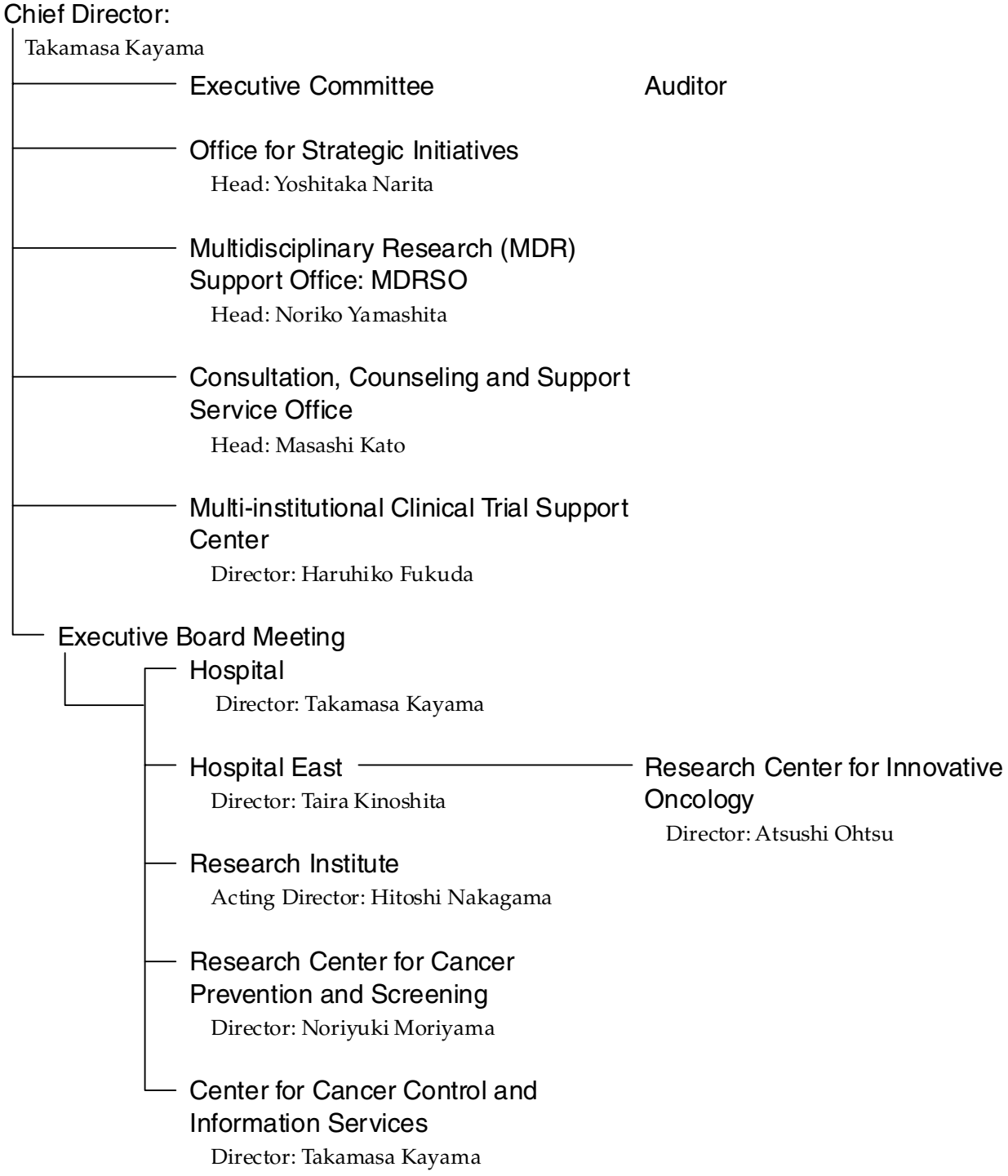
Sections Directed by Chief Director

Organization of the National Cancer Center



MULTIDISCIPLINARY RESEARCH (MDR) SUPPORT OFFICE: MDRSO

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Introduction

The Multidisciplinary Research Support Office (MDRSO) was set up on August 12, 2010, under the direct control of the Chief Director of the National Cancer Center to promote clinical research, public health research, and basic research and to help the NCC departments work closely together. To be specific, the MDRSO works on the biobank and develops the infrastructure for research. The MDRSO also provides information that may be helpful to conduct research projects.

