://seer.cancer.gov/tools/seerrx/ | 2005-current |
| Surveillance, Epidemiology, and End Results Program. *SEER Program Self Instructional Manual for Tumor Registrars, Book Eight: Antineoplastic Drugs*, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute, NIH Pub. No 94-2441, 1994. | 1994-2005. |
| Surveillance, Epidemiology, and End Results Program. Johnson C, ed. *The SEER Program Coding and Staging Manual 2004*, Revision 1. Bethesda, MD: National Institutes of Health, National Cancer Institute, NIH Pub. No. 04-5581. http://www.seer.cancer.gov/tools/codingmanuals/ | 2004-current |
| Surveillance, Epidemiology, and End Results Program. *SEER Program Code Manual*. Third Edition, Revision 1, SEER Field and Code Changes for 2003. http://www.seer.cancer.gov/tools/codingmanuals/historical.html | 2003 |
| Surveillance, Epidemiology, and End Results Program. Fritz A, Ries L, eds. *The SEER Program Code Manual*. Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute, January 1998.<br>Site-Specific Surgery Codes (Appendix D)<br>SEER Site-Specific Surgery of Primary Site Codes (Appendix F)<br>http://www.seer.cancer.gov/tools/codingmanuals/historical.html | 1998-2003<br>1998-2002<br>2003 |
| Surveillance, Epidemiology, and End Results Program. Cunningham J, Hankey B, Lyles B, Percy C, Ries L, Seiffert J, Shambaugh E, Van Holten V, eds. *The SEER Program Code Manual*, Revised Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute, June 1992. http://www.seer.cancer.gov/tools/codingmanuals/historical.html | 1992-1997 |
| **CANCER TREATMENT – COMMISSION ON CANCER MANUALS** | |
| Commission on Cancer. *FORDS Facility Oncology Registry Data Standards*. Revised for 2004. Chicago: American College of Surgeons, 2002. http://www.facs.org/cancer/coc/fordsmanual.html | 2004-current |
| Commission on Cancer. *FORDS Facility Oncology Registry Data* | 2003 |

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|---|---|
| *Standards*. Chicago: American College of Surgeons, 2002. http://www.facs.org/cancer/coc/fordsmanual.html | |
| Commission on Cancer. *Standards of the Commission on Cancer Volume II: Registry Operations and Data Standards (ROADS), Revised 1/1/98.* Chicago: American College of Surgeons, 1998.<br><br>• Update Pages (dated August 2000)<br>• Update Pages for Appendix D, Site-specific Surgery Codes (dated August 2000)<br>• Race 1-5 (dated January 2001, for implementation with 2000 diagnoses)<br><br>http://www.facs.org/cancer/coc/roads.html | 1998-2002<br><br>2000-2002<br>2000-2002<br>2000-2002 |
| Commission on Cancer. *Data Acquisition Manual.* Revised Edition. American College of Surgeons, September 1994. | 1994-1995 |
| Commission on Cancer. *Standards of the Commission on Cancer Volume II: Registry Operations and Data Standards (ROADS).* Chicago: American College of Surgeons, 1996. http://www.facs.org/cancer/coc/roads.html | 1996-1997 |
| **OCCUPATION AND INDUSTRY CLASSIFICATION AND CODING** | |
| U.S. Census Bureau, Housing and Household Economic Statistics Division. Census 2000 "Alphabetical Indexes of Industries and Occupations." http://www.census.gov/hhes/www/ioindex/view.html. | |
| **ADDRESS CODING** | |
| U.S. Postal Service. *Postal Addressing Standards.* U.S.P.S. Pub 28, November 2000. http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf. | |
| **NAACCR STANDARDS** | |
| North American Association of Central Cancer Registries. Havener L, Hultstrom D, eds. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Eleventh Edition, Version 11.1. Springfield, IL: NAACCR, April 2006. | 2007 |
| North American Association of Central Cancer Registries. Hultstrom D, Havener L, eds. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Tenth Edition, | 2006 |

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|---|---|
| Version 11. Springfield, IL: NAACCR, November 2004. | |
| North American Association of Central Cancer Registries. Hultstrom D, Havener L, eds. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Ninth Edition, Version 10.2. Springfield, IL: NAACCR, March 2004. | 2005 |
| North American Association of Central Cancer Registries. Hultstrom D, Havener L, eds. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Eighth Edition, Version 10.1. Springfield, IL: NAACCR, March 2003. | 2004 |
| North American Association of Central Cancer Registries. Hultstrom D, ed. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Seventh Edition, Version 10. Springfield, IL: NAACCR, March 2002. | 2003 |
| North American Association of Central Cancer Registries. Hultstrom D, ed. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Sixth Edition, Version 9.1. Springfield, IL: NAACCR, March 2001. | 2002 |
| North American Association of Central Cancer Registries. Johnson CH, ed. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Fifth Edition, Version 9. Sacramento, CA: NAACCR, May 2000. | 2001 |
| North American Association of Central Cancer Registries. Johnson CH, ed. *Standards for Cancer Registries, Volume II. Data Standards and Data Dictionary*. Fourth Edition, Version 8. Sacramento, CA: NAACCR, March 1999. | 2000 |
| North American Association of Central Cancer Registries. Seiffert J, ed. *Standards for Cancer Registries, Volume II. Data Standards and Data Dictionary*. Third Edition, Version 6. Sacramento, CA: NAACCR, March 1998. Changed Data Dictionary entries, April 1998. | 1998-1999 |
| North American Association of Central Cancer Registries. Seiffert J, ed. *Standards for Cancer Registries, Volume II. Data Standards and Data Dictionary*. Second Edition, Version 5.1. Sacramento, CA: NAACCR, March 1997. | 1997 |
| American Association of Central Cancer Registries. Menck HR, Seiffert J, eds. *Standards for Cancer Registries, Volume I. Data Standards and Data Dictionary*. Version 3.0. Sacramento, CA: AACCR, February 1994. | 1994-1996 |

