Monitoring the current status of cancer care is essential for effective cancer control and high-quality cancer care. To address the information needs of patients and physicians in Japan, hospital-based cancer registries are operated in 397 hospitals designated as cancer care hospitals by the national government. These hospitals collect information on all cancer cases encountered in each hospital according to precisely defined coding rules. The Center for Cancer Control and Information Services at the National Cancer Center supports the management of the hospital-based cancer registry by providing training for tumor registrars and by developing and maintaining the standard software and continuing communication, which includes mailing lists, a customizable web site and site visits. Data from the cancer care hospitals are submitted annually to the Center, compiled, and distributed as the National Cancer Statistics Report. The report reveals the national profiles of patient characteristics, route to discovery, stage distribution, and first-course treatments of the five major cancers in Japan. A system designed to follow up on patient survival will soon be established. Findings from the analyses will reveal characteristics of designated cancer care hospitals nationwide and will show how characteristics of patients with cancer in Japan differ from those of patients with cancer in other countries. The database will provide an infrastructure for future clinical and health services research and will support quality measurement and improvement of cancer care. Researchers and policy-makers in Japan are encouraged to take advantage of this powerful tool to enhance cancer control and their clinical practice.

Key words: cancer registry – data infrastructure – national database – quality of care

INTRODUCTION

Cancer control activities in Japan have accelerated since the enactment of the Cancer Control Act in 2007 (1). To ensure high-quality cancer care nationwide, the government designated 289 hospitals as cancer care hospitals throughout Japan. These hospitals, referred to as Designated Cancer Care Hospitals (DCCHs), function as hubs that support cancer care in the area by providing training to health professionals and highly specialized care to patients (e.g. radiation therapy and palliative care) and by fulfilling the information needs of patients (2).

The DCCHs also play a leading role collecting information on cancer care. As part of the requirement for earning the designation, the hospitals operate hospital-based cancer registries that collect basic information on all new patients with cancer who visited the hospitals (2,3). To properly manage the registry, the hospitals are required to hire one or
more tumor registrars who have completed a basic training course offered by the National Cancer Center (2). The hospital-based cancer registry is the first uniform registry system implemented nationwide in Japan for all types of cancer. The registry supports the population-based cancer registries operated by prefectural governments by ameliorating data submission from large volume hospitals and also has the potential to effectively collaborate with the site-specific registries managed by medical specialty societies (4).

The DCCHs first started submitting registry data from cases they had encountered in 2007 to the Center of Cancer Control and Information Services at the National Cancer Center. The National Cancer Center compiles the cases and enters them into the National Database of the Hospital-based Cancer Registries. In the first year of compilation, 327,889 cancer cases were submitted; this number comprises 44% of all incident cancer cases in Japan that have been estimated based on the information from the population-based cancer registry (5,6). The cancer cases encountered in 2010, the newest cases at the time of this manuscript preparation, comprise almost 67% of all incident cancer cases in Japan. This percentage is estimated based on the number of cancer deaths (7). The National Database of the Hospital-based Cancer Registries provides an overall picture of cancer care in Japan. The purposes of this review are to familiarize readers with the registry database by describing how the hospital-based cancer registry is organized and how it collects information and to discuss future directions for this information structure.

DATA COLLECTION

TYPES OF DCCHS

The number of DCCHs has increased from 289 in 2007 to 397 in April 2012 (8). There are two types of DCCHs: the prefectural DCCH and the community DCCH. Each of the 47 prefectures is composed of basically one or two prefectural DCCHs and several community DCCHs, depending on the population and geographic size of the prefecture. The prefectural DCCHs play the leading role and organize training programs in disciplines such as palliative care, patient support skills and tumor registration for health professionals in the prefecture. The prefectural DCCHs are typically large cancer centers or university hospitals. The community DCCHs tend to be local general hospitals that provide care for patients in their areas. The requirement for registry operation does not differ between prefectural and community DCCHs.

TARGET NEOPLASMS AND CASE FINDINGS

The hospital-based cancer registries collect information on all malignant neoplasms, including intraepithelial tumors in any part of the body and intracranial benign neoplasms (3). The definition of malignancy corresponds to a behavioral code of 2 or 3 in the International Classification of Diseases for Oncology, third edition (ICD-O-3) (9). Benign tumors in the skull are included because they can be fatal more often than other benign tumors and therefore are considered worthy of attention.