Routine Activities

1. Biobank related office work

1) Preparation for Biobank organization

The MDRSO is involved with setting up a "National Cancer Center Biobank Coordination Committee" that constantly oversees the correct and consistent working of the National Cancer Center Biobank. After its establishment on January 13, 2011, the MDRSO works as this Committee's secretariat. The MDRSO reviewed the current system of research partnership requests, then coordinated and distributed throughout the NCC in the shift to a new system. Specifically, the MDRSO organized five briefing sessions for the NCC staff. One thousand and six staff members in total participated, which contributed to improve the environment. The Tsukiji campus shifted to the new system on May 13, 2011, and Kashiwa campus did so on June 13, 2011. The MDRSO held one briefing session for newcomers to the Tsukiji campus on November 17, and 43 staff members participated in the session.

2) Research Concierge Desk

The MDRSO is in charge of asking hospital patients for their cooperation in research projects after giving them an adequate explanation. The MDRSO hired six "Research Concierges" and trained them to be able to handle the explanation to patients. Their duty started on May 13, 2011. By the final working day of the year, which was December 28, 3,845 new patients were approached, from whom 3,616 agreed, giving a consent rate of 94.0%. Also the Concierges support new patients with processes as explaining common preliminary diagnosis cards and infection tests. The MDRSO supported 5,650 new patients from May 13 through December 28.

3) National Cancer Center Biobank Coordination Committee Secretariat

The MDRSO works not only as a secretariat of the Committee, but also a supporter of working groups in many fields. The MDRSO organized 10 Coordination Committees in total and 9 WGs during the year.

2. Research infrastructure building and offering functions

1) Clinical research education

1)-1 Planning and coordinating for research ethics seminars

The MDRSO organized research ethics seminars three times for the NCC staff in cooperation with the Cancer Control Programs Administration Division. The total participants were 538 persons.

Date	Mar 24, 2011	Apr 27, 2011	Nov 17, 2011
Programs & Speakers	1. Research Ethics and Human Research Protection by Dr. Akihiro Sato 2. How to write a good Informed Consent Form by Ms. Yoko Kishimoto 3. Application procedure for a new protocol by IRB Office	1. Lecture on the ethical guideline for clinical Research by Dr. Yasuhiro Fujiwara 2. Research Ethics and Human Research Protection By Dr. Masashi Ando 3. Application procedure for a new protocol by IRB Office	1. Research Ethics and Human Research Protection By Dr. Masashi Ando 2. Application procedure for a new protocol by IRB Office
No. of Participants	180	217	180

1)-2 Management of the completion history of seminars by researchers

The MDRSO created a database which manages researchers' attendance history at research ethics seminars in a unified manner. Moreover, the MDRSO began issuing an attendance history from the seminar of April 27, which helps researchers to keep on track by themselves.

1)-3 Creation of clinical research teaching materials

The MDRSO constructed teaching materials on "Guidance on the Method of Clinical Trial Registration" and "How to write an informed consent form" then uploaded these to the NCC's internal server where researchers can easily access them.

2) Construction of quality control of, and the quality assurance system for, clinical research

2)-1 Arrangement of the acceptance procedure of the audit and monitoring from the outside

The MDRSO is now in the preparation of issuing a manual on accepting audits and monitoring of clinical studies.

2)-2 Construction and preparation of an internal audit system for clinical research

To enable self-checking whether clinical research is being properly done based on the ethics guidelines, the MDRSO is planning to establish an internal audit system and is now writing a manual to cover this.

3) Inquiry about clinical research for patients

The MDRSO started a system where receptionists primarily respond to inquiries, complaint s and so on from patients regaring clinical studies and related matters.

The MDRSO has now started to serve as the first contact for patients who have complaints, questions and inquires about clinical researches.

4) Planning for and coordinating of reseach conferences

To encourage joint research inside the NCC, the MDRSO planned and carried out 7 research conferences jointly with the Office for Strategic Initiatives (OSI), at which 21 researchers made presentations and led discussions. The speakers and the number of participants at each conference are as follows. The total participants were 1,190 persons.

5) Alliance / partnership activity support

The MDRSO held two meetings to support cooperative activities between the NCC researchers and companies that match alliance contracts, aiming for early development tests. (No. of participants: 57 on May 13, 83 on October 2)

6) Holding of various meetings

6)-1 An open forum on radioactive exposure

As a joint program with the OSI, the MDRSO held an open forum on radioactive exposure on June 22, 2011, aiming to understand the influence of radiation correctly and to minimize the influence of future exposure as much as possible. Three hundred and ninety-six attendees participated, including those affected by radiation, scientists, health professionals, and members of the media (62 from the public, 114 from Designated Hospitals, and 220 from the NCC) What was debated there was put into a book and published on December 22.