# Appendix G: Timeline of Data Item Requirements: Diagnosis Years 1997-2008

| | NPCR REQUIRED STATUS TABLE - NAACCR LAYOUTS 5 through 11.2 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **NAACCR LAYOUT** | | | **11.2** | **11.1** | **11.0** | **10.2** | **10.1** | **10.0** | **9.0, 9.1** | **8.0** | **7.0** | **5.0, 6.0** |
| **DIAGNOSIS YEAR** | | | **2008** | **2007** | **2006** | **2005** | **2004** | **2003** | **2001-2** | **2000** | **1999** | **1997-8** |
| **Item #** | **Item Name*** | **Source of Standard** | | | | | | | | | | |
| 10 | Record Type | NAACCR | R | . | . | . | . | . | . | . | . | . |
| 20 | **Patient ID Number** | Reporting Registry | R | R | R | R | R | R | R | S | S | S |
| 35 | *FIN Coding System* | NAACCR | . | . | . | S | S | S | S | S | S | . |
| 40 | **Registry ID** | NAACCR | R | . | . | S | S | S | S | S | S | S |
| 45 | NPI--Registry ID | NAACCR | . | . | . | . | . | . | . | . | . | . |
| 50 | **NAACCR Record Version** | NAACCR | R | . | . | R | R | R | S | S | S | S |
| 60 | *Tumor Record Number* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 70 | **Addr at DX--City** | COC | R | R | R | R | R | R | R | R | R | R |
| 80 | **Addr at DX--State** | COC | R | R | R | R | R | R | R | R | R | R |
| 90 | **County at DX** | FIPS/SEER | R | R | R | R | R | R | R | R | R | R |
| 100 | **Addr at DX--Postal Code** | COC | R | R | R | R | R | R | R | R | R | R |
| 110 | **Census Tract 1970/80/90** | SEER | RH* | RH* | RH* | RH | RH | RH | R | R | R | R |
| 120 | **Census Cod Sys 1970/80/90** | SEER | RH* | RH* | RH* | RH | RH | RH | R | R | R | R |
| 130 | Census Tract 2000 | NAACCR | R | R | R | R | R | R | . | . | . | . |
| 150 | *Marital Status at DX* | SEER/COC | . | . | . | S | S | S | S | S | S | S |
| 160 | **Race 1** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 161 | Race 2 | SEER/COC | R | R | R | R | R | R | R | S | . | . |
| 162 | Race 3 | SEER/COC | R | R | R | R | R | R | R | S | . | . |
| 163 | Race 4 | SEER/COC | R | R | R | R | R | R | R | S | . | . |
| 164 | Race 5 | SEER/COC | R | R | R | R | R | R | R | S | . | . |
| .190 | **Spanish/Hispanic Origin** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 191 | NHIA Derived Hisp Origin | NAACCR | D | D | D | R | . | . | . | . | . | . |
| 192 | IHS Link | NPCR | R* | R* | R* | . | . | . | . | . | . | . |
| 200 | **Computed Ethnicity** | SEER | R | R | R | S | S | S | S | S | S | S |
| 210 | **Computed Ethnicity Source** | SEER | R | R | R | S | S | S | S | S | S | S |
| 220 | **Sex** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 230 | **Age at Diagnosis** | SEER/COC | R | R | R | R | R | R | R | S | S | S |
| 240 | **Birth Date** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 250 | **Birthplace** | SEER/COC | R* | R* | R* | R* | R* | R* | R* | S | S | S |
| 270 | **Occupation Code--Census** | Census/NPCR | R* | R* | R* | S | S | S | S | S | S | S |
| 280 | **Industry Code--Census** | Census/NPCR | R* | R* | R* | S | S | S | S | S | S | S |
| 290 | **Occupation Source** | NPCR | R* | R* | R* | S | S | S | S | S | S | S |
| 300 | **Industry Source** | NPCR | R* | R* | R* | S | S | S | S | S | S | S |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 310 | **Text--Usual Occupation** | NPCR | R* | R* | R* | R* | R* | R* | R* | R* | R* | R* |
| 320 | **Text--Usual Industry** | NPCR | R* | R* | R* | R* | R* | R* | R* | R* | R* | R* |
| 330 | **Occup/Ind Coding System** | NPCR | R* | R* | R* | S | S | S | S | S | S | S |
| 364 | Census Tr Cert 1970/80/90 | SEER | RH* | RH* | RH* | RH | RH | RH | R | . | . | . |
| 365 | Census Tr Certainty 2000 | NAACCR | R | R | R | R | R | R | . | . | . | . |
| 366 | GIS Coordinate Quality | NAACCR | R* | R* | R* | . | . | . | . | . | . | . |
| 380 | **Sequence Number--Central** | SEER | R | R | R | R | R | R | R | S | S | S |
| 390 | **Date of Diagnosis** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 400 | **Primary Site** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 410 | **Laterality** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 420 | **Histology (92-00) ICD-O-2** | SEER/COC | RH | RH | RH | RH | RH | RH | R+ | R | R | R |
| 430 | **Behavior (92-00) ICD-O-2** | SEER/COC | RH | RH | RH | RH | RH | RH | R+ | R | R | R |
| 440 | **Grade** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 442 | Ambiguous Terminology DX | SEER/COC | . | . | | | | | | | | |
| 443 | Date of Conclusive DX | SEER/COC | . | . | | | | | | | | |
| 444 | Mult Tum Rpt as One Prim | SEER/COC | . | . | | | | | | | | |
| 445 | Date of Multiple Tumors | SEER/COC | . | . | | | | | | | | |
| 446 | Multiplicity Counter | SEER/COC | . | . | | | | | | | | |
| 447 | Number of Tumors/Hist | SEER/COC | . | . | | | | | | | | |
| 450 | Site Coding Sys--Current | NAACCR | R | R | R | S | S | S | S | . | . | . |
| 470 | Morph Coding Sys--Current | NAACCR | R | R | R | S | S | S | S | . | . | . |
| 490 | **Diagnostic Confirmation** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 500 | **Type of Reporting Source** | SEER | R | R | R | R | R | R | R | R | R | R |
| 522 | Histologic Type ICD-O-3 | SEER/COC | R | R | R | R | R | R | R+ | . | . | . |
| 523 | Behavior Code ICD-O-3 | SEER/COC | R | R | R | R | R | R | R+ | . | . | . |
| 540 | **Reporting Facility** | COC | R | R | R | S | S | S | S | S | S | S |
| 545 | NPI--Reporting Facility | NAACCR | R* | R* | . | . | . | . | . | . | . | . |
| 550 | *Accession Number--Hosp* | COC | . | . | . | S | S | S | S | S | S | S |
| 560 | *Sequence Number--Hospital* | COC | . | . | . | S | S | S | S | R | R | R |
| 580 | **Date of 1st Contact** | COC | R | R | R | R | R | R | R | R | R | R |
| 600 | *Date of Inpatient Disch* | COC | . | . | . | . | . | . | | S | S | S |
| 610 | **Class of Case** | COC | R | R | R | S | S | S | S | S | S | S |
| 630 | *Primary Payer at DX* | COC | R* | . | R | . | . | . | . | . | . | . |
| 759 | SEER Summary Stage 2000 | SEER | RH | RH | RH | RH | RH | R | R+ | . | . | . |
| 760 | **SEER Summary Stage 1977** | SEER | RH | RH | RH | RH | RH | RH | R+ | R | R | R |
| 780 | *EOD--Tumor Size* | SEER/COC | . | . | . | . | . | S | S | S | S | S |
| 790 | *EOD--Extension* | SEER | . | . | . | . | . | S | S | . | . | . |
| 800 | *EOD--Extension Prost Path* | SEER | . | . | . | . | . | S | S | . | . | . |
| 810 | *EOD--Lymph Node Involv* | SEER | . | . | . | . | . | S | S | . | . | . |
| 820 | *Regional Nodes Positive* | SEER/COC | . | . | . | S | S | S | S | S | S | S |
| 830 | *Regional Nodes Examined* | SEER/COC | . | . | . | S | S | S | S | S | S | S |
| 1200 | *RX Date--Surgery* | COC | . | . | . | S | S | S | S | S* | S* | S* |
| 1210 | *RX Date--Radiation* | COC | . | . | . | S | S | S | S | S* | S* | S* |
| 1220 | *RX Date--Chemo* | COC | . | . | . | . | . | . | S | S* | S* | S* |
| 1230 | *RX Date--Hormone* | COC | . | . | . | . | . | . | S | S* | S* | S* |
| 1240 | *RX Date--BRM* | COC | . | . | . | . | . | . | S | S* | S* | S* |
| 1250 | *RX Date--Other* | COC | . | . | . | S | S | S | S | S* | S* | S* |
| 1260 | **Date of Initial RX--SEER** | SEER | R# | R# | R# | # | # | # | # | #* | #* | #* |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1270 | **Date of 1st Crs RX--COC** | COC | R# | R# | R# | # | # | # | # | #* | #* | #* |
| 1280 | *RX Date--DX/Stg Proc* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1290 | **RX Summ--Surg Prim Site** | SEER/COC | R | R | R | R | R | R | R | #* | #* | #* |
| 1292 | **RX Summ--Scope Reg LN Sur** | SEER/COC | R | R | R | R | R | R | R | #* | #* | #* |
| 1294 | **RX Summ--Surg Oth Reg/Dis** | SEER/COC | R | R | R | R | R | R | R | #* | #* | #* |
| 1296 | *RX Summ--Reg LN Examined* | COC | . | . | . | RH | RH | . | R | #* | #* | #* |
| 1310 | *RX Summ--Surgical Approch* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1320 | *RX Summ--Surgical Margins* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1330 | *RX Summ--Reconstruct 1st* | COC | . | . | . | . | . | . | S | #* | #* | #* |
| 1340 | **Reason for No Surgery** | SEER/COC | R | R | R | S | S | S | S | R* | R* | R* |
| 1350 | *RX Summ--Dx/Stg Proc* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1360 | *RX Summ--Radiation* | SEER/COC | D | . | . | . | . | . | S | #* | #* | #* |
| 1370 | *RX Summ--Rad to CNS* | SEER/COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1380 | **RX Summ--Surg/Rad Seq** | SEER/COC | R | R | R | S | S | S | S | R* | R* | R* |
| 1390 | **RX Summ--Chemo** | SEER/COC | R | R | R | S | S | S | S | #* | #* | #* |
| 1400 | **RX Summ--Hormone** | SEER/COC | R | R | R | S | S | S | S | #* | #* | #* |
| 1410 | **RX Summ--BRM** | SEER/COC | R | R | R | S | S | S | S | R* | R* | R* |
| 1420 | **RX Summ--Other** | SEER/COC | R | R | R | S | S | S | S | R* | R* | R* |
| 1430 | *Reason for No Radiation* | COC | . | . | . | S | S | S | S | #* | #* | #* |
| 1440 | *Reason for No Chemo* | COC | . | . | . | . | . | . | S | #* | #* | #* |