All target neoplasms newly encountered at the hospitals are registered. The target neoplasms include both newly diagnosed cases and newly evaluated cases at the hospital after the neoplasm had been diagnosed or treated in other facilities. Patients who come to the hospital for a second opinion only are not required to be registered, but they may be registered depending on the hospital’s policy. Cases such as these are classified by the ‘class of cases’ coding, which is described later in this review.

As the focus of the data collection is cancer, the unit of registration is the tumor. If one patient has two cancers that are judged to be independent based on pathology, each cancer is registered separately. Additionally, if a patient with cancer has visited two DCCHs, each DCCH registers the tumor, and is required to submit data to the National Cancer Center. Because the data are submitted after deleting personal identifiers from the patient’s medical record, there are often duplications, which we cannot correct. A prior analysis revealed that ~8% of the total cancer cases submitted have common characteristics that could lead to suspicion of duplication (10).

Finding all cancer cases encountered in the hospitals is a challenge. According to a survey of DCCHs, the majority of hospitals use pathologic reports, discharge summaries and diagnostic codes on insurance claims to identify cases (11). Some hospitals also use chemotherapy records and surgery records as well. The tumor registrars play a major role in identifying cancer cases. In 2009, only 34% of the DCCHs allowed physicians to be involved in the process of identifying cancer cases (11).

STANDARD ITEM SETS FOR PATIENTS AND CODING RULES

The standard item sets, defined nationally, include 49 items (3). The item sets include information on the patients, their tumor(s) and the first-course treatment provided at the facility. Table 1 presents the items collected. By standard, the information is collected about 6 months after diagnosis. In addition, several optional items, such as the date of surgery and depth of invasion in the gastrointestinal cancer, are also defined. These items can be collected in each hospital but not submitted to the National Database, thus, these items are not discussed in this review.

Patient characteristics collected include date of birth, gender, current address and route of hospital visits. When submitted to the National Database, the date of birth is rounded to years and months, and only prefecture of residence is provided instead of the current address for privacy protection. Route of hospital visits is basically defined by whether patients came to the hospital on their own or they were referred by another facility. The place of diagnosis and
Identification and demographic information
- Name, date of birth, sex, current address, sequence number for multiple tumors
- Route of hospital contact, place of diagnosis/treatment (class of case)

Diagnostic information
- Date of first visit for the tumor,
- Diagnostic test, date of diagnosis,
- Tumor characteristics
  - Primary site, morphology (ICD-O-3), cTNM, pTNM (UICC), extent of disease (clinical/pathological)

First course of treatment
- Presence/absence of open surgery, endoscopic resection, laparoscopic resection, chemotherapy, radiation, hormone therapy, immunotherapy and other therapy

Follow up information
- Vital status, date of last follow-up

Table 1. Items collected in hospital-based cancer registries (excerpt)

- Identification and demographic information
  - Name, date of birth, sex, current address, sequence number for multiple tumors
  - Route of hospital contact, place of diagnosis/treatment (class of case)

- Diagnostic information
  - Date of first visit for the tumor,
  - Diagnostic test, date of diagnosis,
  - Tumor characteristics
    - Primary site, morphology (ICD-O-3), cTNM, pTNM (UICC), extent of disease (clinical/pathological)

- First course of treatment
  - Presence/absence of open surgery, endoscopic resection, laparoscopic resection, chemotherapy, radiation, hormone therapy, immunotherapy and other therapy

- Follow up information
  - Vital status, date of last follow-up

treatment determines the ‘class of cases.’ These are coded as: (1) diagnosed only in the registering hospital, (2) diagnosed and treated in the registering hospital, (3) diagnosed in another hospital and treated in the registering hospital, (4) visited the registering hospital after the start of treatment in another hospital including first visits after recurrence and (5) other (e.g. second-opinion visits).

Tumor characteristics include the topology (site) and morphology (histology) codes of ICD-O-3 for all cancers and stages coded for the five major cancers in Japan, including breast, colorectal, liver, lung and stomach cancer. While the Japanese medical specialty societies define their unique staging systems, the registry uses the International Union against Cancer Tumor-Node-Metastases (UICC TNM) staging system (12). For liver cancer only, the Japanese staging system is also registered because the system is far different from the UICC TNM system (13). Both clinical (c-) stages and pathologic (p-) stages are collected. If presurgical therapy (i.e. chemotherapy or radiation) was performed, p-stages are not collected. Although stage information for cancers other than the five major cancers is not required, about 75% of the cases have the stage entered (5).