6)-2 A workshop for medical equipment development

In cooperation with the OSI, the MDRSO planned and held a workshop for medical equipment development with the Faculty of Technology, the University of Tokyo on Oct 31, 2011. Its objective was to connect medicine and engineering, technology (seeds) and problems (needs) in the medical field. In part I, the instructors and the students of the Faculty of Technology, the University of Tokyo, had a clinical field tour. In the following part II five lecturers gave presentations regarding proposals introducing cooperative research between medical engineering and the clinical field. The total number of participants was 182 persons (from the University of Tokyo, 79; from the NCC, 103).

Date	Presenter	No. of Participant
Feb 21, 2011	Yasuhiro Matsumura/Tetsuya Hamaguchi	167
Apr 13, 2011	Toshikazu Ushijima/Takeshi Nakajima	217
Jun 14, 2011	Yoshitaka Narita/Tesshi Yamada	168
Jul 5, 2011	Yae Kanai/Yuji Heike/Shoichiro Tsugane/Noriyuki Moriyama/Jun Itami	164
Aug 8, 2011	Toshikazu Ushijima/Hiroaki Onaya/Hirtoshi Tsuda/Yoshitaka Narita/Atsushi Ochiai	203
Aug 30, 2011	Tetsuya Nakatsura/Takuji Okusaka/Yuji Heike	130
Dec 22, 2011	Yukio Kobayashi/Issay Kitabayashi	141

CONSULTATION, COUNSELING AND SUPPORT SERVICE OFFICE

Masashi Kato, Yukiko Higuchi, Mariko Suda, Kayoko Miyata, Shogo Arihara, Ryuta Suyama, Maki Tanaka, Mieko Yamagata, Natsuko Moroi, Eri Hirayama, Yukari Nakagawa, Maiko Fujimori, Keiko Nozawa, Tomoko Takayama, Chikako Yamaki, Yuko Ogo

Introduction

Since its establishment in August 2010, Consultation, Counseling and Support Service Office (CCSSO) has been placed as an independent section under the direct control of the Chief Director of National Cancer Center. The staff members called "cancer counseling and support specialists" work mainly at Consultation, Counseling and Support Service Center of National Cancer Center Hospital (NCCH). The staff cope with various problems of cancer patients and their families with the ultimate aim to help patients feel relieved and receive medical treatment. By putting ourselves in the patients' position, we can make real efforts to solve the problems.

Routine Activities

1 Consultation, Counseling and Support Services
  (1) Consultation and counseling in person
  (2) Consultation and counseling on the telephone

On September 15, 2010, "Kanja-Hikkei Support Center", our so-called telephone counseling center, was established. Center for Cancer Control and Information Services (CIS) published booklets, with the idea that the booklets, "Kanja-Hikkei", should be a 'must-have' item for the patients. We counsel on the telephone in the hope that patients can see the benefit of the information in the booklets, and make use of this information by themselves.

From January to December, 2011, the CCSSO handled 12,755 cases in total (1,063 cases per month). 7,322 of those were new cases: 1,003 cases were from the NCCH inpatient unit.

One of the characteristics of this Center is that most advice seekers are other hospitals' patients and they contact us most of the time, by telephone.

2 Activities accompanying Consultation, Counseling and Support Services
  (1) Cooperation with other hospitals and institutions
  (2) Cooperation inside the hospital
  (3) Administration of group program for patients and their families

We cooperate with other hospitals and institutions so that cancer patients can live with as high a quality of life as possible. we rearranged community services were required and helped patients to change hospitals.

In the hospital, we discuss with the doctors and medical staff about patients. We are participating in the medical meetings of six specialties. We hold classes designed for outpatients after bone marrow transplantation named "GVHD and living a life". We also hold classes for patients with pancreatic cancer or biliary tract cancer named "The pancreatic cancer and biliary tract cancer classroom". Additionally, we developed and conducted a new class for families of brain tumor patients, and a body image class for women before receiving breast cancer surgery, in collaboration with other in-hospital experts.

3 Activities of cooperation with other regional hospitals and institutions
  (1) Support for holding information exchange meetings with regional hospitals and institutions
  (2) Administration of database on information about regional hospitals and institutions

4 Activities related to volunteers of NCCH
5 Activities related to committees of NCCH
6 Activities related to education of NCCH staff
7 Others
  (1) Administration of the patient library

Research Activities

We analyze information and opinions obtained by counseling. In addition, we develop effective procedures for counseling and support for cancer patients and their families.