| 1450 | *Reason for No Hormone* | COC | . | . | . | . | . | . | S | #* | #* | #* |
| 1460 | **RX Coding System--Current** | NAACCR | R | R | R | R | R | R | R | S | S | S |
| 1500 | *First Course Calc Method* | NAACCR | . | . | . | . | . | . | . | S | S | S |
| 1570 | Rad--Regional RX Modality | COC | R | R | R | S | S | S | . | . | . | . |
| 1639 | RX Summ--Systemic/Sur Seq | COC | R | R | R | . | . | . | . | . | . | . |
| 1640 | *RX Summ--Surgery Type* | SEER | . | . | . | . | . | . | . | #* | #* | #* |
| 1642 | *RX Summ--Screen/BX Proc1* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1643 | *RX Summ--Screen/Bx Proc2* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1644 | *RX Summ--Screen/Bx Proc3* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1645 | *RX Summ--Screen/Bx Proc4* | COC | . | . | . | . | . | . | . | #* | #* | #* |
| 1646 | *RX Summ--Surg Site 98-02* | SEER/COC | . | . | . | RH | RH | RH | . | . | . | . |
| 1647 | *RX Summ--Scope Reg 98-02* | SEER/COC | . | . | . | RH | RH | RH | . | . | . | . |
| 1648 | *RX Summ--Surg Oth 98-02* | SEER/COC | . | . | . | RH | RH | RH | . | . | . | . |
| 1750 | **Date of Last Contact** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 1760 | **Vital Status** | SEER/COC | R | R | R | R | R | R | R | R | R | R |
| 1791 | Follow-up Source Central | NAACCR | R* | R | R | . | . | . | . | . | . | . |
| 1860 | *Recurrence Date--1st* | COC | . | . | . | S | S | S | . | . | . | . |
| 1880 | *Recurrence Type--1st* | COC | . | . | . | S | S | S | . | . | . | . |
| 1910 | **Cause of Death** | SEER | R | R | R | R | R | R | R | R | R | R |
| 1920 | **ICD Revision Number** | SEER | R | R | R | R | R | R | R | S | S | S |
| 1940 | **Place of Death** | NPCR | R | R | R | S | S | S | S | S | S | S |
| 1990 | **Over-ride Age/Site/Morph** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2000 | **Over-ride SeqNo/DxConf** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2010 | **Over-ride Site/Lat/SeqNo** | SEER | R | R | R | S | S | S | S | S | S | S |
| 2020 | **Over-ride Surg/DxConf** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2030 | **Over-ride Site/Type** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2040 | **Over-ride Histology** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2050 | **Over-ride Report Source** | SEER | R | R | R | R | R | R | R | S | S | S |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2060 | **Over-ride Ill-define Site** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2070 | **Over-ride Leuk, Lymphoma** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2071 | **Over-ride Site/Behavior** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2072 | *Over-ride Site/EOD/DX Date* | SEER | . | . | . | S | S | S | S | S | S | S |
| 2073 | *Over-ride Site/Lat/EOD* | SEER | . | . | . | S | S | S | S | S | S | S |
| 2074 | **Over-ride Site/Lat/Morph** | SEER | R | R | R | R | R | R | R | S | S | S |
| 2110 | **Date Case Report Exported** | NPCR | R | R | R | S | S | S | S | S | S | S |
| 2111 | **Date Case Report Received** | NPCR | R | R | R | R | R | R | R | S | S | S |
| 2112 | **Date Case Report Loaded** | NPCR | R | R | R | S | S | S | S | S | S | S |
| 2113 | **Date Tumor Record Availbl** | NPCR | R | R | R | S | S | S | S | S | S | S |
| 2116 | ICD-O-3 Conversion Flag | SEER/COC | R | R | R | R | R | R | R | . | . | . |
| 2120 | *SEER Coding Sys--Current* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 2130 | *SEER Coding Sys--Original* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 2140 | *COC Coding Sys--Current* | COC | . | . | . | S | S | S | S | S | S | S |
| 2150 | *COC Coding Sys--Original* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 2230 | **Name--Last** | NAACCR | R | R | R | R | R | R | R | R | R | R |
| 2240 | **Name--First** | NAACCR | R | R | R | R | R | R | R | R | R | R |
| 2250 | **Name--Middle** | COC | R | R | R | R | R | R | R | R | R | R |
| 2280 | **Name--Alias** | SEER | R | R | R | S | S | S | S | S | S | S |
| 2300 | **Medical Record Number** | COC | R | R | R | S | S | S | S | S | S | S |
| 2310 | *Military Record No Suffix* | COC | . | . | . | . | . | . | . | S | S | S |
| 2320 | **Social Security Number** | COC | R | R | R | R | R | R | R | R | R | R |
| 2330 | **Addr at DX--No & Street** | COC | R | R | R | S | S | S | S | S | S | S |
| 2335 | Addr at DX--Supplemental | COC | R | R | R | S | S | S | . | . | . | . |
| 2350 | *Addr Current--No & Street* | COC | . | . | . | . | . | S | . | . | . | . |
| 2352 | Latitude | NAACCR | R* | R* | R* | . | . | . | . | . | . | . |
| 2354 | Longitude | NAACCR | R* | R* | R* | . | . | . | . | . | . | . |
| 2380 | **DC State File Number** | State | R | R | R | S | S | S | S | S | S | S |
| 2390 | **Name--Maiden** | SEER | R | R | R | S | S | S | S | S | S | S |
| 2520 | **Text--DX Proc--PE** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2530 | **Text--DX Proc--X-ray/Scan** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2540 | **Text--DX Proc--Scopes** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2550 | **Text--DX Proc--Lab Tests** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2560 | **Text--DX Proc--Op** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2570 | **Text--DX Proc--Path** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2580 | **Text--Primary Site Title** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2590 | **Text--Histology Title** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2600 | **Text--Staging** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2610 | **RX Text--Surgery** | NPCR | R^ | R^ | R^ | R^ | R^ | R^ | R^ | S | S | S |
| 2620 | **RX Text--Radiation (Beam)** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2630 | **RX Text--Radiation Other** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2640 | **RX Text--Chemo** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2650 | **RX Text--Hormone** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2660 | **RX Text--BRM** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2670 | **RX Text--Other** | NPCR | R^ | R^ | R^ | S | S | S | S | S | S | S |
| 2680 | *Text--Remarks* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 2690 | *Text--Place of Diagnosis* | NAACCR | . | . | . | S | S | S | S | S | S | S |
| 2800 | *CS Tumor Size* | AJCC | R | . | . | S | S | . | . | . | . | . |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2810 | CS Extension | AJCC | R | R | R | R | R | . | . | . | . | . |
| 2820 | *CS Tumor Size/Ext Eval* | AJCC | R | . | . | S | S | . | . | . | . | . |
| 2830 | CS Lymph Nodes | AJCC | R | R | R | R | R | . | . | . | . | . |
| 2840 | *CS Reg Node Eval* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2850 | CS Mets at DX | AJCC | R | R | R | R | R | . | . | . | . | . |
| 2860 | *CS Mets Eval* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2880 | CS Site-Specific Factor 1 | AJCC | RS | RS | RS | RS | RS | . | . | . | . | . |
| 2890 | *CS Site-Specific Factor 2* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2900 | CS Site-Specific Factor 3 | AJCC | RS | RS | RS | RS | RS | . | . | . | . | . |
| 2910 | *CS Site-Specific Factor 4* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2920 | *CS Site-Specific Factor 5* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2930 | *CS Site-Specific Factor 6* | AJCC | . | . | . | S | S | . | . | . | . | . |
| 2935 | CS Version 1st | AJCC | R | R | R | R | R | . | . | . | . | . |
| 2936 | CS Version Latest | AJCC | R | R | R | R | R | . | . | . | . | . |
| 2940 | *Derived AJCC T* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 2950 | *Derived AJCC T Descriptor* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 2960 | *Derived AJCC N* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 2970 | *Derived AJCC N Descriptor* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 2980 | *Derived AJCC M* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 2990 | *Derived AJCC M Descriptor* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 3000 | *Derived AJCC Stage Group* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 3010 | *Derived SS1977* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 3020 | Derived SS2000 | AJCC | D | D | D | D | D | . | . | . | . | . |
| 3030 | *Derived AJCC--Flag* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 3040 | *Derived SS1977--Flag* | AJCC | . | . | . | D | D | . | . | . | . | . |
| 3050 | Derived SS2000--Flag | AJCC | D | D | D | D | D | . | . | . | . | . |
| 3170 | *RX Date--Most Defin Surg* | COC | . | . | . | S | S | S | . | . | . | . |
| 3230 | *RX Date--Systemic* | COC | . | . | . | S | S | S | . | . | . | . |
| 3250 | RX Summ--Transplnt/Endocr | COC | R | R | R | S | S | S | . | . | . | . |
| 3300 | RuralUrban Continuum 1993 | NAACCR | D | D | D | D | D | D | . | . | . | . |
| 3310 | RuralUrban Continuum 2003 | NAACCR | D | D | D | D | D | D | . | . | . | . |

