made in the medical treatment of cancer, checking on the improvements in the probability of survival, correction of the regional gaps in cancer treatment, etc., and the importance of support at the national level.

As of 2012, 45 out of 47 prefectures and one city had implemented population-based cancer registries. The last two registries, which planned to establish their cancer registries in 2012, were Tokyo and Miyazaki. Incidentally, the Basic Plan to Promote Cancer Control Program was recently reviewed in 2012, 5 years after its launch. The national conference received a supplementary resolution for the cancer registry, and made an announcement asking for a legal basis for the cancer registry within the following 5 years.

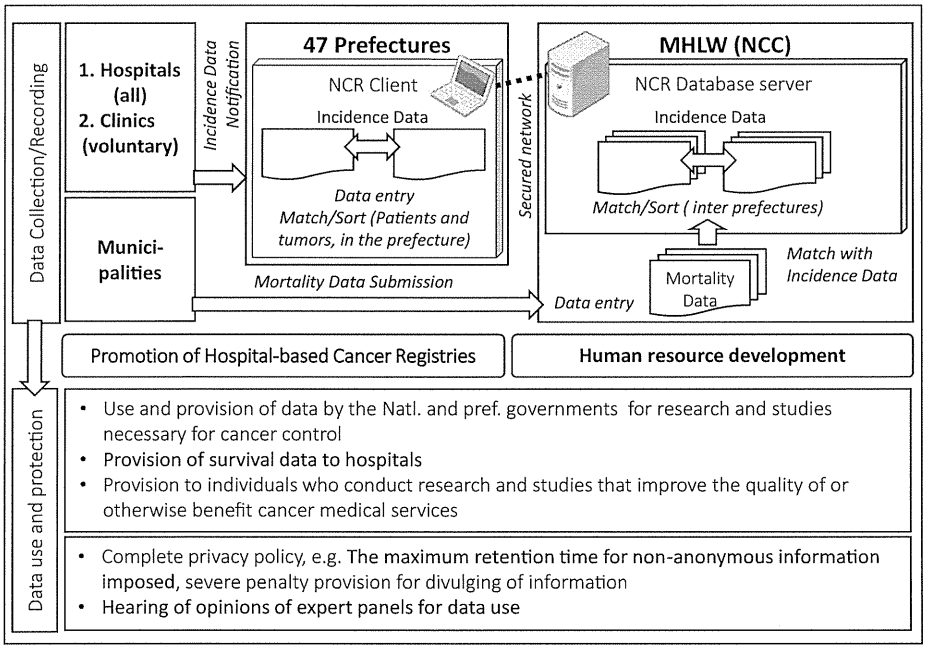
The movement toward legislation by a nonpartisan lawmaker, and especially by cancer patient advocacy groups, contributed to the enactment of the Cancer Control Act. A petition for legislation regarding regional population-based cancer registries was submitted to the MHLW by the JACR, the patient groups and other academic associations, such as the Japanese Association of Medical Sciences, Japanese Cancer Association, Japan Society of Clinical Oncology, Japanese Society of Medical Oncology and the Japanese Association of Clinical Cancer Centers.

After almost 80 meetings among the lawmakers, patient groups, the MHLW, the Legislative Bureau House of Councilors, the NCC and other stakeholders, as well as two rounds of public comments, the Act on Promotion of Cancer Registries was finally enacted in Japan on December 6, 2013. This Act provides for the implementation of an NCR in accordance with the purpose of the Cancer Control Act with a special emphasis on information protection (Table 1).

The NCR system

According to the Act on Promotion of Cancer Registries, managers of a hospital will report to the prefectural governors concerning information on any primary cancer first diagnosed in their institutions from January 1, 2016 onward. Prefectural governors review and record the coordination of cancer information, and enter the data in the NCR database in the MHLW/NCC, which is directly connected to the prefectural cancer registries via a secured network. The NCC will match the cancer registry data inter-prefecturally, and then link with the death index database which has received a high standard of regulation for >100 years in Japan. In fact, the NCC will be entrusted with almost all of the practical business of data and record-keeping. The MHLW/NCC then reviews and records the information to determine the yearly cancer statistics (Fig. 2).

The MHLW, the NCC, prefectural governors and mayors of municipalities are obliged to undertake suitable data control measures (Chap. 2.V.1). Use and provision of data are promoted, but at the same time, privacy protection in relation to personal data is to be considered (Chap.2.V.2).



MHLW: Ministry of Health, Labour and Welfare, NCC: National Cancer Center, NCR: National Cancer Registry,

