Managing Clinical Data: A Cancer Registries Update

by Sue Watkins, RHIA (formerly RRA), CTR

Introduction

The American Cancer Society estimates that about 1.38 million new cancer cases will be diagnosed, and about 560,000 Americans will die of cancer, in 1997.[1] These estimates do not include carcinoma in situ or basal and squamous cell skin cancer. To monitor trends in cancer incidence and mortality, cancer surveillance is necessary. Cancer surveillance, the ongoing, systematic collection and analyses of cancer incidence and mortality data, is also used to guide cancer control planning and evaluation; to assist in prioritization of health resource allocation; and to advance population-based epidemiological and health services research. [2] A number of events have occurred during the past few years that have had a significant impact on cancer surveillance and control in the US.

The first occurred in October 1992, when Congress established the National Program of Cancer Registries (NPCR) by enacting The Cancer Registries Amendment Act (Public Law 102-515). Prior to the passage of this legislation, 10 states had no population-based cancer registry. Other states had registries operating at various levels, but many of them lacked the financial support and personnel to gather complete, timely, and accurate data or to ensure minimum standards of quality. In addition, a number of states lacked legislative support for their registry operations.

The National Program of Cancer Registries has been implemented by 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 develop model legislation and regulations for states to enhance viability of registry operations; to set standards for completeness, timeliness, and quality; and to provide training. As of September 1996, nine states were receiving CDC support for developing cancer registries where none existed, and 34 states and the District of Columbia were receiving support for the enhancement of established registries.

Prior to the implementation of the NPCR, only 33 of the funded states had a statewide, population-based cancer registry. By the end of the fiscal year, 41 funded states had statewide cancer data collection. In addition, 40 states have authorizing legislation that is in compliance with Public Law 102-515, and 25 states have established the required regulations.

How will Public Law 102-515 affect healthcare facilities and health information management? For those healthcare facilities, defined as hospitals, therapeutic radiation facilities, freestanding surgical centers, and pathology laboratories, operating in states that had statewide, population-based cancer registries prior to the Cancer Registries Amendment Act, the impact will be minimal. Depending on the legislation and regulations already in effect, the healthcare industry may or may not be affected. In California, for example, the 1987 legislation is so explicit that Public Law 102-515 has had no impact on the collection of statewide cancer data. Enhancement monies awarded through the NPCR to California have, however, provided funds for epidemiological support in areas of the state that lacked this support. In other states like Oregon, a statewide, population-based cancer registry has been implemented where none previously existed. The healthcare facilities in California have felt no impact as they have been reporting their cases since 1988 or earlier. In Oregon, however, facilities that never reported their cancer cases are now required to report them.

The methods used by statewide, population-based cancer registries to collect reportable cases vary from state to state. In the Tri-Counties Regional Cancer Registry, one of the 10 regions that compose the California Cancer Surveillance System, healthcare facilities have three options: they may have their own cancer registry report their cases directly to the region; they may authorize another facility with a cancer registry, or a vendor to report their cases; or they may contract with the regional registry to collect the required data. Regardless of the method, the health information management department will need to provide access to health records and provide adequate working space for the registry professional charged with collecting the required data. If the cases must be reported electronically, as is the requirement in California, then adequate software and

hardware may also impact the healthcare facility. The California Cancer Surveillance Section, Department of Health Services, provides free software to reporting facilities within the state. Hardware specifications are provided, but the purchase and maintenance costs are borne by the facility.

Health information management professionals should know the exact status of statewide, population-based cancer reporting and what their facility needs to do to meet the legislative requirements. What are the reporting options, and which one will meet the mission of the healthcare facility, as well as comply with the law? What computerization is required? How can computerized reporting be incorporated in the organization's electronic warehouse? How can the organization capitalize on the reporting requirement?

Hospital cancer registries have been collecting, processing, analyzing, and disseminating clinical data on cancer patients since the 1800s. Today these clinical repositories for oncology data are gaining importance as more oncology care is provided in the outpatient setting. In response to the changing healthcare market and increased demands for and use of cancer registry data, the Commission on Cancer has instituted a series of initiatives. These initiatives include significant changes in the standards for approval for hospital cancer programs. They are designed to strengthen the four existing components of the cancer program: leadership-cancer committee; patient management-clinical program and cancer conferences; evaluation-patient care evaluation; monitoring of results-management of cancer database. The initiatives also recognize other programmatic services that cover the full spectrum of cancer care including prevention, diagnosis, treatment, patient support, and long-term patient follow-up.

