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ORIGINAL ARTICLE

Current status of site-specific cancer registry system for the clinical researches: aiming for future contribution by the assessment of present medical care

Koichi Hirata[1,17] · Masafumi Imamura[1] · Toshiyoshi Fujiwara[2] · Tsuguya Fukui[3] · Toshiharu Furukawa[4] · Mitsukazu Gotoh[5] · Kenichi Hakamada[6] · Megumi Ishiguro[7] · Yoshihiro Kakeji[8] · Hiroyuki Konno[9] · Hiroaki Miyata[10] · Masaki Mori[11] · Kenji Okita[1] · Masami Sato[12] · Akiko Shibata[13] · Ichiro Takemasa[1] · Michiaki Unno[14] · Kohei Yokoi[15] · Toshihiko Nishidate[1] · Masahiko Nishiyama[16]

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Abstract

Background The current status of site-specific cancer registry has not been elucidated, but sufficient system is found in some societies. The purpose of this study was to clear the present condition of site-specific cancer registries in Japan and to suggest for the improvement.

Methods The questionnaire was conducted by the study group of the Ministry of Health, Labor, and Welfare. It consisted of 38 questions, conflicts of interest, clinical research method, informed consent and funding for registry. We distributed this questionnaire to 28 academic societies, which had published the clinical practice guideline(s) assessed under Medical Information Network Distribution Service (MINDS).

Results The concept of the importance in assessment for medical quality by the data of the site-specific cancer registry was in good consensus. But the number of the society with the mature registry was limited. The whole-year registry with the scientific researches in the National Clinical Database (NCD) and in the Translational Research Informatics Center (TRI) might seem to be in success, because assured enhancement may be estimated. Now, academic societies have the structural factors, i.e., the financial limitation in the registry maintenance and the data analysis, and in the difficulty of employment of the researchers with skill and talent.

Conclusions To manage the site-specific cancer registry effectively, the scientific registry system will be essentially important. Each academic society had much experienced highly qualified clinical researches in past. Accordingly, the scientific suggestion and co-operation should be of great importance for the improvement.

Keywords The site-specific cancer registry · Assessment of medical quality · Clinical research

Introduction

Clinical and epidemiological researches involving the constant evaluation of cancer medicine are expected under the site-specific cancer registry at the nationwide level. At present, the national systematic data on survival, recurrence, and mortality can be utilized in researches precisely since 2019 January. On the basis of the law, i.e., Cancer Registry Promotion Act (CRPA); the utilization of such data is available for analysis, which should be highly reliable, and its data will garner global attention, as shown in the reports from foreign countries [1–6]. Such data display the actual results of present medical care and can evaluate the characteristics of medical systems. Up to date in Japan, there have been the systems of site-specific cancer registry supported by the individual efforts of academic societies. Surely, many publications from Japanese academic societies based on those data have been highly evaluated as the international level [7–10]. Otherwise, even as of December 2018 in Japan, nationwide cancer registry data was comprised only in the estimated values based on cancer registry data from the selected regions [11, 12]. However, CRPA is now ongoing,

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✉ Koichi Hirata
khirata@sapmed.ac.jp; kouichi.hirata@jrhokkaido.co.jp

Extended author information available on the last page of the article therefore, academic societies will plan to utilize those data scientifically in near future.

Japanese academic societies still hold conflicting opinions on the argument of the necessity of site-specific cancer registry in details and making it necessary to resolve such differences to facilitate future developments. Therefore, with the aim of an accurate framework with the above context, we organized a research team with a Grant-in-aid for Scientific Research from the Ministry of Health, Labor and Welfare [with the research theme: Research on the construction of a National Clinical Database (NCD) long-term prognosis input system for a high-quality treatment database and the promotion of a large-scale cohort study utilizing site-specific cancer registration coordinated with national cancer registry]. Our purpose of this study was to clarify the current status in developing the site-specific cancer registry and to propose the recommendations for the development in future. Our questionnaire had been sent to 28 academic societies (Table 1) that had been conducted in the databases of the National Cancer Center Japan, and the Japan Society of Clinical Oncology and the Medical Information Network Distribution Service (Minds) on October 2016 to identify academic organizations. They were responsible for clinical practice cancer guidelines.

Research methods

Subjects in this research group and societies responded for the questionnaire

All of the researchers and collaborators in this group were recommended by academic societies specializing in the site-specific cancer medicine, and/or with the publication of clinical cancer guidelines.