Fig. 2 The national cancer registry system

Table 2 Cancer registry-related laws

Law, notice, guideline, etc.	Date	Contents
Ethics Guidelines of the Epidemiological Study (Ministry of Education, Culture, Sports, Science and Technology)	June 17, 2002 December 28, 2004 (amendment) June 29, 2005 (partly amended)	Status of the population-based cancer registry (The population-based cancer registry is not epidemiological research, but a municipal work)
Health Promotion Law Art. 16 (Ascertainment of trends in lifestyle-related diseases)	August 2, 2002 (promulgation) July 26, 2005 (amendment) May 1, 2006 (enforcement)	Promotion of a population-based cancer registry by the national and local (prefectural) government
Cancer Control Act Art. 17 (2) (Improvement of collection and provision of data regarding cancer treatment)	June 23, 2006 (promulgation) April 1, 2007 (enforcement)	
Cancer Control Act Supplementary provision 16	June 15, 2006	
Notice no. 0108003, January 8, 2004 (Director of the Health Service Bureau of the Ministry of Health, Labour and Welfare)	January 8, 2004	Reporting to the population-based cancer registry without prior informed consent of the individual is an exception to the Privation Information Protection Law's Art. 16 (restriction by the purpose of utilization) and Art. 23 (restriction of provision to a third party)
Guidelines for the appropriate handling of personal information by medical and care-related enterprises (Ministry of Health, Labour and Welfare)	December 24, 2004	
Prefectural ordinances allowing the registry to obtain the personal information of cancer patients	(In several prefectures)	
Act on the Promotion of Cancer Registries	December 6, 2013	Cancer registry data are collected in the National Cancer Center Cancer is a reportable disease in the hospitals and designated clinics. Reporting to the population—based cancer registry without prior informed consent of the individual is an exception to Privation Information Protection Law's Art. 16 (restriction by the purpose of utilization) and art. 23 (restriction of provision to a third party)

Hearing the opinions of expert panels set up in the MHLW and in each prefecture is required prior to any data use. The maximum retention time for non-anonymous cancer registry information was set in order to reduce the burden of protecting sensitive information (Chap. 2.V.3). Any employees engaged in the NCR must ensure the confidentiality and proper use of the data (Chap. 2.V.4-8). The Act does not approve direct requests for disclosure by patients in consideration of the optimal delivery of medical care (Chap. 2.V.9).

It is essential to balance the privacy policy and personal information protection with active utilization of cancer registry data for research. The Act newly introduced penal regulations even for people commissioned by the minister or the prefectural governors (Chap. 6). Anyone who compromises the personal information will be imprisoned for a maximum of 2 years. The Act imposes tougher standards than the existing personal information protection law.

The Act promotes data use by researchers, including those in the private sector; however, the consent of the person concerned, e.g., cohort study participants, must be one of the requirements for the provision of non-anonymous cancer registry information (Chap. 4). On the whole, the privacy policy in the Act is stricter and more specific than those of other developed countries.

Inevitable problems for the period of transition

The period of transition, 2014–2016, will inevitably face several problems. Most regional cancer registries have experienced changes in the cancer registry database system in the past. However, the transition is different this time, because the registries are not allowed to interrupt their activities for the replacement of the database to meet the deadline for the work. The deadline for the data collection activities for the year 2016 cases will be the end of 2017. The regional registries therefore have to work on 2014 and 2015 cases simultaneously at their own pace.

In addition, the owners of the data are different than in the past. Data before 2016 belong to the local governments, while data after 2016 belong to the national government. The Promotion of Cancer Registries does not mention the

Table 3 Changes in cancer registration after 2016

	Contents	Before (–2015)	After (2016–)
Structure	Title	Regional (Prefectural) Cancer Registry	National Cancer Registry
	Legal basis	Health Promotion Law, Art. 16	Act on the Promotion of Cancer Registries
		(Ascertainment of trends in lifestyle-related diseases)	
		Cancer Control Act, Art. 17 (2)	
		(Improvement of the collection and provision of data regarding cancer treatment	
		Cancer Control Act, Supplementary provision 16	
	Agent	Local governments (+ 1 city)	National government (Ministry of Health, Labour and Welfare)
	Cost burden	Local governments	National government and local governments
	Financial support of the research group	Financial support for the MCIJ project participation.	No
		Provision of StdDBS	
	Consultative body	Depending on the prefectures	Health Science Council (MHLW) and local expert panels
Computer system	Database system	Depending on the prefectures (StdDBS, recommended by the JCSRG)	National Cancer Registry Database System
Incidence information	Source	Depending on the prefectures (Hospital reports, active recording, pathological reports)	Hospitals and clinics
	Is cancer a reportable disease?	No	Yes (for hospitals and the designated clinics)
	Sanction for breach of duty	–	Adjuration and publication of the name of the institute
	Compensation for hospitals	Requirement for designated cancer treatment hospital	New support not yet determined
		DPC hospitals	
		Compensation for each report (Depending on the prefectures)	
	Deadline for reporting	Depending on the prefectures (the end of the following year is recommended by the JCSRG)	One year after the diagnosis (cases will not be recorded if more than 5 years have passed) (proposed)
	Report destination	Depending on the prefectures (e.g. only for the residents in the prefectures)	Prefectures where the institute belongs, regardless of the address of the patients
	Transfer of the reports to other prefecture	Depending on the prefectures	No need (central database server)
	Reportable cancer	Depending on the prefectures	Based on the ministerial ordinance
		(Recommendation of the JCSRG)	
	Report items	Depending on the prefectures (25 items recommended by the JCSRG)	Based on the ministerial ordinance (26 items) (proposed)
Cancer mortality information	Source	Matching with National Vital Statistics, which are allowed for follow back survey	New national statistics (copy of the vital statistics) specialized for National Cancer Registry
Data input	Incidence	Local governments	Local governments
	Mortality	Local governments (paper report form)	National governments (electronic data)
	Coding rule	Depending on the prefectures (ICD-O-3 recommended by the JCSRG)	ICD-O-3
Matching	Incidence-incidence	(Within prefecture) Local governments	(Within prefecture) Local governments
		(Inter-prefecture) Not done	(Inter-prefecture) National government
	Incidence-mortality	Local governments	National government