Two new manuals were published in 1996 for implementation on January 1, 1997. The first of the manuals is *Cancer Program Standards* (Volume I). [3] It defines the criteria for an approved program and describes the 10 required programmatic areas. The 10 areas cover institutional and programmatic resources; program management and administration; clinical management; inpatient and outpatient care; supportive and continuing care services; research; quality management and improvement; cancer data management; public education, prevention and detection; and professional education and staff support. A self-assessment checklist is also included in this volume for use by established programs preparing for a survey, or for the development of a new program.

The second volume, *Registry Operations and Data Management,* contains detailed information about the requirements for cancer registry operations and the specifications for required, supplementary, and optional data item standards for an approved cancer registry. [4] The general principles and requirements provided in Volume II encompass the reference date, reportable list, case finding, suspense system, accession register, patient index, abstract, quality control, follow-up, confidentiality and release of information, reporting, retention of documents, and procedure manual. The requirements for case eligibility, instructions on interpretation of ambiguous terminology and revising the original diagnosis or stage, and guidelines for determining multiple primaries, stage of disease at initial diagnosis, and first course of treatment, are also provided.

Major areas of change for 1997 are as follows:

- Program management: approved programs are required to monitor the quality of all oncology care provided to their cancer patients, *including services in a referral system to nonapproved facilities*
- Clinical management: two conferences each month are required in community hospitals where *annual analytic accessions exceed 500 cases. Institutions with 750 analytic cases per year must meet a weekly conference frequency*
- Research: A *formal mechanism must be in place to ensure patient access to clinical research. Community hospitals with an analytic caseload of 750 per year or more, teaching hospitals, and NCI Cancer Centers must enter a minimum of 2 percent of the number of analytic cases on clinical trials each year*
- Quality management: *Two quality care improvements or enhancements are documented each year*
- Cancer data management: *The registry submits data to the National Cancer Data Base (NCDB) and meets the standards of* Volume II: Registry Operations and Data Standards (ROADS), *which includes the required data set and coding guidelines*

Included in the new standards are areas of evaluation already being addressed by most approved cancer programs: inpatient and outpatient care; public education, prevention and detection; and professional education and staff support.

Inpatient and outpatient care includes eight standards:

1. Oncology services provide multidisciplinary care
2. All internal or external resources providing oncology services establish written policies to ensure quality care
3. Clinical laboratory and routine diagnostic imaging services are available
4. If a mammography center is available, it is accredited by the American College of Radiology (ACR)
5. An inpatient oncology unit, or its functional equivalent, is in place at the Community Hospital Comprehensive Cancer Program, Teaching Hospital Cancer Program, and NCI-designated Comprehensive Cancer Program categories
6. Patients have access to a full range of radiation therapy services
7. Radiation therapy facilities are accredited by a recognized authority
8. Nursing care is provided by nurses with specialized knowledge and skills in oncology

There are three standards established for public education, prevention and detection:

1. Public education programs are promoted and offered to the community
2. Prevention programs are promoted and available to the public
3. Screening programs are promoted and available to the community

Three standards have also been defined for professional education and staff support:

1. Professional education is available to all members of the multidisciplinary team, including primary care physicians
2. Education programs are provided for allied health professionals of the cancer care team
3. Members of the multidisciplinary cancer care team are required to attend meetings to meet the continuing education requirements of their national credentialing organization

Effective January 1998, another significant area of change in the mandatory standards for approved cancer programs will be a requirement for a process that ensures capture of information on patients who are diagnosed and treated only in staff physician offices. In preparation for the implementation of this requirement, a pilot project is under way to define the benefits for the patients, physicians, and hospitals; to evaluate physician compliance; to establish guidelines for successful case finding and abstracting methods; to assess the availability of data and the impact on registry workload; and to identify barriers and solutions. Results of this pilot project are scheduled for release sometime this year.