The 28 academic societies (Table 1) had been nominated as the responsible society, because they had officially published the clinical practice cancer guideline(s) which are introduced in the database of the National Cancer Center Japan and also in the Japan Society of Clinical Oncology and the Medical Information Network Distribution Service (Minds).

Table 1 A list of academic organizations in Japan which published cancer-related clinical practice guidelines

#	Academic organizations
1	The Research Group for Rare Neoplasms of Japan
2	Japanese Society for Cancer of the Colon and Rectum
3	Japanese Gastric Cancer Association
4	The Japan Society of Hepatology
5	Japanese Society of Hepato-Biliary-Pancreatic Surgery
6	Japan Society of Clinical Oncology: Proper management using Antiemetic agent
7	Japan Society of Clinical Oncology: Proper management using G-CSF
8	Japanese Society for Palliative Medicine
9	Japanese Society of Hematology
10	Japanese Society of Oral Oncology
11	Japanese Society of Thyroid Surgery
12	The Japanese Society of Pediatric Hematology Oncology
13	The Japan Esophageal Society
14	Japan Neuroendocrine Tumor Society
15	Japan Pancreas Society
16	The Japanese Orthopedic Association
17	Japan Society for Head and Neck Cancer
18	Japanese Breast Cancer Society
19	Japan Association of Breast Cancer Screening
20	The Japan Society for Neuro-Oncology
21	The Japan Lung Cancer Society
22	The Japanese Urological Association
23	Japanese Skin Cancer Society
24	Japan Society of Gynecologic Oncology
25	Japanese Society for Radiation Oncology
26	The Japanese Association of Rehabilitation Medicine
27	Japanese Society of Medical Oncology
28	The Japanese Lymphedema Society

Questionnaire

The questionnaire was overseen mainly by this research group, the research topics of which were “research for the establishment of a system for continuous improvement in medical care quality” and “research on the preparation of frameworks to enable continuous medical care evaluation. The draft questions had been confirmed by all of members. Finally, it consisted of 32 questions, i.e., 15 questions about registry rules concerned to medical information, 7 about conflicts of interest, 6 about clinical research/data analysis, and 4 about financial fund. The entire content of the questionnaire has been omitted in this paper, because of the utilization partly from the questionnaire data and of the size of these resources was too much. If the details of the questionnaire were desired to observe, it might be found in the 2017 research team report (written by Japanese) present on the homepage of the Ministry of Health, Labor and Welfare Japan, which is planned for release after July 2018. The questionnaire was sent out from November 1, 2016 and collected for 2 months. Responses were sent to Sapporo Medical University, where the principal investigator was affiliated.

Results

Responses for the questionnaire were fortunately received from all of the academic societies that we sent, within the planned period. Upon confirming the responses and their question items, it was found that some of the question items were not applicable to certain academic societies. Therefore, the results after adjustments were shown in the adequate manner under the responses, including not requiring answers for certain questions.

The number of the societies with establishment of site-specific cancer registry

Nineteen (67.9%) academic societies were implementing the site-specific cancer registry throughout the year (including the academic societies presently planning to start doing so), while 5 (17.9%) were implementing registry regularly or irregularly [Table 2-Column (a) and (b)]. Of the latter academic societies, two were planning to implement the whole-year registry in the near future. Moreover, two (7.1%) academic societies had no such plans, and two academic societies answered this question as not applicable. Therefore, 26 academic societies will be considered for the development of registry.

The number of the societies with registry web sites and with improvement system for the site-specific cancer registry

Thirteen academic societies were already implementing site-specific cancer registry with a history of > 3 years and have made efforts for the improvement of completion in the registry. In terms of adjustments to improve the logical system as the registry, it was found that four academic societies began the new registry system under the scientifically objective concept. They clearly obligated to engage in cancer case registry. As a condition for being recognized under the medical specialty board system, the other four academic societies

Table 2 The present state in concern with the site-specific cancer registries among the societies with the field specialty in Japan