Table 3 continued

	Contents	Before (–2015)	After (2016–)
Follow back, consolidation of tumors	Follow back	Depending on the prefectures (recommended by the JCSRG)	Yes (Hospitals are obliged to respond to follow back survey)
	Consolidation of tumors	(Within prefecture) Local governments	(Within prefecture) Local governments
		(Inter-prefecture) Not done	(Inter-prefecture) National government
	Multiple primary rule	Depending on the prefectures (IARC/IACR, recommendation of the JCSRG)	IARC/IACR rule
Follow-up survey	Source	Matching with National Vital Statistics, which are allowed for follow back surveys (No death record = alive)	Matching with the new national statistics (copy of the vital statistics) specialized for the National Cancer Registry (No death record = alive)
		Refer to resident registry	
	Period	Indefinite	100 years (proposed)
Statistics	National incidence	Estimation	Crude
Data storage limitation	Incidence	Indefinite	100 years (proposed)
	Mortality	1–5 years (just after the practice of follow back survey)	100 years (proposed)
Patients' rights	Refusal, information disclosure, deletion	Depending on the prefectures	No
Data use	Feedback of patients' survival to the reporting hospital	Not allowed (against Statistic law)	Allowed
	Procedure	Depending on the prefectures	Based on the national guideline
	Quality control of cancer screening	Defined as a research activity	Provision of data based on the law (Chap.19)
Education/ training	Training for tumor registrars and administrative officers	Training course organized by National Cancer Center, Japanese Association of Cancer Registries, and the JCSRG.	Training course organized by National government

regional cancer registry data, meaning that the NCR has no legal right to maintain regional cancer registry data in the NCR database. It is necessary to think of this matter practically and legally in order to link the two databases to realize continued cancer statistics.

Although this legislation was the long-cherished dream of researchers and administrative officers who are engaged in the cancer registry, this drastic change is causing needless friction between the national government and some regional cancer registries (Tables 2, 3). Some of the cancer registries were launched almost 60 years ago, and some of them are still not compliant with the changes instituted 10 years ago. The financial support from the government will likely be insufficient to develop the regional cancer registries.

Some registries think therefore that the Act will make the situation worse; it is believed that the local researchers and workers at registries may be discouraged because the 'outcome' of the activities will be published by the national government.

Currently, the experts of the Health Science Council, which was organized in July 2014, have been discussing ministerial ordinances to establish the details of the NCR practice. All of the stakeholders have to consider the division of roles between the national government and local government, and to determine ways to cooperate.

Conclusion

The first cancer statistics from the NCR will be reported by the end of 2018. It is expected that there will be some instability in the first published incidence and survival statistics. However, by 3 years at the latest, the cancer statistics in Japan should be stable, reliable and complete.

Name- and birthdate-based aggregation is the remaining weak point even in this new NCR system. Preceding the Act on the Promotion of Cancer Registries, the Personal ID Act was enacted on May 24, 2013. Following stabilization of the NCR, we expect to use the Personal ID Act for more accurate data aggregation. In addition, this Personal ID Act can be used as a key to link the NCR database to other medical and socio-economic databases. We hope that the cancer registry data will be of use for evidence-based cancer control, and will be a model disease registry.

The speed of aging of the Japanese population is faster than that in any other developed country, and the number

of cancer patients is expected to continue increasing, so we estimate that the first national cancer incidence data in 2016 will show around 1 million cases. It would be impossible to keep our cancer registries under the present circumstances, and a change was required to provide reliable cancer statistics in our country because of the hyper-aging society, and because there will be an estimated to two to three million cancer patients who will require entry of detailed information. We appreciate the long history of the Japanese cancer registry, but all must embrace the dramatic changes in order to keep pace with the changes in society and with the changes in technology.

Conflict of interest The authors declare that they have no conflict of interest.

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The National Database of Hospital-based Cancer Registries: A Nationwide Infrastructure to Support Evidence-based Cancer Care and Cancer Control Policy in Japan

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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

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 reportedly referred from 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 2. The number of data-submitting hospitals and cancer cases by year

	2007	2008	2009	2010
No. of DCCH	288	351	377	388
No. of hospitals analyzed	287	359	370	387
No. of cases	327 889	428 195	487 441	548 979

Note: reproduced from ref. (7).