* Bold - Items in data set for every diagnostic year

Italic - Items not in current data set

**Codes for Recommendations**

| | |
|---|---|
| R | Required |
| R* | Required when available |
| R^ | Required, requirement may be met with one or several text block fields |
| R+ | Required by diagnosis year |
| RH | Historically collected, transmitted |
| RH* | Historically collected, transmitted when available |
| RS | Required, site specific |
| D | Derived value |
| O | Optional |
| S | Supplementary/recommended |
| # | Treatment information may be coded with SEER or COC codes |
| . | Not in data set |

# Appendix H: Program Evaluation Instrument (PEI)

**PURPOSE STATEMENT**

The NPCR Program Evaluation Instrument (PEI) is a web-based survey instrument designed to evaluate NPCR-funded registries' operational attributes and their progress towards meeting program standards. The PEI also provides information about advanced activities and "success stories" that highlight ways registry data is being used.

Based on *CDC's Updated Guidelines for Evaluating Public Health Surveillance Systems*, (http://www.ihs.gov/MedicalPrograms/InjuryPrevention/Documents/rr5013a1.pdf), the PEI monitors the integration of surveillance and health information systems, the utilization of established data standards, and the electronic exchange of health data. Data provided by this report can be used for public health action, program planning and evaluation, and formulating research hypotheses.

Specific knowledge about operational activities NPCR registries are engaged in is used to provide valuable insight to CDC regarding programmatic efficiencies/deficiencies that have contributed to the success/challenges of the NPCR. The results of this instrument inform CDC and NPCR Program Consultants where technical assistance is most needed in order to continue to improve and enhance the NPCR.

Many of the questions in the 2007 PEI provide baseline data that will be used when measuring future progress with the NPCR Program Standards expected to be implemented this year. These questions, and the standard they reference, are noted throughout the instrument (e.g., *"Program Standard I.a."*)

Using all available information as of **June 30, 2007**, the appropriate Central Cancer Registry (CCR) staff should complete the PEI.

**ADMINISTRATIVE DATA**

| | |
|---|---|
| State / Territory | |
| NPCR reference year | |
| Registry reference year | |
| Registry Program Director | |
| Cooperative Agreement # | U58/DP000 |
| Most Current Grant Award Amount | $ |
| CDC Program Consultant | |

| | |
|---|---|
| Your name | |
| Title | |
| Phone number | |
| Date completed | |

## STAFFING

**The following questions** use the concept of a "Full-time Equivalent" also known as an "FTE". In each question you will be asked to report the total number of FTEs (FTE count). To do this, please convert each position to the appropriate FTE using the guidelines below, rounding each position to the nearest quarter of an FTE (e.g., 34 hrs/week would convert to 0.75 FTE, whereas 35 hrs/week would convert to 1.0 FTE):

0.25 FTE = 10 hrs/week
0.50 FTE = 20 hrs/week
0.75 FTE = 30 hrs/week
1.00 FTE = 40 hrs/week

Then add each converted position for the total number of FTEs. For example, if the CTR works 35 hours a week and another CTR works 25 hours a week, the combined hours for the CTR positions = 60 hours = 1.5 FTEs.

1. On **June 30, 2007,** how many total FTE central cancer registry (CCR) staff positions were **funded**? In this table, *you may include positions outside the registry**, ONLY IF the registry pays a portion of the salary.** Remember to use the calculation method above when computing partial FTEs.*

| | **Total Count FTEs** | |
|---|---|---|
| **Funding Category** | **Filled** | **Vacant** |
| Number of **NPCR-funded (non-contracted)** FTE positions | | |
| Number of **NPCR-funded, Contracted** FTE positions | | |
| Number of **State-funded (non-contracted)** FTE positions | | |
| Number of **State-funded, Contracted** FTE positions | | |
| Number of **non-contracted** FTE positions **funded by other sources** | | |
| Number of **Contracted** FTE positions **funded by other sources** | | |
| **TOTALS** | | |

2. Please complete this table with the number of FTEs who *work in the capacity of* the position titles listed. In this table, **include both filled and vacant,** as well as ***access to* these staff (outside the registry), regardless of funding,** in your

total FTE count. So, if a position is vacant, it still counts as a position.
**Remember to use the same FTE calculation method as described above.**
***Please note CTR credentials may be held by several registry positions and should be counted accordingly.***

| | Total Count FTEs | |
|---|---|---|
| **Position (FTE or percentage of FTE)** | **Non-Contractor** | **Contractor** |
| Principle Investigator | | |
| Program Director | | |
| Registry Administrator | | |
| Program Manager | | |
| Budget Analyst | | |
| CTR Quality Control Staff | | |
| Non-CTR Quality Control Staff | | |
| CTR Education/Training Staff | | |
| Epidemiologists | | |
| Statisticians | | |
| Computer/IT/GIS Specialists | | |
| Other staff, specify: | | |
| | **Total Count CTRs** **Non-Contracted** | **Contracted** |
| **Total Number CTRs** (may overlap with above categories) | | |

**Staffing Section Comments** (You may add comments regarding your responses in the "Staffing" section above)

## LEGISLATIVE AUTHORITY

3. Does your state/territory have a current law authorizing a population-based central cancer registry? *(Program Standard I.a.)*

☐ Yes
☐ No

4. Does your state/territory have current legislation or regulations in support of all 8 criteria of the Public Law authorizing the NPCR? *(Program Standard I.b.)*

☐ Yes
☐ No

5.

a. Are there any penalties in place regarding reporting compliance as mandated by current legislation or regulations?

☐ Yes
☐ No

b. If "Yes", in which law/regulations are the penalties included? **(check only one)**:

☐ Cancer-specific reporting law/regulations
☐ General public health law/regulations
☐ Both
☐ None of the above

c. If "Yes," have you had to impose the penalty?

☐ Yes
☐ No

6.

a. With passage of Public Law 107-260 (the Benign Brain Tumor Cancer Registry Amendment Act), NPCR-funded registries are required to collect data on benign brain tumors beginning in diagnosis year 2004. Do regulations or legislation in your State or territory authorize you to collect data on benign brain tumors?

☐ Yes
☐ No

b. If "No," what are your plans, including timeframes, to modify your State or Territory's legislation or regulations to allow you to collect benign brain tumor data?

Specify _____

_____

7. Does your State or Territory have legislation or regulations prohibiting you from reporting county level data?

☐ Yes
☐ No

8. Does your state law/regulations protect your cancer registry data from the Freedom of Information Act (FOIA)?

☐ Yes

☐ No

9.

a. Does your state law/regulations protect your cancer registry data from subpoena?

