

## Newsletter of the Japanese Gynecologic Oncology Group (JGOG)

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## JGOG's goal

Kazunori Ochiai, M.D., Ph.D. President, JGOG

I am very pleased to announce the launch of the JGOG International. I strongly hope that this newsletter will gain wide attention and contribute to making clinical research on gynecologic oncology in Japan universally known.

The non-profit organization, the Japanese Gynecologic Oncology Group (JGOG), was established 7 years ago. When the General Assembly and the new Board of Directors of JGOG met on December 5, 2008, I was elected by the Board of Directors as the new president, following in the footsteps of my predecessor, Professor Noda, M.D., Ph.D. I am so honored to succeed him, who is the founder of this organization.

The JGOG offers excellent opportunities for gynecologic oncologists to perform clinical research. Our main goal is to carry out clinical studies that meet high international standards. Therefore, it is essential to create well-designed protocols that will answer important research questions, authorize highly competent institutions capable of putting such protocols into practice, and establish an independent data center for case management. The JGOG has promoted the structure required to meet these conditions. Currently, the number of full members stands at 780 and the number of institutions authorized to participate in JGOG's clinical trials was 248 as of July 31, 2009. Our next challenge is to discover how to strengthen the audit system of institutions and improve the quality of clinical research. The JGOG is one of the organizations in Japan that allows high quality phase III studies to be implemented, and has expanded its activities by supporting development of new drugs and clinical trials, as well as engaging in international joint research. Also, the JGOG is a unique organization that actively promotes international studies in cooperation with overseas organizations.

In addition to clinical studies, the JGOG engages in educational and public awareness activities. A 3-day seminar is held each summer at which doctors who work on the front lines conduct one-to-one training courses. Also, we are dispatching young gynecologic oncologists to overseas institutions and academic societies so that they can return with a cosmopolitan outlook. Furthermore, we are planning to establish systems that provide incentives to our members. As the JGOG aims to be an open organization in every aspect, we welcome your frank opinions as to how to blossom as a study group for members. We will appreciate your cooperation.

In conclusion, I am confident that the JGOG has steadily grown because of the precious contributions from all members and supporting companies. I would like to take this opportunity to express my deep appreciation and ask for your further cooperation.



## Commemorating the launch of JGOG International

Kiichiro Noda, M.D., Ph.D. Honorary President, JGOG

The JGOG is a nationwide organization established in 2002 with the aim of developing effective chemotherapy of gynecological cancer through studies jointly implemented by a multicenter trial network. The business activities of the JGOG can be roughly classified into clinical trials, international cooperation education, public relations and publications. The primary role of this organization is to conduct clinical research, including phase III studies using approved medicines. It also conducts phase I and phase II studies, meeting high quality requirements, and already has attained some achievements highly rated by the ASCO. In addition, this organization has begun to conduct joint studies with the Gynecologic Oncology Group (GOG) and Gynecologic Cancer Intergroup (GCIG), while actively engaging in the development of young researchers, who will become the driving force of future gynecologic oncology in Japan, by providing overseas dispatch programs and educational seminars for them. These programs have already started to bear fruit. The JGOG is one of the top research organizations specializing in the development of chemotherapy of gynecological cancer.



JGOG general assembly held every year

## About JGOG's activities



## Clinical Research activities

**Toru Sugiyama M.D., Ph.D.** Vice President, JGOG

The JGOG mainly engages in clinical research activities, such as trial groups, which comprises the Disease Committees and the Supporting Committees.

The Disease Committees are the Cervical Cancer (Vulva Cancer) Committee, Uterine Cancer Committee and Ovarian Cancer Committee. Within these committees, clinical research on gynecologic cancers are discussed to work out protocols. Also, promotional activities are implemented for on-going tests to check the progress of each protocol. The schedule of activities of these committees is posted on the website. As meetings of these committees are held on an open basis, non-committee members can also participate by applying to the JGOG Administration Office. At the same time, these committees participate in the GOG and GCIG trials in conjunction with the GOG Japan Committee and GCIG Committee, which engage in activities related to international cooperation and public relations.

The Committees that provide support for clinical research are the Data Management Committee, Radiotherapy Committee, Pathology Review Committee and Clinical Trial Audit Committee. These activities are directed toward enhancing the quality of research.