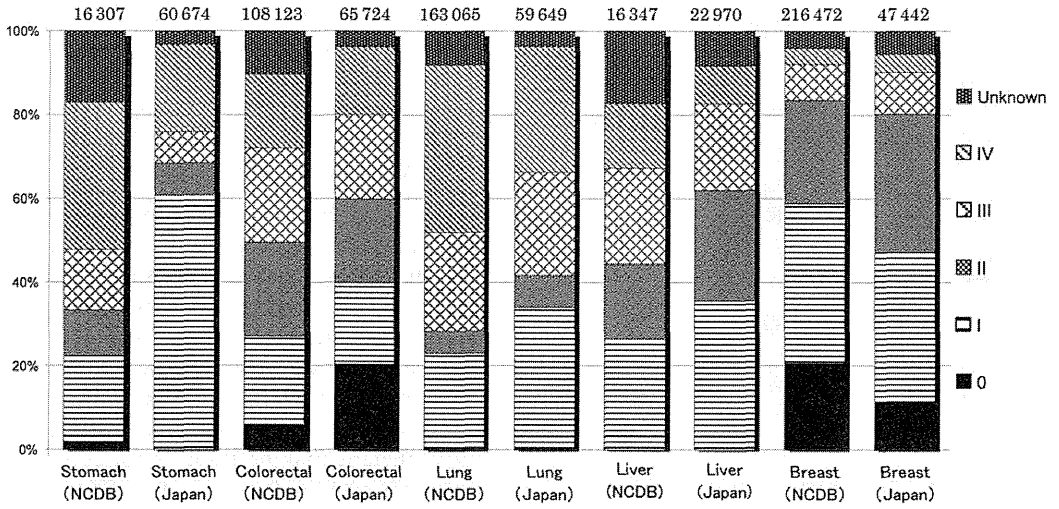

Figure 1. The International Union against Cancer (UICC) stage distribution for stomach, colorectal, lung, liver and breast cancers in the US National Cancer Database (NCDB) (20) and Japanese hospital-based cancer registry (diagnosed in 2009).

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,

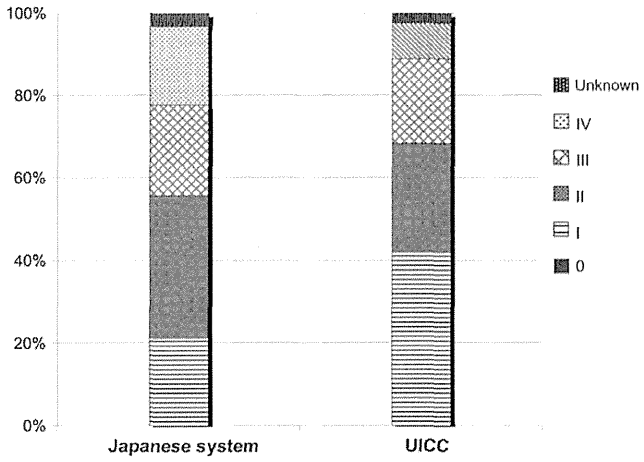

Figure 2. Distribution of stages in 2010 liver cancer cases by the International Union against Cancer (UICC) and the Japanese staging systems.

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 prefectural 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.

Funding

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Conflict of interest statement

None declared.

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5. がん登録等の推進に関する法律とがん登録

The Role of the Act on Promoting Cancer Registries

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Akiko Shibata
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Summary

平成25年12月，がん登録等の推進に関する法律（以下，「がん登録推進法」）が成立し，平成28年1月施行に向けて準備が進められている（法律第111号）。がん登録推進法に基づく全国がん登録は，がん診療のアウトカム指標のひとつである生存率の計測にかかせない，患者の生死情報の有力な情報源となることが期待されている。平成28年1月以降，全ての病院と指定された診療所はがん患者を診療した時，都道府県を経由し国に届け出なければならない。届け出た病院等は，申請によって，全国がん登録に登録された自らの届出情報と生死情報の提供を受けることができる。一方，病院等は提供を受けた全国がん登録情報等を活用し，国民に役立つ情報を提供しなければならない。がん登録推進法を理解しその基本理念である，がん医療の質の向上，国民に対する情報提供の充実，科学的知見に基づくがん対策のために登録情報が活用されなければならない。

Surgery Frontier 21(4)：35-39，2014

Key Words　がん登録，地域がん登録，がん登録の推進に関する法律，個人情報保護法

はじめに

平成25年12月6日，がん登録等の推進に関する法律（以下，「がん登録推進法」）が成立し，平成28年1月施行に向けて準備が進められている（平成25年12月13日　法律第111号）。本法律は，がん登録を充実させることで，がん医療の質の向上，国民に対するがん・がん医療等・がん予防についての情報提供の充実，がん対策を科学的知見に基づき実施して欲しいという，がん患者団体の熱心な要望を受けて成立した。そのため，法律の目的に，単なるがん統計の作成に留まらず，登録された情報を利用することが明記されたことは特筆すべき点である。もう一点特筆すべきことは，個人情報を徹底して保護する立場で法設計がされている点である。

本特集のテーマ「質の向上のための可視化とその後の責任」では，診療の質の向上のために，診療のプロセスをいかに可視化できるか，が関心事項と考えられる。がん登録推進法に基づく全国がん登録は，がん診療のアウトカム指標のひとつである生存率の計測にかかせない，患者の生死情報の有力な情報源となることが期待されている。

本稿では，本法律の成立の背景，本法律によって病院等が何をしなければならないのか，本法律に基づくがん登

メモランダム

- 平成25年12月，がん登録等の推進に関する法律が成立した（法律第111号）。
- 平成28年1月以降，全ての病院と指定された診療所は，がん患者を診療した時，都道府県を経由し，国に届け出なければならない。
- 届け出た病院等は，申請によって，全国がん登録に登録された自らの届出情報と生死情報の提供を受けることができるので，それらの情報を診療の質の向上のために活用しなければならない。