☐ Yes
☐ No

b. If no, are data received through interstate data exchange protected from subpoena?

☐ Yes
☐ No

**Legislation Section Comments** (You may add comments regarding your responses in the "Legislation" section above)

| |
|---|
| |

## ADMINISTRATION

10. Does your CCR maintain an operational manual that describes registry operations, policies and procedures that, at a minimum, contains the following? *(Program Standard II.a.)* ***Check all that apply:***

| | YES | NO |
|---|---|---|
| Reporting laws/regulations | | |
| List of reportable diagnoses | | |
| List of required data items | | |
| Data processing operational procedures for (check all that apply): | | |
| a. Monitoring timeliness of reporting | | |
| b. Receipt of data | | |
| c. Database management including a description of the Registry Operating System (software) | | |
| d. Conducting death certificate clearance | | |
| Procedures for Implementing and maintaining a quality assurance/control program including (check all that apply, f-h) | | |
| f. Conducting follow-back to reporting facilities on quality | | |

| | | |
|---|---|---|
| assurance issues | | |
| g. Conducting record consolidation | | |
| h. Maintaining detailed documentation of all quality assurance operations | | |
| Procedures for insuring confidentiality and data security including disaster planning | | |
| Procedures for data release including access to and disclosure of information | | |
| Procedures for maintaining and updating the operational manual | | |

11. Do you believe that your CCR policies and procedures are sufficient and clear as to what data may and may not be disclosed and how this should occur?

☐ Yes
☐ No

12. Do you believe that your CCR policies and procedures are sufficient and clear for protection of confidentiality for all routine registry activities?

☐ Yes
☐ No

13. Do you believe that your CCR staff possesses sufficient knowledge and resources to meet risk-appropriate threats to security and confidentiality?

☐ Yes
☐ No

14. Does your CCR produce reports that are used to monitor the registry operations and database, including processes and activities? *(Program Standard II.b.)*
***Check all that apply:***

Quality control report (central registry)
Quality control reports for each facility
Data completeness report for each facility
Timeliness of data report for each facility
Data workflow report
Other, specify _____

None of the above

15. Does your CCR have an abstracting and coding manual that is provided for use by all reporting sources? *(Program Standard II.c.)*

☐ Yes
☐ No

**Administration Section Comments** (You may add comments regarding your responses in the "Administration" section above)

## REPORTING COMPLETENESS

16. What types of facilities and health care providers report to your CCR? Please list the percentage of facilities, by type, that actually reported in the past year (do not record the percentage reporting according to your CCR's timeliness schedule), and calculate what percentage of the reports, by facility type, are received electronically.

***Note:***

- *"Hospital cancer registry" is defined as one (single or joint institution) who collects data to be used internally and who would continue to do so regardless of the central cancer registry requirements to collect and report cancer data.*
- *Provide the number of facilities required to report and, where indicated, use your best estimate if the exact number is not available.*
- *For those facilities which are not applicable to your state/territory (e.g., IHS Hospitals), record zero (0) in 'Number Required to Report' and 100 in 'Percent Compliant with Reporting'. In these instances, 'Percent Reports Received Electronically' is to be left blank and will be validated against the 'Number Required to Report'. (Program Standards III.a-c)*

| **Facilities Required to Report Cancer Cases by Type** | **Number Required to Report (Denominator)** | **Percent Compliant by Reporting**** | **Percent Reports Received Electronically** |
|---|---|---|---|
| Hospitals with a cancer registry (non-federal) | | | |
| Hospitals without a cancer registry (non-federal) | | | |
| VA Hospitals | | | |
| IHS Hospitals | | | |
| Tribally Owned Hospitals | | | |
| | | | |
| Health Centers (IHS, Tribal) | | | |
| Surgery Centers | | | |
| Independent Radiation Therapy Centers | | | |
| | | | |
| In-State Independent Pathology Laboratories | | | |
| Out-of-State Independent Pathology Laboratories* | | | |

| | | | |
|---|---|---|---|
| Dermatologists* | | | |
| Urologists* | | | |
| Oncologists*/Hematologists* | | | |
| Other Physicians* | | | |
| | | | |
| Other facilities, specify: | | | |

**Provide best estimate **Those facilities who report rather than those reporting in a timely manner*

17. Within 24 months of the close of the diagnosis year, what percentage of physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients submit all reportable cases to your CCR? ***Exception:*** Physicians are not required to report cases directly referred or previously admitted to, and reported by, a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State/Territory? *(Program Standard V.a.)* ***Check only one:***

- ☐ 100%
- ☐ 75% - 99%
- ☐ 51% - 74%
- ☐ 10% - 50%
- ☐ 1% – 9%
- ☐ None

18. Of the pathology lab reports your CCR receives, what percentage are in the College of American Pathologists (CAP) cancer protocol checklist format? ***(Provide best estimate)***

- ☐ 100%
- ☐ 75% - 99%
- ☐ 51% - 74%
- ☐ 10% - 50%
- ☐ 1% – 9%
- ☐ None

19. Do you require that non-analytic (classes 3 and 4) cases be reported to your CCR?

- ☐ Yes
- ☐ No

20.

a. Do you receive data from the **Department of Defense's** Automated Central Tumor Registry (ACTUR) dataset? ***(If "No," skip 20b – 20d)***

Yes ☐ No ☐

b. If yes, how often? **Please check only one.**

☐ Every quarter
☐ Every 6 months
☐ Once a year
☐ Other, specify

c. If yes, have these data proven to be helpful in finding new incident cases?

☐ Yes
☐ No

d. If not, why not? (**Please check all that apply)**

☐ Data are incomplete.
☐ Data are not in the proper format for us to consolidate with existing records.
☐ We don't have time to deal with it.
☐ Other, specify: _____

| | | **Number of Facilities** |
|---|---|---|
| 21. | To how many VA facilities do you currently send central registry staff for data collection/abstracting? | _____ |
| 22. | At how many VA facilities are data collected by a combination of VA facility staff and central registry staff? | _____ |
| 23. | How many VA facilities currently report to your CCR indirectly from the VA central cancer registry in Washington, DC? | _____ |

24. If there are VA facilities not reporting, please explain why in the space provided below:

25. Based on historical data, how many cases per diagnosis year do you estimate are missed (i.e., not ever received) by your CCR because of non-reporting by VA facilities?

Number of cases missed: _____

**Reporting Completeness Section Comments** (You may add comments regarding your responses in the "Reporting Completeness" section above)

## DATA EXCHANGE

26. Does your CCR use and require the standardized, NPCR-recommended data exchange record layout for the electronic exchange of cancer data for *(Program Standards III.a.):*

    a. Abstract reports (*The NAACCR record layout version specified in Standards for Cancer Registries Volume II: Data Standards and Data Dictionary*)?

    ☐ Yes
    ☐ No

    b. Pathology reports *(NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting*)?