Subjects						
(a) Registry	In force [24]					Not in force [4]
(b) Duration of registry	Whole-year [19]				No plan [2]	No plan [2]
(c) Enhancement for registry	In force [13]			Not in force [5]		
(d) Actual behavior for enhancement	B** [2]	C*** [2]	Repeated request for each institute [9]	Not in force [11]		
(e) Site for registry	NCD**** [8]		Society with clinical specialty field [15]			
(f) System for informed consent	Opt-out [7]	Opt-out + Opt-in## [4]	Opt-in [2]	Opt-out or –in in discussion [6]	no answer [5]	

*A: no answer

**B: One of the requirements as the application for a specialist

***C: One of the requirements as the application of the authorized institute

****NCD: general incorporated foundation National Clinical Database

#D: Translational Research Informatic Center

##Opt-out mainly and opt-in as the occasion of the research classification registered, limited in surgery cases rather than only cancer cases. Among them, four were obligated to register all these cases as a condition for being recognized under the medical specialty board system (Table 2-column I and (d)). Of these four, two academic societies qualified as the terms of the individuality and the institute in the medical specialty board system, and other two did as the term of only the institute, that they were formally evaluating their patient-registry. Finally, 10 academic societies relied upon or planned the autonomous efforts of the registry.

As regarding a related contribution, the following were being thoroughly implemented: (1) research on "the popularization of medical care recommended in treatment guidelines and the validity of recommended medical practice"; (2) the release of a "Guideline Handbook for Patients" to aid in patients understanding of recommended medical practice; and (3) displaying information on (1) and (2) on its homepage. The former thirteen societies and one of latter ten societies have not yet (not been indicated as the data).

Site-specific cancer registry websites

Of the academic societies engaging in registry projects aimed at studying the annual variations of medication for cancer cases and at researching that evaluates the recommended medical care, three had outsourced their registry website to the NCD (involving three cancers: liver, pancreas, and breast) [13] and one (neuroendocrine tumor) to the Translational Research Informatics Center(TRI) [Table 2-column (e)]. In addition, more than two academic societies have plans to follow the similar system in the near future. Other academic societies were internally implementing registry projects for the time being. Other than the four described above indicated that the outsourcing of the new logical system was in consideration.

Informed consent system related to the site-specific cancer registry

In Japan, the clinical research should be implemented in accordance with the "ethical guidelines for clinical research with human subjects" in which modern ethical content has been organized based on international standards. This had come to be fundamentally implemented over the past 10 years. In the last 7–8 years, follow-up, surveillance and clinical research under these guidelines have publically been required. As described before, the follow-up data under a research-object should be engaged as the registry is based on those guidelines. As described in the research methods, the data have been maintained under the guidelines in Japan since the end of October 2016, when their applications have been started.

Regarding informed consent (IC) for data registry before that time, thirteen academic societies answered that the action is being taken; other six academic societies answered that some actions taken are in consideration and five academic societies had no response [Table 2-column (f)]. Namely, the IC acquisition system was observed to be different, i.e., the complete opt-out method for registry, the opt-in method, and different response for each research depending on the research style (namely adequate determination was approved), respectively.

Problem of integrated administration for site-specific cancer registry

No academic societies at present had proposed an integrated administration for the site-specific cancer registry. There were 11 academic societies that were considering the introduction of such system, 11 that had recognized the necessity of such a system and were discussing it but had not reached a specific conclusion, and 6 that had not considered such a system at all (Fig. 1).

For the former two types, the reasons for issues being faced while implementing such a system were shared. Between two groups (11 societies in each), the present problems for the advancement of the integrated administration system resulted completely in the same manner. The significant work load of the integrated administration and difficulty in establishing the comfortable finance for an overall integrated administration system accounted for 90.9% of the reasons, respectively (Fig. 2). In addition, lack of human resources was cited by 81.8% (Fig. 2).

Utilization of the site-specific cancer registry

The number of English reports related to the assessment of the quality of medical care presented by each academic society has been introduced in a stratified manner based

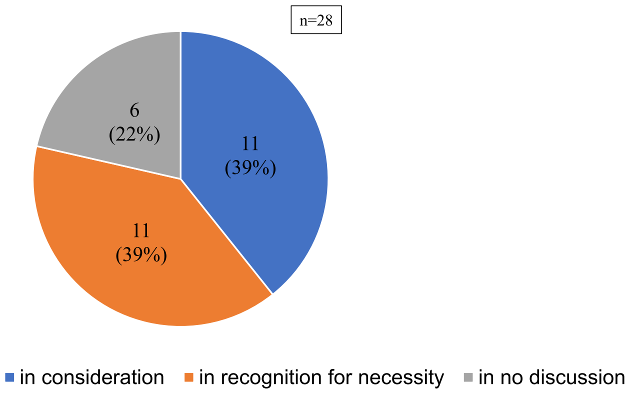

Fig. 1 Present integrated management of the site-specific cancer registry. Differences at present sites among societies