録情報の活用のあり方の3点について紹介する。

がん登録推進法成立の背景

図1[1]は，世界保健機関の一組織である国際がん研究機関が数年おきに作成，公表しているGLOBOCANというウェブサイトから，自由にダウンロードできる2012年の結腸・直腸がんの年齢調整罹患率の世界地図である。日本は，罹患率のもっとも高いグループに属していることがわかるが，この日本の罹患率のデータ，愛知県，福井県，広島県，宮城県，長崎県，新潟県，大阪府，佐賀県，計8県の地域がん登録から提供された2003～2007年の罹患データを用いて推計されている。図2[2]は，経済協力開発機構のウェブサイトから自由にダウンロードできる，加盟18カ国の結腸・直腸がんの5年相対生存率である。この日本の生存率のデータは，宮城県，山形県，新潟県，福井県，大阪府，長崎県の6県の地域がん登録から提供された2002年～2005年の罹患データを用いて推計されている。このように限られた都道府県のデータだけで日本の代表値が推計されている理由は，日本では，がんの罹患を把握する仕組みである地域がん登録が，都道府県の努力義務として行われてきたからである。がん対策基本法の成立施行によって，平成24年にようやく全47都道府県に地域がん登録室が設置され（表1），各登録の精度も上がってきたが，届出義務なくしては登録精度の向上に限界がある。このような状況を知ったがん患者団体等が，がん登録を充実させることでがん医療の質の向上，国民に対するがん・がん医療等・がん予防についての情報提供の充実，がん対策を科学的知見に基づき実施してほしいと国会議員に要望し，2年以上におよぶ多岐にわたる課題の検討の結果，超党派による議員立法「がん登録等の推進に関する法律」が成立した。

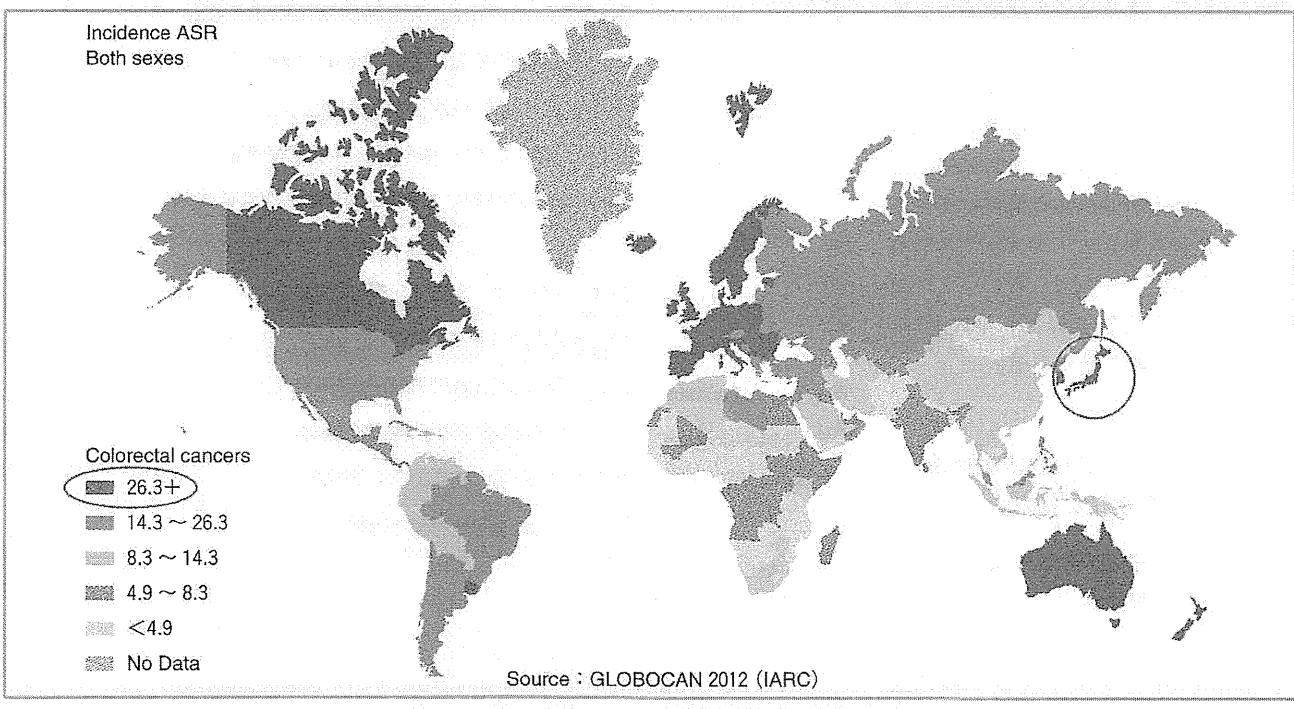

図1　結腸・直腸がんの年齢調整罹患率の国際比較

（文献1より引用）

がん登録推進法と病院等の義務

がん登録推進法6条に届出に関することが定められている。すべての病院と指定された診療所は，2016年1月以降がん患者を診療した場合，都道府県を経由し国に届け出なければならない。届出対象は原発性のがんである。自らの病院において初回の診断が行われたときに一度届け出れば，再発時等の繰り返しの届出は不要である。ここでいう「診断」には，病理診断が施行されていないものも含まれる。その意味において，ある患者の診断名として「がん」が自らの病院の診療録に初めて記録されるとき，届出対象のがんが発生したといえる。届け出る先は患者の住所地にかかわらず，自らの病院の所在地の都道府県がん登録室である。届出の項目や期限は，厚生科学審議会がん登録部会（平成26年6月4日設置承認）での検討を経て，平成26年中に決定される予定である。