    ☐ Yes
    ☐ No
    ☐ Not Applicable, not receiving electronic pathology reports

27. Does your exchanged data meet the following minimum criteria? *(Program Standards V.d.)***:**

a. Within 12 months of the close of the diagnosis year, your CCR exchanges data with other central cancer registries where a data-exchange agreement is in place (the data file includes all cases not previously exchanged):

☐ Yes
☐ No

b. **Regardless of residency**, your CCR collects data on all patients diagnosed and/or receiving first course of treatment in the registry's state/territory:

☐ Yes
☐ No

c. The recommended frequency of data exchange is at least two times per year. Your CCR exchanges data at the following frequency:

☐ Annually
☐ Biannually (two times per year)
☐ Other, explain _____

d. Exchange agreements are in place with all bordering central cancer registries:

☐ Yes, with all bordering CCRs
☐ No, *not all*
List existing agreements here:

_____
_____

e. Exchanged data includes a dataset that consists of NPCR core data items:

☐ Yes
☐ No

f. 99% of exchanged data passes an NPCR-prescribed set of standard edits:

☐ Yes
☐ No

g. Exchanged data are transmitted via a secure encrypted Internet-based system:

☐ Yes
☐ No

h. The standardized, NPCR-recommended data exchange format is used to transmit data reports (*The NAACCR record layout version specified in Standards for Cancer Registries Volume II: Data Standards and Data Dictionary*):

☐ Yes
☐ No

**Data Exchange Section Comments** (You may add comments regarding your responses in the "Data Exchange" section above)

| |
|---|
| |

**DATA CONTENT AND FORMAT**

28. Does your CCR collect or derive all required data items using standard codes as prescribed by NPCR?

☐ Yes
☐ No

29. Is your CCR able to receive secure, encrypted cancer abstract data from reporting sources via the Internet?

☐ Yes
☐ Currently being developed and/or implemented
☐ No, not able to receive
☐ No, able to receive, but not receiving

30. What is the primary software system used to process and manage cancer data in your CCR? **Please check only one:**

☐ Commercial Vendor
☐ In-House Software
☐ Registry Plus
  ☐ Abstract Plus
  ☐ Prep Plus
  ☐ CRS Plus
  ☐ Link Plus
  ☐ Web Plus

**Data Content and Format Section Comments** (You may add comments regarding your responses in the "Data Content and Format" section above)

| |
|---|
| |

## DATA QUALITY ASSURANCE

31. Does your CCR's quality assurance program consist of, but is not limited to: *(Program Standard VI.a.)*

| | YES | NO |
|---|---|---|
| A designated CTR is responsible for the quality assurance program | | |
| Qualified, experienced CTRs conduct quality assurance activities | | |
| At least once every 5 years, case-finding and/or re-abstracting audits from a sampling of source documents are conducted for each hospital-based reporting facility, and may include external audits (NPCR/SEER) | | |
| Data consolidation procedures are performed according to an accepted protocol | | |
| Procedures are performed for follow-back to reporting facilities on quality issues | | |

32. Does your CCR have a designated education/training coordinator, who is a CTR, to provide training to CCR staff and reporting sources to assure high quality data? *(Program Standard VI.b.)*

☐ Yes
☐ No

33. In the past year, which of the following type of quality control audits or activities did your CCR conduct?

| | Yes | No |
|---|---|---|
| Casefinding | ☐ | ☐ |
| Re-abstracting | ☐ | ☐ |
| Re-coding | ☐ | ☐ |
| Visual editing | ☐ | ☐ |

34. Does your CCR match *all causes of death* against your registry data to identify a reportable cancer?

☐ Yes
☐ No

35.

a. Does your CCR update the CCR database following death certificate matching:

| | | |
|---|---|---|
| Death information | ☐ Yes | ☐ No |
| Missing demographic information | ☐ Yes | ☐ No |

b. If "Yes", what percentage(s) is updated manually or electronically?: *(Provide best estimate; may be some overlap between automation and manual review)*

Death information: Manually _____% Electronically _____%

Demographic information: Manually _____% Electronically _____%

36. Does your CCR perform record consolidation on the following:

| Data Group | Electronic | Manual | Both | Neither |
|---|---|---|---|---|
| Patient | ☐ | ☐ | ☐ | ☐ |
| Treatment | ☐ | ☐ | ☐ | ☐ |
| Follow-up | ☐ | ☐ | ☐ | ☐ |

37.

a. Does your CCR provide a registry-specific edit set to your reporting facilities and/or vendors for use prior to data submissions to your CCR?

☐ Yes
☐ No

b. If "Yes," are facilities **required** to run registry-specific edits prior to their data submission to your CCR?

☐ Yes
☐ No

**Data Quality Assurance Section Comments** (You may add comments regarding your responses in the "Data Quality Assurance" section above)

## DATA USE

38. Within 12 months of the end of the diagnosis year with data that are 90% complete, did your CCR produce pre-calculated data in tables in an electronic data file or report of incidence rates, counts, or proportions for the diagnosis year for Surveillance Epidemiology and End Results (SEER) site groups as a preliminary monitor of the top cancer sites within your state/territory? *(Program Standard VII.a.)*

☐ Yes
☐ No

39.

a. Within 24 months of the end of the diagnosis year with data that are 95% complete, did your CCR produce pre-calculated data in tables in an electronic data file or report? (The report should include, at a minimum, age-adjusted incidence rates and age-adjusted mortality rates for the diagnosis year by sex for SEER site groups, and, where applicable, by sex, race, and ethnicity). *(Program Standard VII.b.)*

☐ Yes
☐ No

b. What is the most current diagnosis year a data file or report is available?

Year _____

c. In what format is this report available?

☐ Hard copy
☐ Electronic word-processed file
☐ Web page/query system

40.

a. Has the CCR, state health department, or its designee used registry data *for planning and evaluation of cancer control objectives* in ***at least three of the following ways in the past year:*** Comprehensive cancer control detailed incidence/mortality estimates, linkage with a statewide cancer screening program to improve follow-up of screened patients, health event investigation(s), needs assessment/program planning, program evaluation, or epidemiologic studies? *(Program Standard VII.c.)*

☐ Yes
☐ No

b. If “yes,” indicate the number of times data was used for each category in the table below:

| **Data Use Category** | **Number per Year** |
|---|---|
| Comprehensive cancer control | |
| Detailed incidence/mortality estimates | |
| Linkage with a statewide cancer screening program | |
| Health event investigation(s) | |
| Needs assessment/program planning | |
| Program evaluation | |
| Epidemiologic studies | |
| Other, describe: | |

41.

a. Have any of the above uses of data been included in a journal publication

☐ Yes
☐ No

b. If “yes,” please list the citation(s) in the space provided:

| |
|---|
| |

42. During the past year, for which areas of registry data utilization did your CCR acknowledge CDC-NPCR funding, as required in the Notice of Cooperative Agreement Award? ***Check all that apply:***

☐ Publications (e.g.; journal articles, annual report, other reports)
☐ Web site
☐ Presentations, posters
☐ Release of data
☐ Education meeting, training program, conference
☐ Press releases, statements
☐ Requests for proposals, bid solicitations
☐ None

43. Does your CCR use *United States Cancer Statistics* (USCS) data when performing comparative analyses?

☐ Yes
☐ No, explain: _____

**Data Use Section Comments** (You may add comments regarding your responses in the "Data Use" section above)

## COLLABORATIVE RELATIONSHIPS

44. Does your CCR actively collaborate with your state/territory's comprehensive cancer prevention and control (CCC) planning efforts, including establishing a working relationship to ensure the use of registry data to assess and implement cancer control activities? *(Program Standards IX.a.,b.)*

☐ Yes
☐ No

***Please check all of the ways you collaborate:***

☐ Member of our state/territory's comprehensive cancer control (CCC) planning group (coalition, committee, or workgroup)
☐ Provide data for CCC planning
☐ Provide data for CCC Activities
☐ Provide technical assistance and collaborate on data analyses for CCC program publications
☐ Data linkages
☐ Other, specify _____
☐ None, Explain _____

45. Has your CCR established and regularly convened an advisory committee to assist in building consensus, cooperation, and planning for the registry? (Representation should include key organizations and individuals both within and outside the program. Advisory committees may be structured to meet the needs of the state/territory such as the CCC Program committee structure, an advocacy group, or a focus group). *(Program Standard IX.c.)*

☐ Yes
☐ No

## The Advisory Committee includes representation from (check all that apply):

- ☐ Representatives from all cancer prevention and control components
- ☐ Vital Statistics
- ☐ Hospital cancer registrars
- ☐ American Cancer Society
- ☐ Clinical-laboratory personnel
- ☐ Pathologists
- ☐ Clinicians
- ☐ Researchers
- ☐ Other, specify _____

46. If you have an Advisory Committee, how often does this group convene, including in-person and teleconferences? ***Please check only one:***

- ☐ Quarterly
- ☐ Annually
- ☐ Biannually
- ☐ Other, specify _____

47. In what ways does your CCR collaborate with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the National Comprehensive Cancer Control Program (NCCCP)?