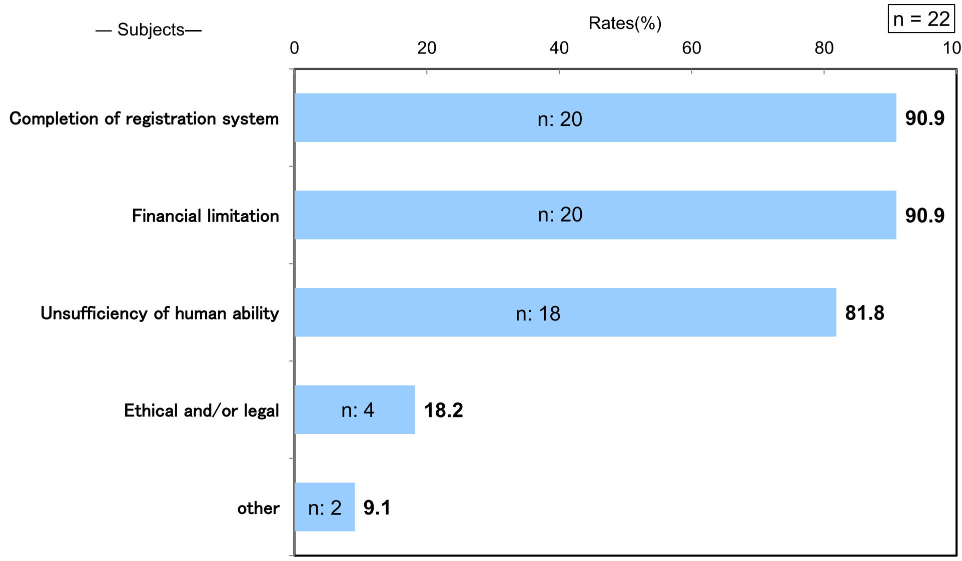

Fig. 2 Current status of the reasons (risk factors) among 22 societies to maintain the registry throughout the year

on reports by the research members in our research team and had been reported this questionnaire survey (not shown in data). Those results were significantly different among the academic societies. To clarify the reason, it might have been difficult under this questionnaire, but excellent efforts in each society were shown as the result of number of the manuscripts.

Discussion

International consensus for the medical practice recommended has been known as the concept of evidence-based medicine (EBM). Most high leveled evidence has been supported by the results under the randomized controlled trial, etc. However, it is well known that the recommendation of medical practice based on such evidence by RCT has sometimes been difficult, because the number of such evidence has not been enough in most fields.

With the aim that the repeated assessment for the medical practice should contribute for the ladder step-up of medical quality, scientific and systematic organization would be considered. The Japan Society of Clinical Oncology established the Clinical Database Committee in 2001 and commenced activities based on the cancer treatment guidelines as its first step [13]. Moreover, some academic societies have altogether engaged in future researches of the assessment in accordance with the spread of the clinical cancer treatment guidelines, and an international contribution as the ideal system. Recently, we have reached the stage in which comprehensive judgment was achieved by taking the "benefit" and "evil" associated with various outcomes, i.e., prognosis, quality of life (QOL), medical expense, reliability and safety associated with implementing medical care into account by experts and patients. As the results of recent efforts by several academic societies, highly qualified reports as the clinical epidemiological cohort studies using nationwide database from Japan [14–22] have been increasing in number. Most of these results have garnered international attention. Similar researches by the utilization of cancer registry database are recognized internationally, as effectiveness- measurement by the assessment for recommended medical practice. Similar international representatives are well known as follows, i.e., the Surveillance Epidemiology and End Results (SEER) [23], National Program of Cancer Registries (NCPR) [24], the EUREG (registry) [25], EUCAN (national estimates) [26], and EUROCIM (downloadable data) [27] of the European Cancer Observatory (ECO) driven by the European Commission (EU).