The date of diagnosis is determined as the date when the most definitive diagnostic test was performed before treatment was prescribed. Diagnostic tests are arranged hierarchically by level of definitiveness. Histopathologic testing sits at the top of the hierarchy, followed by cytology, other lab tests, direct observation (e.g. endoscopic evaluation) and radiologic imaging. For example, if a patient’s lung computed tomography (CT) scan suggested a lung cancer diagnosis and that diagnosis was confirmed by a tissue biopsy, the date of the biopsy would become the date of diagnosis. Alternatively, if the cancer had been surgically resected without biopsy after the diagnosis on the CT scan, the date of the CT scan would have become the date of diagnosis. The most conclusive test performed for the cancer diagnosis is separately coded and that coding includes a pathologic examination after surgery. Therefore, in the second example, the post-surgery pathology would be the most conclusive test, while the date of diagnosis remains the date of the CT scan.

Treatment information for first-course treatments provided in the registering facility is collected. The term ‘first course’ has been defined as the set of standard treatments initially considered and subsequently administered in the facility for the given type of the cancer and its stage. Treatments added after the start of therapy based on new findings or along the disease progression course are by definition not considered ‘first course’ and are thus not registered. For example, if surgical resection was planned for a patient with Stage II colon cancer and surgical findings indicated liver metastases that were treated with post-surgical chemotherapy, the chemotherapy would not be considered the ‘first-course’ treatment. If a patient’s medical records do not provide sufficient information to determine whether the treatment was planned at the start of therapy or the facility standard, any treatment provided within 4 months after the diagnosis is considered ‘first course’ for registration purposes. The first-course treatment also includes watchful waiting. If a tumor has started growing during the watchful waiting period and new therapy is administered, the new therapy is not considered the ‘first-course’ treatment.

These precise rules and definitions, which are covered by the tumor registrar training programs, lead to reliable data collection by non-physician tumor registrars. Details of these rules are available in the coding manual posted on the National Cancer Center web site (3).

DATA QUALITY CONTROL

Data quality is ensured in three ways: (i) rigorous training of tumor registrars, (ii) consistency-checking software and (iii) extensive support provided by the National Cancer Center staff.

TRAINING OF TUMOR REGISTRARS

The tumor registrar training programs include four levels of courses: elementary level, post-elementary level, middle level and instructor level. The elementary-level courses are offered biannually in five regions of Japan as well as at the National Cancer Center. Having at least one tumor registrar who has completed the elementary-level course is mandatory for the DCCHs. The elementary-level course includes web-based e-learning and 2-day schooling. The course material covers basic cancer knowledge, ICD-O-3 coding and the stages of the five major cancers in Japan. As of March 2012, 3185 persons completed the elementary-level course; 357, the middle-level course and 84, the instructor course. The post-elementary-level course is a 1-day seminar that teaches how to use registry data in the hospital and provides in-depth code definitions. The middle-level course includes 5 days of intensive study in Tokyo. This course covers the UICC TNM staging system, which is used to stage the five major cancers.
in Japan as well as other cancers; also covered in the course are differences between the UICC TNM staging system and Japanese cancer staging systems. Applicants must pass a take-in examination to qualify for enrollment in the middle-level course. The instructor-level course aims to develop teachers who can lead hospital-based cancer registries in their respective regions. It is limited to registrars who have completed the elementary-level course, have been involved in the cancer registration for more than 2 years at a DCCH, and have been nominated by the hospital they belong to and the prefectural government. The course is held over 3 days and focuses primarily on hands-on registration and teaching.

**DATA CONSISTENCY CHECK**

A standard software to register cancer information, ‘HosCanR’, is developed and distributed by the National Cancer Center at no charge. The software not only manages data-entry and submission-of-data processes but also provides a consistency check and de-identification. When inconsistent data entry is detected, the software issues a warning or error, depending on the nature of the inconsistency. Since 2011, the consistency check has been provided nationwide via an online system, enabling smooth support for correction by the National Cancer Center.

**SUPPORT PROVIDED BY THE NATIONAL CANCER CENTER STAFF**

To ensure sound operation of a hospital-based cancer registry, close support by the National Cancer Center is provided through internet mailing lists, a specialized web page and site visits to the DCCHs. Questions about both general and specific cases are discussed in the mailing lists. The support web site is customized to each hospital and can be used to share information and files for respective special studies for the participating subsets of the DCCHs. Site-visits provide opportunities to solve unique problems at facilities and discuss how to use the data to fit the needs of the facility. In 2010 and 2011, the staff visited 62 hospitals.