病院等におけるがん登録推進法に基づく登録情報の活用

がん登録推進法47条では，病院等にがん登録情報を活用し，国民に情報提供することを求めている。病院等は20条に基づいて，全国がん登録に登録された情報の提供を受けることができる。全国がん登録の情報の利用および提供の仕組みについては，図3のようにまとめられる。病院等は20条に基づいて病院等へ提供された情報か，21条に定められた研究者への提供の仕組みを用いて全国がん登録情報を利用できる。ただし，21条で定められる提供の仕組みにおいて，非匿名化情報（個人識別性の高い情報）の提供を受けようとする場合，全国がん登録から情報を提供されることについて研究

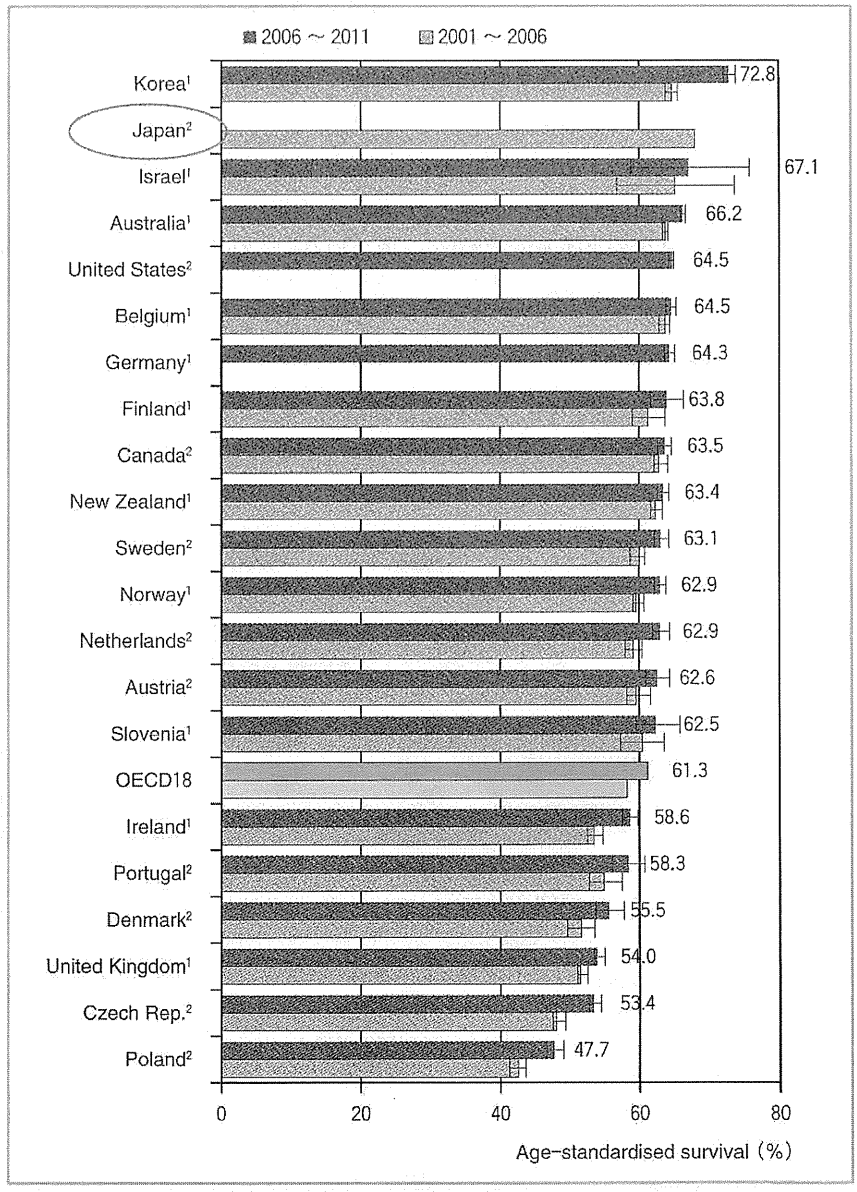

図2　結腸・直腸がんの5年相対生存率の国際比較

2013年10月31日データ更新

（文献2より引用）

対象者本人が同意していることが要件となる。この要件には，全国がん登録で収集された情報は厳格に保護されなければならない，という3条の基本理念が反映されている。

個人情報保護法が成立施行された平成15年以降，学術研究団体主導のがん登録では，多くは登録に関する本人同意を得ずに，個人識別性の高い情報を登録しない方針が選択されていると思われる。全国がん登録情報と，そのほかのがんに関する調査研究のために収集された情報の連結には個人識別情報を要する。そのため，学術研究団体主導のがん登録が全国がん登録に収集された生存確認情報を直接的に利用するには，個人情報の登録と全国がん登録情報から提供を受ける可能性について，研究対象者から同意を得ている登録である必要がある。そうでない場合，学術研究団体主導のがん登録は学会員のみならず学会員が所属する病院等と協力し，病院等が全国がん登録情報からの提供を受けてがん医療の分析および評価等を行い，患者等に適切な情報の提供を行う努力の一環と位置づけ，20条に基づき病院等に提供された生存確認情報等を含めてこれまでどおりに個人情報を含まない登録を用いた調査研究を行う方法も考えられる。