Our research team has continuously engaged in research regarding (1) the advancement of cohort studies utilizing the site-specific cancer registry data, (2) the improvement of the research data quality from the national cancer registry that was founded in 2016, Jan. and (3) the co-operated sharing of such systems among academic societies. On the way of this research process, we conducted the questionnaire survey for academic societies with the clinical cancer treatment guideline. Our results revealed that the major issues shared by many academic societies may include the difficulty improving registry and continuing with observational studies due to the lack of abundant reasons in financial resources. We found the positioning of registry in academic societies, which were the recognition for the interest/prioritization of the development as the registry, and the difference in perceptions in the future of registry, as the key negative factors. Academic societies that were proactively developing both registry and clinical research projects had already implemented countermeasures to ensure the complete registry. Moreover, it was demonstrated that completeness and accuracy had been limited, when registry relies only on the individual efforts by the each member. Some academic societies had even prepared a series of systems connecting verification through site-visits or audits and verifying the results with individual physicians or medical facility evaluations.

In this study, we could clarify the important factors for advancement of present site-specific cancer registry. While we have anticipated the close coordination among academic societies, the further advancement of cross-sectional exchanges among academic societies will be expected for medical and social contribution/reliability. We hope that the data in this questionnaire will aid in achieving the good cycling for the assessment of medical quality.

Conclusions

The implementation of the recommended medical practice in cancer treatment guidelines to date has not been appropriately correlated with the evaluation for the exact medical care through the analysis of site-specific cancer registry data in Japan. In this study, all of academic societies, which published the clinical cancer treatment guideline with public assessment in MINDS, also in the information site of the National Cancer Research Center Japan, and in each site of the academic society, have fortunately contributed. Then, the present structure of the site-specific cancer registry system and of the clinical research utilized such registry data could have been introduced. To manage the site-specific cancer registry effectively, the improvement of scientific registry system is expected among academic society. Since high-qualified clinical researches have much been experienced among them, they hope to study under the ideal system for the repeated researches. Fortunately, such assessment methods may seem to have already been developed in the limited number of societies and the number of reports with high impact factors from Japanese academic societies [28–31] has been increasing. Further development of site-specific cancer registry by each academic society would be expected in the cyclic assessment for medical quality.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

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Affiliations

Koichi Hirata[1,17] · Masafumi Imamura[1] · Toshiyoshi Fujiwara[2] · Tsuguya Fukui[3] · Toshiharu Furukawa[4] · Mitsukazu Gotoh[5] · Kenichi Hakamada[6] · Megumi Ishiguro[7] · Yoshihiro Kakeji[8] · Hiroyuki Konno[9] · Hiroaki Miyata[10] · Masaki Mori[11] · Kenji Okita[1] · Masami Sato[12] · Akiko Shibata[13] · Ichiro Takemasa[1] · Michiaki Unno[14] · Kohei Yokoi[15] · Toshihiko Nishidate[1] · Masahiko Nishiyama[16]

[1] Department of Surgery, Surgical Oncology and Science, Sapporo Medical University, South 1, West 16, Chuo-ku, Sapporo 060-8543, Japan

[2] Department of Gastroenterological Surgery, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama, Japan

[3] St. Luke'S International University, Tokyo, Japan

[4] Keio University Law School, Tokyo, Japan

[5] Osaka General Medical Center, Osaka, Japan

[6] Department of Gastroenterological Surgery, Hirosaki University Graduate School of Medicine, Hirosaki, Japan

[7] Department of Translational Oncology, Tokyo Medical and Dental University, Tokyo, Japan

[8] Division of Gastrointestinal Surgery, Kobe University Hospital, Kobe, Japan

[9] Hamamatsu University School of Medicine, Hamamatsu, Japan

[10] The University of Tokyo, Healthcare Quality Assessment, Tokyo, Japan

[11] Department of Gastroenterological Surgery, Graduate School of Medicine, Osaka University, Osaka, Japan

[12] Thoracic Surgery, Kagoshima University Hospital, Kagoshima, Japan

[13] Center for Cancer Control and Information Services, National Cancer Center, Tokyo, Japan

[14] Department of Surgery, Tohoku University Graduate School of Medicine, Sendai, Japan

[15] Department of Thoracic Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan

[16] Department of Molecular Pharmacology and Oncology, Gunma University Graduate School of Medicine, Maebashi, Japan

[17] JR Sapporo Hospital, North 3, East 1, Chuo-ku,
Sapporo 060-0033, Japan