MULTI-INSTITUTIONAL CLINICAL TRIAL SUPPORT CENTER

Haruhiko Fukuda, Taro Shibata, Kenichi Nakamura, Atsuo Takashima, Harumi Kaba, Noriko Yamashita

Introduction

The Multi-institutional Clinical Trial Support Center was organized as a direct sector to the Chief Director of the National Cancer Center by transferring the Clinical Trials Support Division from the Center for Cancer Control and Information Services in September 2011. The Center supports multi-institutional clinical trials conducted by the Japan Clinical Oncology Group (JCOG) aiming to improve the standard treatment for cancer patients. The JCOG is a nationwide, multi-institutional, multi-disease, multi-modality cooperative study group supported by the National Cancer Center Research and Development Fund and Health Sciences Research Grants from the Ministry of Health, Labour and Welfare. The JCOG has 15 disease-oriented or modality-oriented subgroups covering most cancer types except leukemia and pediatric cancer, and approximately 3,000 physicians from 180 hospitals participate in the JCOG.

The Clinical Investigations Section, Biostatistics and Epidemiology Section, Regulatory Science Section, Data Management Section, and Project Management Section of the Center are jointly managing JCOG headquarters, the JCOG Data Center and the JCOG Operations Office, in collaboration with the non-profit organization named the Clinical Oncology Research and Education (CORE). The Center and the CORE support all JCOG trials for study design, protocol development, patient registration and randomization, data management, interim central monitoring, statistical analysis, adverse event reporting, quality assurance site visit audits, quality control of radiotherapy, central review of imaging and pathology, publication, and various kind of peer-review based committee activities.

Routine Activities

At the end of 2011, the Center had supported 34 open trials, 19 trials on follow-up, 14 trials in preparation, and the yearly patient accrual was 2,743, which increased by 20% compared to 2010. As for safety management, 52 adverse event reports for serious and/or unexpected adverse events were submitted to and reviewed by the Data and Safety Monitoring Committee (DSMC). The DSMC also reviewed 9 interim analysis reports, and 31 protocol amendment/revisions. The Audit Committee made site visits for 30 sites in 6 hospitals, and a total of 87 cases were audited. A central pathology review is on-going in 5 trials (2 lymphoma, 1 osteosarcoma, 1 glioblastoma, 1 gastric cancer). The quality control program for radiotherapy continued in 13 trials. A web-based 24-hour online patient registration system is available in 20 trials among 34 open trials.

As for activity other than support of the JCOG, the Center also acts as the secretariat of the Clinical Trial Working Group (CTWG) under the Liaison Council of Prefectural Designated Cancer Care Hospitals. The CTWG aims to enhance the resources for investigator-initiated cancer clinical trials in the Designated Cancer Care Hospitals and to promote the efficiency of investigator-initiated cancer therapeutic development nationwide.

Research Activities

The Center is conducting intramural studies related to clinical trial methodology including statistical methods and data management, such as a timing analysis for streamlining clinical trial protocol development, a timing analysis of local Institutional Review Board approval, a timing analysis of publication after the final analysis report, exploration of factors associated with serious adverse events, an association analysis between timeliness of case report form submission and protocol deviation, a validity analysis of clinical tumor response and pathological tumor response by chemotherapy, and a validity analysis of surrogate time-to-event endpoints.

Published Papers

1. Kurokawa Y, Sasako M, Sano T, Shibata T, Ito S, Nashimoto A, Kurita A, Kinoshita T. Functional outcomes after extended surgery for gastric cancer. Br J Surg, 98:239-245, 2011

2. Takashima A, Shimada Y, Hamaguchi T, Ito Y, Nakano A, Nakamura K, Shibata T, Fukuda H, Moriya Y. A Phase I/II trial of chemoradiotherapy concurrent with S-1 plus mitomycin C in patients with clinical Stage II/III squamous cell carcinoma of anal canal (JCOG0903: SMART-AC). Jpn J Clin Oncol, 41:713-717, 2011

3. Takeda K, Negoro S, Tanaka M, Fukuda H, Nakagawa K, Kawahara M, Semba H, Kudoh S, Sawa T, Saijo N, Fukuoka M. A phase II study of cisplatin and irinotecan as induction chemotherapy followed by concomitant thoracic radiotherapy with weekly low-dose irinotecan in unresectable, stage III, non-small cell lung cancer: JCOG 9706. Jpn J Clin Oncol, 41:25-31, 2011