**COVERAGE OF CANCER CASES BY THE NATIONAL DATABASE**

The National Database of the Hospital-based Cancer Registries is estimated to cover ~67% of the new cancer cases in 2010, assuming that the total new invasive cases are ~73,800 in Japan (7). The number of new cases was calculated based on the cancer mortality from Vital Statistics (353,499 cancer death in 2010) (14) and the most recent estimate of the mortality to incidence ratio (2.09 in 2007) reported by the Monitoring of Cancer Incidence in Japan Project (6).

**SOME FINDINGS**

**NATIONAL CANCER STATISTICS REPORTS**

Data are submitted by the DCCHs to the National Cancer Center annually. As of September 2012, 1,789,834 cancer cases (registered between 2007–2010) have been submitted (5,7,15,16). The trend of submitting hospitals and their cases is presented in Table 2 (7). Almost all DCCHs have submitted data, all of which have been analyzed except for the few cases that were submitted after the deadline. Statistical reports have been published for each year. Beginning with the 2008 cases, the results for respective DCCHs have been presented in reports that include the number of registered cancer cases (for the five major cancers in Japan) and the respective stage of each cancer at registration. Also included in the reports is the distribution of first-course treatments for the five major cancers by disease stage. The reports, which are published in hard-copy print, are also posted on the National Cancer Center’s web site.

An analysis of DCCHs by the National Cancer Center revealed wide variation among the hospitals. For example, among 2010 cancer cases, the proportion of patients aged ≥75 years ranged from 14.9 to 57.9% (7). In 2009, the proportion of cancer cases reported by other facilities ranged from 20 to 90% (16). This finding may represent the differences in the roles hospitals played in the local areas.

**COMPARISON TO THE NATIONAL CANCER DATABASE IN THE USA**

The National Database of the Hospital-based Cancer Registries in Japan has structural similarity with the National Cancer Database (NCDB) in the USA. The NCDB is a nationwide cancer database that accumulates registered cases from more than 1500 cancer programs accredited by the Commission on Cancer (CoC) of the American College of Surgeons in the USA. (17,18) The Japanese DCCHs correspond to the accredited cancer programs, and both registry systems register all new cancers at the facility and include ~70% of the incident cancer cases nationwide and uses the UICC/American Joint CoC (AJCC) staging system. The comparison of the distribution of cancer types and associated cancer stages using these two databases gives an interesting contrast of the cancer profiles in specialized hospitals between the two countries. Figure 1 shows the side-by-side

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of DCCH</th>
<th>No. of hospitals analyzed</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>288</td>
<td>287</td>
<td>327,889</td>
</tr>
<tr>
<td>2008</td>
<td>351</td>
<td>359</td>
<td>428,195</td>
</tr>
<tr>
<td>2009</td>
<td>377</td>
<td>370</td>
<td>487,441</td>
</tr>
<tr>
<td>2010</td>
<td>388</td>
<td>387</td>
<td>548,979</td>
</tr>
</tbody>
</table>

Note: reproduced from ref. (7).
comparison of the distribution and stage of breast, colorectal, liver, lung and stomach cancers (the five major cancers in Japan diagnosed in 2009) in Japan and in the USA. The graph for the NCDB was created by the authors using the data posted on their web site (18). The cancer stages in this graph were based on the sixth edition of the UICC/AJCC system.

Several points emerged from this comparison. First, the proportions of Stage 0 and Stage I stomach, colorectal, liver and lung cancer cases are larger in the Japanese cancer registry data than proportions of those stages in the USA NCDB indicating that the Japanese DCCHs treat earlier-stage cancer cases than their USA counterparts, the CoC-approved hospitals. This trend is particularly apparent in stomach cancer cases; in Japan 60% of stomach cancer cases are Stage I, whereas 40% of stomach cancer cases are Stage IV in the USA NCDB. Secondly, the number of stomach cancer cases in the Japanese registry was about three to four times larger than the number of stomach cancer cases in the USA NCDB. Considering that the population of the USA is approximately twice that of Japan, stomach cancer is much more common in Japan than that in the USA. It is our hope that this information will be helpful to Japanese clinicians to adapt clinical discoveries in the USA for those who consider stomach cancer in their clinical practices.