表1　地域がん登録事業の実施状況

登録開始年	都道府県
1979年以前	北海道，宮城，山形，千葉，神奈川，富山，愛知，滋賀，大阪，鳥取，高知
1980年代	青森，福井，京都，佐賀，長崎，沖縄
1990年代	岩手，茨城，栃木，群馬，新潟，石川，岐阜，岡山，山口，徳島，香川，愛媛，熊本，鹿児島
2002年	広島
2006年	秋田
2007年	山梨，兵庫
2010年	長野，島根
2011年	福島，埼玉，静岡，三重，奈良，和歌山，福岡，大分
2012年	東京，宮崎

（文献3より引用）

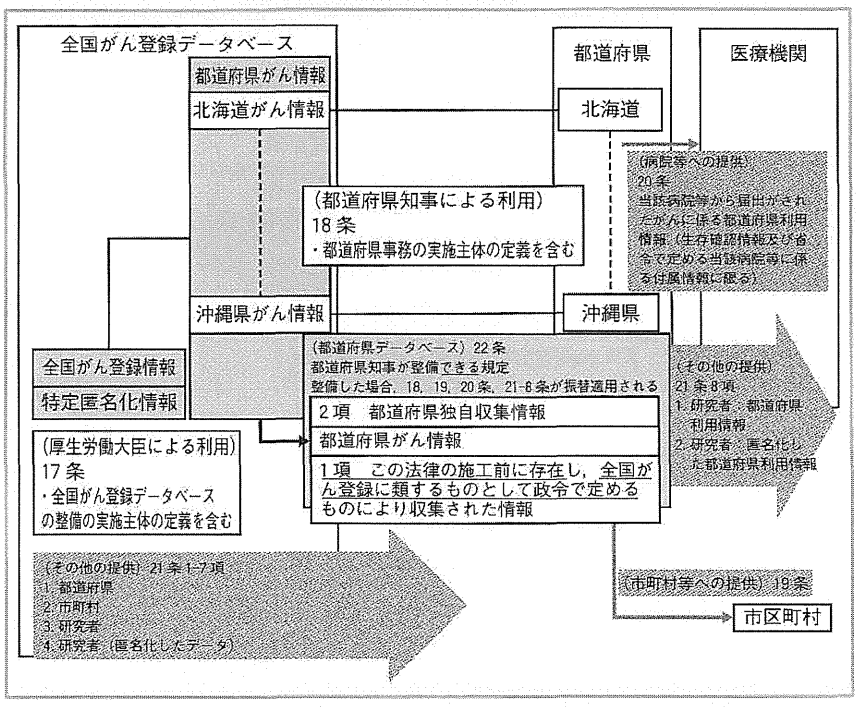

図3　がん登録推進法における情報の利用と提供の仕組みの概要

（2013年12月国立がん研究センターがん対策情報センターがん統計研究部作成）

おわりに

がん登録推進法は，同意を得ることなく収集する個人情報の保護に最大限に配慮しながら同時に，集積されたがん情報の活用を積極的に推進する法律である。本法を上手に活用し，その基本理念であるがん医療の質の向上，国民に対する情報提供の充実，科学的知見に基づくがん対策のために登録情報が活用されることが期待される。

文　献

1）World Health Organization：GLOBCON 2012：Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012 [http://globocan.iarc.fr/Default.aspx]

2）Organisation for Economic Cooperation and Development：OECD iLibrary[http://www.oecd-ilibrary.org]

3）厚生労働省第3次対がん総合戦略研究事業：がんの実態把握とがん情報の発信に関する研究（主任研究者：祖父江友孝）．地域がん登録の標準化と精度向上に関する10年後調査結果報告書．平成26年3月

「厚生の指標」　抜刷

一般財団法人　厚生労働統計協会

投稿

がん患者数計測資料としてのレセプト情報等の利用可能性

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目的　がん患者が何人いるかは社会の関心事であるが，実測値は存在しない。日本では，がん患者数として，患者調査に基づく推計値である総患者数や，罹患数と生存率や死亡率から推計する期間有病数が用いられているが，それぞれに特徴と限界がある。著者らは，厚生労働省が平成23年度から提供を開始したレセプト情報等を用いて，新たながん患者数の指標を得られる可能性を期待して分析を行った。

方法　レセプト情報に基づく月平均レセプト件数，患者調査に基づく総患者数，および推計罹患数と５年生存率から推計した５年有病数を，性，年齢，都道府県，がんの部位別に比較した。レセプト情報等については平成22年４月から23年３月の期間に，悪性新生物，上皮内新生物，良性または性状不詳の脳腫瘍及び性状不詳の血液腫瘍の傷病名でレセプトが請求されたレコードの提供を受けた。患者調査の総患者数については，平成20年調査結果を用いた。がん有病数については，推計罹患数と５年生存率を用いて推計された2010年から2014年における年平均の５年有病数を利用した。