One of the main roles of the JGOG is to support the development of clinical trials. To intensify these activities, we have newly established the Development Trial and Clinical Trial Promotion Committee to discuss whether pharmaceutical companies and the JGOG should conduct trials, keeping in mind the future development of molecular targeting therapy. This committee will also discuss what protocol concepts we should promote. Furthermore, in the Committee, cutting-edge treatments for gynecologic cancer are reviewed by the Committee members and external specialists on a regular basis to try to hammer out a course of action for the future.

## About JGOG's activities



## Education, Publication and Public Relations activities

**Yasuhiro Udagawa M.D., Ph.D.** Vice President, JGOG

The Board of Education supports the dispatch of JGOG's young members to internationally highly rated cancer treatment facilities, especially those in the USA, as well as to meetings of academic societies including the Society of Gynecologic Oncology, American Society of Clinical Oncology, International Gynecologic Cancer Society, etc. Thus far, 73 members have participated in this program and are in positions of leadership in clinical trials, education and research in the field of the gynecologic oncology.

Beginning in 2007, 3-day training seminars have been offered with the aim of "training young gynecologic oncologists to become well versed in chemotherapy for gynecolog-

ic cancer and clinical trials, and of teaching them to become capable of implementing global activities." Thirty-two doctors have participated over these 2 years. Furthermore, CRC seminars are offered for nurses and data managers who support clinical trials. We also hold town hall meetings to increase awareness and enlighten the general public on gynecologic cancer.

The Public Relations Committee manages our organization's website, provides information on JGOG to the general public, oversees the delivery of information to members and prepares the annual report of activities. This JGOG newsletter is also issued by this Committee.

In the area of publication, the journal titled “Chemotherapy News” is edited and issued quarterly by the Chemotherapy News Editorial Committee. The journal offers the latest news and information about new chemotherapies in a time-

ly manner through “feature articles” and “voices from members.” It also reports on progress of clinical studies currently implemented by the JGOG.

## About JGOG's activities



# International Collaboration activities

**Masayuki Hatae M.D., Ph.D.** Vice President, JGOG

International Collaboration is handled by the Gynecologic Oncology Group (GOG) Japan Committee, the GCIG Committee, Committee of Japan-Korea Relations, and the AGOG Committee.

Through joint research projects with the GOG, the GOG Japan Committee has played a leading role in introducing structure and several functions to clinical study organization such as a quality assurance system, web registration, etc. GOG clinical trial 218 (GOG 218), which evaluates the efficacy of the combination of the molecular targeting agent Bevacizumab with standard therapy (carboplatin and paclitaxel: TC) for advanced Mullerian tumor, is currently in progress. This combined study data of GOG and GOG Japan from this protocol aims at official approval of this drug for ovarian cancer treatment. This first study is innovative and important as a Japanese clinical trial because of support by Health Science and Labor Research Grants (HSLRG) from the Japanese government and shortening of the period of official approval by the Ministry of Health, Labour and Welfare.

In 2008, JGOG 3016 (NOVEL study: comparative study of dose-dense weekly TC versus tri-weekly TC for advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer) was published at the ASCO meeting held in Chicago, and has been highly rated by international study groups. European study groups have acclaimed the study outcome and will adopt this dose-dense administration concept in upcoming protocols. This accomplishment paper was accepted by Lancet in June 2009. It is noteworthy that JGOG has achieved a positive result of a Phase III trial after 26 years since the founding of a nation-wide clinical study group for gynecologic oncology in Japan.

Japanese members of the GCIG committee attend a semi-annual meeting for discussions of the aims of clinical trials proposed by several international study groups as well as JGOG. An international study dispatched from the JGOG is in progress. JGOG 3017 (clear cell carcinoma study) was taken up as a GCIG study, and case accruals are increasing

domestically as well as from Korea. MRC, GINECO, and MITO are preparing for participation in this trial.

Arbeitsgemeinschaft Gynäkologische Onkologie (AGO), one of the members of GCIG, requested JGOG to participate in the new clinical study AGO-OVAE16/VEG110655, which intends to evaluate the efficacy of the molecular targeting drug, pazopanib, for ovarian cancer treatment. The JGOG embarked on these studies because of the limited extent of new drug choices for treatment of epithelial ovarian cancer.