To promote access to quality care for all cancer patients, categories of approval have also been established for very small hospitals and nonhospital environments such as freestanding and integrated cancer programs and managed care organizations.

The Affiliate Cancer Program category brings the resources of an approved cancer program to small, often rural, hospitals that diagnose and treat fewer than 50 analytic cases annually. Since small hospitals may not have enough cases to warrant an in-house cancer program, they will benefit from affiliation with a sponsoring institution through access to program resources such as a cancer registry and cancer conferences. A successful affiliation demands strong leadership and serious commitment from each partner.

A freestanding or nonhospital cancer center is defined as an independent facility that treats a significant number of patients with cancer. Two of the three major treatment modalities (surgery, medical oncology, and radiation oncology) must be present, with documented evidence that the third modality is available for consultation.

An integrated program is defined as an independent, freestanding (nonhospital) entity with a single treatment modality, such as radiation oncology, that treats a significant number of patients with cancer. The facility cannot by itself meet the standards for approval, and therefore chooses to partner with a hospital. The freestanding facility is surveyed simultaneously with its hospital partner.

Managed care programs coordinate and provide patient care under the direction of a single organization. It is a comprehensive population-based system in which physicians employed by or contracted with the managed care organization (MCO) render

cancer care. Each institution, owned or contracted to treat this defined patient group, must have approval of its cancer program independent of the MCO's corporate approval.

The Approvals Program of the Commission on Cancer is voluntary. The major goals of the Approval Program are to decrease the morbidity and mortality of patients with cancer and to improve the quality of patient care. Another significant change implemented by the Commission on Cancer in 1996 is in the approval awards. Today, a program that meets the standards for approval, whether a new or existing program, receives a four-year approval. Prior to this change, the maximum number of years a cancer program could receive was three. As in the past, a three-year approval with contingency is awarded when a previously approved program has one or more measurable deficiencies that could easily be corrected and for which documentation of corrective action could be easily provided. One-year approval is granted when a previously approved program has multiple deficiencies, and the potential and motivation of the administration and professional staff indicate that the deficiencies will be corrected within a reasonable period of time. Nonapproval is used when broad and multiple deficiencies exist in previously approved programs, and the likelihood for correction appears remote.

Today there are 1450 approved cancer programs in the US. These programs provide a model of integrated, quality healthcare delivery. This model or many of its components are also found in other facilities involved in cancer patient management. The impact of changes in healthcare, partnering with others involved in accreditation, and the demand for access to performance measures, will increase the purpose, use, and value of cancer registry data. [5]

Definitions

Analytic cases
Class of case divides the data into analytic and nonanalytic categories. Analytic cases are classed as those first diagnosed and/or where the first course of therapy is given at the reporting institution since the registry's reference date.

Categories of Cancer Programs approved by the Commission on Cancer
Comprehensive Cancer Program (NCI-designated program); Teaching Hospital Cancer Program; Community Hospital Comprehensive Cancer Program; Community Hospital Cancer Program; Hospital Associate Cancer Program; Integrated Cancer Program; Freestanding Cancer Center Program; Affiliate Hospital Cancer Program; Managed Care Organization.

National Cancer Data Base (NCDB)
A nationwide outcomes database for oncology that includes data from 1600 hospitals in 50 states. It is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society. The three primary products of the NCDB are hospital comparative reports, state and local reports, and scientific reports.

Notes

1. American Cancer Society. *CA: A Cancer Journal for Clinicians* 47, no. 1, (1997): p. 6.

2. Centers for Disease Control and Prevention. *At-A-Glance.* Atlanta, GA: Centers for Disease Control and Prevention, 1997, p. 2.

3. American College of Surgeons, Commission on Cancer. *Cancer Program Standards.* Chicago: American College of Surgeons, 1996, pp. 9-59.

4. American College of Surgeons, Commission on Cancer. *Registry Operations and Data Standards* (ROADS). Chicago: American College of Surgeons, 1996, pp. 29-34.

5. Clive, Rosemarie. "Update from the Commission on Cancer." *Topics in Health Information Management* 17, no. 3 (February 1997): 10-14.

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