結果　全部位の悪性新生物について，月平均レセプト件数は約240万件，総患者数は約150万人，５年有病数は約230万人であった。総患者数と比較した場合，レセプト件数は，性別，年齢別，都道府県別，部位別に，すべて総患者数を１～2.9倍上回った。年齢別には，高年齢層ほど総患者数とレセプト件数のかい離が大きい傾向がみられた。部位別には，罹患数の多い部位では，総患者数と比べて，レセプト件数は約２から2.4倍，５年有病数は約1.5から２倍であった。

結論　新たに利用できるようになった電子レセプト情報等について，日本のがん患者数計測資料としての可能性を，患者調査の総患者数と推計５年有病数との比較において記述した。総患者数は，調査対象が調査期間と調査施設に依存する標本調査であること，有病数は，限られた資料源を用いた推計値であることに加えて，他の指標と異なり，受療割合が反映されていない値であることを考慮する必要がある。毎月自動的に，一定の様式で，ほぼ全数調査に近いデータが蓄積されるレセプト情報は，既存資料を利用した日本のがん患者数計測資料として一定の利用可能性があると考えられた。

キーワード　がん，患者数，有病数，レセプト

Ⅰ はじめに

日本にがん患者が何人いるかは，社会の関心事である。患者とは，一般に，病気で医者の治療を受ける人，病気にかかっている人と定義されるが，がんの場合，種類や罹患時の進行度に

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よって，初回治療で完全治癒が期待できたり，治療は行われないが再発の可能性が残るために検査観察が継続されたり，再発防止のために一定期間治療が継続されるなど，どの範囲を病気にかかっている人と考えるかを一律に定義することは難しい。一方で，日本のがん患者数として，患者調査による総患者数（以下，総患者数）が広く認知されている。その他，がん患者数に類似した統計指標として，がん罹患数と生存率や死亡率から推計するがん有病数が知られている[1)]。

厚生労働省は，平成23年３月に公表された「レセプト情報・特定健診等情報の提供に関するガイドライン（以下，ガイドライン）」[2)]に基づくレセプト情報等の提供を，平成23年５月頃から開始した。レセプトとは，健康保険法ならびに国民健康保険法の規定に基づき，医療提供者が被保険者ごとに月単位で作成し，保険者に提出する診療報酬明細書のことである。ガイドラインにおいて，レセプト情報とは，高齢者の医療の確保に関する法律の規定に基づき，保険者および後期高齢者医療広域連合から厚生労働大臣に提供され，厚生労働省が収集および管理する診療報酬明細書および調剤報酬明細書に関する情報をいう。本研究では，この新たに利用可能になったレセプト情報等を利用して得られる値ががん患者数の指標となり得るかどうか，総患者数および罹患率と５年生存率から推計した５年有病数との比較によって分析し，それぞれの指標の特徴と限界と有用性を明らかにすることを目的とした。

Ⅱ 方　法

レセプト情報に基づく月平均レセプト件数，患者調査に基づく総患者数，および罹患率と５年生存率から推計した５年有病数を，性，年齢，都道府県，がんの部位別に比較した。各統計値は，以下に記載する方法で得た。

（１） レセプト情報に基づく月平均レセプト件数

レセプト情報は，医療機関が被保険者ごとに月単位で作成するものであるから，著者らは，がんの傷病名を含んで診療報酬を請求された１カ月当たりのレセプト件数は，任意の１カ月の間に継続的に医療を受けているがん患者の概数であるという仮定をおいた。レセプト情報は，ガイドラインに定められた手続きに従って，平成22年４月から平成23年３月の期間に，悪性新生物，上皮内新生物，良性または性状不詳の脳腫瘍及び性状不詳の血液腫瘍の傷病名で医科レセプト（外来・入院）またはDPC（Diagnostic Procedure Combination）レセプトが請求されたレコードの提供を受けた。提供レコードには手書き書類で作成されたレセプト情報は含まれない。厚生労働省によると，平成22年８月請求分までに，医科領域のレセプトの約93％が電子レセプトで提出されている。医科領域の電子レセプトには，医科レセプトと，DPC対象病院が作成するDPCレセプトがある。DPC対象病院とは，がんを含む診断群分類包括評価を用いた入院医療費の定額支払い制度を適用している病院である。DPC対象病院でがんの傷病名で医療を受けていた患者が退院し，同じ月の中で同じ病院の外来で診療を受けた場合は，入院分についてはDPCレセプトが，外来分については医科レセプトが発行される。DPC対象病院数は，平成22年７月時点で1,390で，全一般病院数の約18％であった。

１件のレセプトは当該患者に関する複数のレコード（例：レセプト共通レコード，傷病名レコード等）から構成されており，レセプト番号をキーとして連結できる構造である。本研究のために，医療機関の所在地の都道府県，診療年月，性別，５歳年齢階級，傷病名コード，修飾語コードの提供を受けた。レセプトの傷病名は独自のコード体系で管理されていることから，公開されている傷病名マスターのレセプトの傷病名コードと疾病，傷害，死因および統計分類（ICD-10 2003年版準拠）（以下，ICD-10）[3)]の対応を用いて，ICD-10のコードC00-C97，D0109，D32-33，D35.2-35.4，D42.0，D42.9，D43.0-43.3，D43.7-9，D44.3-44.5，D45-47に対応する傷病名コードを持つ対象の提供を