***Please check all that apply:***

- ☐ Regular meetings with NBCCEDP and/or NCCCP departmental staff
- ☐ Provides assistance in staging NBCCEDP cases
- ☐ Provides training/technical assistance to NBCCEDP and/or NCCCP staff
- ☐ Provides data to NBCCEDP and/or NCCCP
- ☐ Provides technical material for publications
- ☐ Provides subject matter expertise to NBCCEDP and/or NCCCP
- ☐ Data linkages (NBCCEDP database, Minimum Data Elements (MDE) Study
- ☐ Other, specify _____

☐ None of the above, explain _____

_____

**Collaborative Relationship Section Comments** (You may add comments regarding your responses in the "Collaborative Relationship" section above)

## ADVANCED ACTIVITIES

As the capacity of central cancer registries to collect and maintain population-based cancer data increases, so does their ability to engage in new activities designed to improve the completeness, timeliness, quality, and use of their data. In this section, we are interested in learning more about your "advanced activities."

48. Please complete the table below regarding CCR receipt of electronic records from the reporting sources listed. **For each facility type, either check "Yes" and enter the format, as text, in which the electronic records are received, or check "No". No line is to be left blank.**

| Facility Type | YES | Specify Type of Electronic Format | NO |
|---|---|---|---|
| Hospital Radiation Therapy Dept. | | | |
| Physician Offices | | | |
| State-wide Disease Index | | | |
| Freestanding Radiation Centers | | | |
| Hospital Disease Indices | | | |
| Nuclear Medicine Facilities | | | |
| Other, specify | | | |

49. If your CCR receives electronic pathology reports, in which format are these received? (**Please check all that apply)**

☐ NAACCR, HL7 Format (Volume V)
☐ NAACCR, Pipe Delimited Format (Volume V)
☐ NAACCR, HL7 Format (NAACCR Volume II, Version 10, Chapter VI)
☐ NAACCR, Pipe Delimited Format (NAACCR Volume II, Version 10,
☐ Chapter VI)
☐ Other, specify: _____
☐ Not applicable

50. What method is used to identify reportable conditions from pathology lab reports:

☐ Manual review
☐ Search routine based on NAACCR search term list
☐ Other, specify _____

51. For which of the following cancer surveillance needs has your CCR been in contact with your Health Department's PHIN / NEDSS staff?
**Please check all that apply.**

☐ Pathology laboratory reporting
☐ Physician disease reporting

☐ Other healthcare data reporting
☐ None of the above

52. Has your CCR planned or developed a cancer data collection system that will be integrated into a Public Health Information Network (PHIN) compatible health surveillance system?

☐ Yes
☐ No

53. Does your CCR conduct at least one of the following advanced activities:
***Check all that apply:***

☐ Survival analysis
☐ Quality of care studies
☐ Clinical Studies
☐ Publication of research studies using registry data
☐ Geo-coding to latitude and longitude to enable mapping
☐ Other healthcare data reporting
☐ Other innovative uses of registry data, describe_____

_____

☐ None of the above

54. How often does your CCR link to the National Death Index (NDI)?
***Please check only one. (If Never, skip to question 57.)***

☐ Every year
☐ Every other year
☐ Every 3-5 years
☐ Other, specify _____
☐ Never

55. For which of the following has the NDI linkage proven to be useful?
***Check all that apply:***

☐ Casefinding
☐ Survivorship
☐ Data quality
☐ Research
☐ Other, please specify:_____
☐ Not applicable

56. Does your CCR update your database following NDI linkage?

☐ Yes
☐ No
☐ Not applicable

57. With which *databases* has your CCR linked its records in the past year (2006) for follow-up or some other purpose? ***Check all that apply:***

☐ State Vital Statistics
☐ National Death Index
☐ Department of Motor Vehicles
☐ Department of Voter Registration
☐ Indian Health Service
☐ Medicare (Health Care Financing Administration)
☐ Medicaid
☐ Managed Care Organizations
☐ Breast and Cervical Cancer
☐ Blue Cross/Blue Shield
☐ Hospital Discharge
☐ Other, specify: _____
☐ None

58.

a. As noted in an August 13, 2004 e-mail, CDC-NPCR has negotiated an agreement with SNOMED International for several tools for use by NPCR registries. Has your CCR downloaded any of these tools (the SNOMED CT CLUE Browser, the SNOMED CT Technical Reference Guide, the ICD-O topography to SNOMED CT Map, the SNOMED CT User's Guide, and the full set of the 42 SNOMED CT encoded CAP cancer protocols and checklists)?

☐ Yes
☐ No

b. Does your CCR use any of these SNOMED tools?

☐ Yes
☐ No

c. If "No," does your CCR have plans to use them in the next year?

☐ Yes
☐ No

d. Does your CCR need additional information or training on these tools?

☐ Yes
☐ No

**Advanced Activities Section Comments** (You may add comments regarding your responses in the "Advanced Activities" section above)

## SUCCESS STORIES

59. Please provide a summary, as a separate document, of innovative activities in which your CCR has been engaged within the past year. This can include ways in which cancer registry data has been used, journal citations, as well as other activities that may be of interest to other central registries and to NPCR (e.g., advances in any area of electronic reporting, GIS activities, death clearance activities, automated database activities that have improved data processing efficiencies, any other activities that have improved data quality, completeness, or timeliness advances in data security, or implementation of cancer inquiry response system, or success in job re-classifications) in the format suggested below:

**Suggested format:**
The registry highlights should fit on one page, in 12-point font and single-spaced. Information needs to be in simple language and should avoid public health jargon and scientific language.

**Suggested components:**
1. The name of the NPCR registry program.
2. Contact name, phone number, and e-mail address for further information
3. Title of the initiative, project, or type of data use
4. General timeframe (year(s) or month(s) during which the initiative/project/data use occurred)
5. A statement of the cancer surveillance issue, concern, or problem
6. Evidence that the activity was effective in addressing the above (#5)
7. Implications regarding the success of this activity or increased data use.

Please contact your NPCR Program Consultant if you need more detailed information about the submission of your cancer registry "success story".

**Success Stories Section Comments** (You may add comments regarding the "Success Stories" section above; do not record the success story in this comment box)

60. Please comment below about your experience completing this evaluation instrument by selecting the choice which best represents your thoughts and experience:

    a. All or most of the questions are clearly stated

    ☐ Agree ☐ Disagree

    b. I understand the importance of all or most of the questions

    ☐ Agree ☐ Disagree

    c. For the most part, I found the web technology of the instrument to be user-friendly

    ☐ Agree ☐ Disagree

    d. For the most part, I consider the time spent completing the instrument to be a worthwhile contribution to NPCR and the cancer surveillance community

    ☐ Agree ☐ Disagree

    e. Our central registry uses data that is collected in this instrument

    ☐ Agree ☐ Disagree

**OPTIONAL**

61. I would like to participate in discussions regarding next year's evaluation instrument.

    ☐ Yes *Please enter your name and phone number here:*

    ☐ No _____

62. I have the following suggestions/revisions for questions or web formatting regarding next year's evaluation instrument (please comment in the space provided below):

***Thank you for participating in the NPCR Program Evaluation!***

# Appendix I: DCPC Forms Recognition Software Analysis

**September 2006**

Northrop Grumman Web Applications Team
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Centers for Disease Control and Prevention (CDC)

## Disclaimers

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## Overview

The Division of Cancer Prevention and Control (DCPC) have implemented standards requiring state Central Cancer Registries (CCR) to electronically receive cancer incidence reports. Many CCRs will host a web application that will allow hospitals, physicians, etc. to submit reports via the internet. Because small physician's offices, etc. do not always have internet access, DCPC is requesting the analysis of forms recognition software options that would allow the CCRs to receive forms via fax and eliminate the need for manual data entry.

## Project Goals

The goal of this analysis is to eliminate manual data entry for the CCRs. For offices that do not have internet access, they would ideally fax the completed form to the CCR and it would be received by the forms recognition application, parsed, and automatically written to the database. A second option would be for the CCR to physically take the faxed form and scan it. The data would then be parsed by the forms recognition application and automatically written to the database.

## Forms Recognition Software Solution Selection

The software evaluation was focused on identifying potential forms recognition products in the market to meet the CCRs needs. Based on the research to date, the recommended forms recognition solution is ***ReadSoft Documents for Forms***.