DIFFERENCE IN STAGING SYSTEMS

As mentioned above, Japanese clinicians use the Japanese cancer staging system in daily clinical practice. This system is slightly different from the UICC system, which limits the international discussion to clinical experiences and research findings. The use of the UICC system by the Japanese hospital-based cancer registry ameliorates problems from the different staging systems. Fortunately, the difference between the two systems is becoming relatively smaller for most cancers, and recent revisions in both systems have made them more compatible. However, the discrepancy in the staging of liver cancer in the two systems remains relatively large (13), partially because of the difference in the etiology of liver cancer in Japan and western countries. The most common cause of liver cancer in Japan is hepatitis C virus, whereas in western countries liver cancer is associated more frequently with hepatitis B or other etiologies (19). As too much departure from stages used in actual clinical practice hampers the usefulness of the data, the hospital-based registries record both the UICC and Japanese cancer staging systems for liver cancer. The distribution of stages is tangibly different for the same group of patients, as shown in Fig. 2. The Japanese system appears to distribute stages more evenly than the UICC system. When survival data for these patients become available, we may be able to compare the performance of the two cancer staging systems on a much larger scale.

FUTURE DIRECTIONS

SURVIVAL FOLLOW-UP

While the Japanese hospital-based cancer registry is currently focused on initial encounters with patients with cancer, the follow-up patient survival system remains underdeveloped. Follow-up of registered cases is important because it produces information on how well patients with cancer are treated and ways to effectively construct future practice. However, a privacy law, which took effect in 2005, has made this follow-up task difficult. Under the law, vital statistics (personal data) are controlled by municipal governments and the Ministry of Justice. Although the law literally allows vital statistics to be released for use in public health research,
the operation and actual criteria for the release vary across municipalities, making the application for release extremely difficult. A 2009 survey of DCCHs in Japan revealed that only 27% of hospitals followed the survival of their patients who had stopped visiting the hospitals (11). Calculation of the survival rate that is based on the data with a large proportion of censoring is likely to overestimate the true survival (21). Thus, a system is needed to ensure that sufficient follow-up occurs.

ENSURING QUALITY OF CANCER CARE

Ensuring the quality of cancer care nationwide in Japan is a major goal of the Cancer Control Act. The hospital-based cancer registry can contribute to this purpose. The registry helps to define target patients when considering the 5-year survival rate of patients. Once the system to follow up patient survival is established, the chronologic trend can be monitored easily. To examine the process of care, the registry can provide basic information about the provision of standard care (e.g. chemotherapy after surgery for Stage III colon cancer). We understand that the information obtained from registry data is preliminary and cannot provide a definitive conclusion on the quality of care for two reasons. First, the comorbidity outcome information is too limited to adequately adjust for the case mix of patients; secondly, the recommended therapy can be administered in a hospital other than the one that submitted the data and is therefore not coded. Nonetheless, the preliminary data can become a starting point for the exploration of quality and will hopefully lead to improvement. The NCDB in the USA provides feedback and comparative information on six standard-of-care therapies for breast and colorectal cancers to participating hospitals using the Cancer Programs Practice Profile Reports (CP3R) web site (17). Recently, CP3R evolved into the Rapid Quality Reporting System that provides feedback on a real-time basis. Although our registry system is still in its infancy, it has the potential to provide similar services in Japan.

SECONDARY ANALYSIS BY RESEARCHERS

In September 2012, the Rules for the Secondary Use of the National Database were approved by the Association of Prefectural Designated Cancer Care Hospitals. These rules opened the way for researchers who belong to the DCCHs and the prefectoral governments to analyze the data. The applications for secondary use are evaluated by the Data Use Committee and approved. The data are handed to the researchers after deleting the link to the original patient identifiers, thereby making it unlinkable to real patients in any ways. This enables the safe and effective use of the National data.

EXPANSION OF PARTICIPATING HOSPITALS

The National Database in Japan has been collecting data only from the DCCHs designated by the national government. Recently, increasing numbers of prefectural governments have been designating wider ranges of cancer hospitals. Often, the conditions for such designations include operation of a hospital-based cancer registry, resulting in a larger number of hospitals with registry systems. Provided that data quality is adequately controlled, we can expect the increase in coverage to give a more comprehensive picture of cancer care in Japan.

CONCLUSIONS

The hospital-based cancer registry provides an important infrastructure for producing evidence for both clinical medicine and cancer policy in Japan. The system is constructed to ensure the quality of the data in multiple layers, which include precise and clear definitions of coding, avoidance of ambiguity as much as possible, rigorous training of tumor registrars and close communication between the National Cancer Center, which works as the registry headquarters, and the DCCHs nationwide. Statistical reports have so far revealed the national profile of DCCHs and evidence-based comparisons of patients with cancer in the USA and Japan. We believe the future evolution of the hospital-based cancer registry will lead to quality monitoring and continuous improvement in cancer care in Japan.

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