## Evaluation Approach

The starting point for the evaluation began with a meeting with the DCPC stakeholders to gain a solid understanding of the objectives in order to evaluate a viable solution.

After gaining an understanding of the specific business needs and the desired approach, the next step was researching the various forms recognition software packages available in the market and identifying the products that met the requirements of the evaluation. From that selection, a group of top contenders were chosen for a more detailed evaluation including product comparison, platform support, ease of use, support, and cost analysis. The detailed evaluation involved researching online documentation as well as telephone and email correspondence with sales and technical contacts to gain specific knowledge about each product.

After reviewing the information, additional research was conducted to validate the viability of each solution. Two approaches have been identified to potentially meet the needs of the CCRs.

**Approach 1:** A centralized forms recognition server (fax server) would receive all incoming faxes from one or multiple fax lines. The data could be stored in a centralized database and each CCR would have access to the database.

The main advantage of this approach is having centralized software and data, and this approach is less expensive compared to the other options.

The main disadvantage of this approach is data ownership. All data would be stored at a central site rather than stored at each CCR. Due to the sensitivity of the data, this may not be a viable solution.

**Approach 2:** In this approach a desktop version of the forms recognition software would be installed and housed at each CCR. The incoming fax would be received by the desktop version of the Forms Recognition software via:

1. *User intervention*: Each CCR would have a scanner and a desktop version of the forms recognition software installed. Upon reception of the incoming fax, the document would be manually scanned, and the data would be automatically sent to the forms recognition software. The software would process the document, and store the data in the CCRs database.
2. *Electronic fax*: This approach would eliminate the need for user intervention. The incoming electronic fax (i.e. eFax) would forward an email to the desktop forms recognition software hosted by the CCR. The software would process the data and store the data in the database.

The advantage of using the automated electronic fax is that it would eliminate the need to have a user scan all incoming faxes. Scanning could potentially affect the quality of the scanned document which in turn could adversely affect data quality.

## Solution Comparison

The solution comparison provides information on several products available in the market today and is focused on the CCR desktop implementation of the forms recognition software.

The following products were reviewed in order to determine the most appropriate solution for DCPC's forms recognition software initiative:

| SOFTWARE | PROS | CONS | PRICE |
|---|---|---|---|
| ABBYY FormReader | • Product is very good<br>• Built for large volume transactions<br>• Provides .Net support for integration with other applications or custom programming<br>• Exports data to flat files such as .CSV or XML or writes directly to a database using Open Database Connectivity (ODBC) or automated scripts | • Product is comparatively very expensive | • FormReader 6.5 Desktop Edition: $7,500<br>• FormReader 6.5 Enterprise Edition: $12,500<br>• FormReader 6.5 Developer Edition (API): $4,900 |

| SOFTWARE | PROS | CONS | PRICE |
|---|---|---|---|
| CharacTell FormStorm Enterprise | • Product is very good<br>• Built for large volume transactions | • They do not offer a desktop or scaled down edition of the product<br>• Sales and support were not easily accessible<br>• Requires the purchase of additional components along with the enterprise edition of the software<br>• The product is very expensive compared to other solutions<br>• The price to value ratio compared to other solutions is low | • FormStorm Enterprise Server: $4950 |

| SOFTWARE | PROS | CONS | PRICE |
|---|---|---|---|
| Creative ICR Inc EzData | • Provides complete support for the creation and processing of forms created by EzData<br>• Automatic Microsoft Access compatible database generation<br>• The price is low compared to the other products | • The solution appears highly dependent upon the manufacturer's standard form templates, although it is stated that custom form template support is provided<br>• Unable to reach sales support<br>• Unable to verify any experience working with the CDC or other federal agencies<br>• Unclear whether programming interfaces are available for product customization<br>• Unclear whether the product supports database platforms other than Microsoft Access | • EzData Plus: $299.00 |

| SOFTWARE | PROS | CONS | PRICE |
|---|---|---|---|
| Kofax Ascent Capture | • Very stable and widely used in Enterprise applications<br>• Both enterprise and desktop editions are available<br>• The desktop edition stores meta-data in a flat file<br>• Developer's package is available for an additional fee | • SQL Server support is only available in the enterprise edition of the product<br>• No experience working with CDC<br>• Product is overkill for a desktop edition<br>• Comparatively very expensive | • Desktop edition: $995.00 for 5K of scanning/month<br>• Developer API: $2695.00. |

Recommended Solution

| SOFTWARE | PROS | CONS | PRICE |
|---|---|---|---|
| ReadSoft Documents for Forms | • Easy to automatically get information from any document (email, web, fax, paper, etc.) using the latest data capture technology<br>• Data is easily extracted, interpreted, verified and transferred into any computer system<br>• Robust product that provides an open programming interface (API) for easy integration<br>• Sales support is excellent and very prompt to respond<br>• Has a CDC designated account manager<br>• Other program areas at CDC (NCID, PEMS, HIV, etc.) have been trained and are currently using the software<br>• Natively supports Microsoft SQL as underlying database (unlike other solutions)<br>• Support staff is willing to work with CCRs in redesigning the initial form so that it works effectively with their software | • More costly compared to EzData or Kofax | • $2700 per installation (salesperson willing to negotiate price based on volume)<br>• ReadSoft is currently working with the Coordinating Centers for Health Promotion on enterprise wide license |

**System recommendations for a full installation**

**Recommended PC configuration:**
- Pentium family processor, 2.8 GHz
- 256 MB RAM (512 MB RAM*)
- Color monitor with SVGA graphics with resolution set to 1024 x 768
- Hard disk with at least 40 GB free disk space
- Mouse
- CD-ROM drive

**Minimum PC requirements:**
- Pentium family processor, 450 MHz (766 MHz*)
- 128 MB RAM (256 RAM*)
- Color monitor with VGA, with resolution set to at least 800 x 600
- Hard disk with at least 200 MB free disk space
- Mouse
- CD-ROM drive

**Databases**
- RDM Server 4.0 (from FORMS 5-2 SP6)
- Velocis 2.1 on Win NT4.0 SR6
- MS SQL Server 2000
- MS SQL Server 2005 Standard and Enterprise (FORMS 5-2 SP12 and later)

**Certified scanners**
Scanner models from the following manufacturers are certified for use with FORMS 5-2:
- Böwe Bell + Howell
- Canon
- Fujitsu
- InoTec
- Kodak
- Panasonic
- Ricoh

**Scanner interfaces**
- SCSI: Adaptec 2940AU, 29160N, 29160
- FireWire IEEE 1394
- Kofax: Adrenaline and KF series • USB 2

**Scanner drivers**
- SCSI/FireWire: ISIS Pixel, or ISIS-compatible driver
- Kofax: ImageControls 3.2 or later, VRS 3.x or later
- USB: Manufacturers' standard scanner installations are supported

**Operating systems**

- Microsoft Windows 2000 Prof (recommended)
- Microsoft Windows XP Prof (from FORMS 5-2 SP4)
- Microsoft Windows Server 2003 Standard Edition (servers only) (From FORMS 5-2 SP9)
- Microsoft Windows 98 & ME
- Microsoft Windows NT 4.0

**Network compatibility**

- Microsoft networks, IP and SMB

## Cost Estimating

Depending upon geographic location, direct and indirect costs of the recommended solution may vary.

## Cost Considerations

| Item | Locally Installed Forms Recognitions Software Cost Component | Notes |
|---|---|---|
| 1. | ReadSoft Documents for Forms | Cost of the core software package |
| 2. | Yearly Maintenance | Provides access to upgrades for the system |
| 3. | Yearly Software Support | Provides access to the vendor's customer support team |
| 4. | Initial Installation and Configuration | Applies when vendor is used to assist with installation and configuration of product |
| 5. | CDC Certification and Accreditation | This CDC C&A process typically takes 4-6 months if software has not already been through the C&A process |

## Conclusion

*ReadSoft Documents for Forms* is an effective, user-friendly solution for automating forms recognition. This solution has been adopted by a number of federal, state, and local government agencies including other program areas at CDC. ReadSoft has been successful implementing similar solutions across CDC.