The Committee of Japan-Korea Relations and the AGOG Committee are organizing a joint study group in east Asia. The Phase III study comparing S-1 plus cisplatin to cisplatin alone for advanced and recurrent cervical cancer is in progress with South Korea, Taiwan and Japan as an international collaborative study. The establishment of a global framework for joint studies in East Asia will become a landmark for future expansion of clinical trials. With the adoption of online registration and a data entry system in English, this standardization will take place in studies management as part of the global collaboration process.

The randomized clinical trial, which was proposed to GOG by the Korean Gynecologic Oncology Group (KGOG), of adjuvant chemoradiation in post-operative cervical cancer with intermediate risk factors is about to be approved. We are increasingly required not only to submit completed protocols, but to contribute to proposal of new studies beyond our borders. Moreover, we must inform patients who will accept comparative treatment of the significance of international clinical studies to promote new strategies in cancer therapy. The joint activities with international clinical trial groups will be a crucial means to more quickly provide innovative treatment (including new drugs) to our patients.

In recent news, the GOG is likely to nominate China GOG as a new member of GOG. As a larger accrual number and swiftness of trial completion provide the power for clinical research, world trends in international group study are constantly changing.



## International Collaboration



## GOG Japan Committee

Junzo Kigawa, M.D., Ph.D. Chairperson, GOG Japan Committee

The GOG Japan Committee aims to contribute to the improvement of clinical trials related to gynecologic oncology in Japan by participating in the planning of the GOG studies and gaining knowledge of activities implemented by the most advanced clinical research groups. At the same time, by participating in clinical trials based on the established infrastructure, it will play an important role in educating and training young researchers.

Originally, the GOG Japan was established

in response to the request from the GOG to participate as an International Provisional Member (IPM) in January 2001. In March 2001, a small examination committee was organized within the JGOG, and in April 2001, the GOG Japan Committee was officially established after being approved by the JGOG Council. In January 2002, it was approved as an IPM of the GOG. In March 2003, the first case study was registered.

Currently, there are 15 member hospitals in the GOG Japan along with their labora-

tories. Main activities are registration of case studies and attendance at the GOG Business Meetings held semiannually. The number of case studies registered during 2008 was 37 patients (222 points) and the quality of data is highly rated by the membership evaluation and laboratory audits implemented by the GOG.

We are committed to contributing to the training of young researchers while assuring and stabilizing the number of case studies registered.

## International Collaboration



## Gynecologic Cancer InterGroup (GCIG) Committee

Satoru Sagae, M.D., Ph.D. Chairperson, GCIG Committee

In 2003, for the first time, representatives of the JGOG participated in the General Meeting of the GCIG held in the US. The JGOG started to formally participate in GCIG activities since the Ovarian Cancer Consensus Meeting held in Baden-Baden,

Germany, in 2004. The General Meeting is held semiannually. In the spring, the meeting is held around the ASCO, whereas in autumn the meeting is held in conjunction with international congresses, academes, such as IGCS, ESGO, etc. The meeting is

scheduled for 1 day and a half. Initially, the Executive Board is joined by representatives of 18 groups to discuss critical issues, and each individual committee convenes with about 20 members. Those committees are mainly about "Uterine Cervix" (by Satoru Sagae, JR Sapporo Hospital), "Uterine Corpus" (by Nobuyuki Susumu, Keio University), "Ovary" (by Keiichi Fujiwara, Saitama Medical University), "Harmonization (Operations and Statistics)" (by Eriko Aotani and Masahiro Takeuchi, Kitasato University) and "Translational Research" (by Aikou Okamoto, The Jikei University). The following day, the General Meeting is held, which is attended by all participants, to examine the protocols closed, ongoing, and under development. Each group takes away certain issues for further consideration. Finally, the Executive Board meeting is held to confirm future policies and conclude the General Meeting.



GCIG Ovarian Cancer Consensus conference September, 2004 Baden-Baden, Germany

So far, the JGOG has made efforts to promote clinical trials on understanding details, statistics, and data centers with the objective of participating in clinical studies currently implemented by the GCIG. In 2005, we proposed to the GCIG the clinical study JGOG3017, stressing the necessity of global development of chemotherapies by

histology. We continued to discuss this issue at each of the General Meetings. Since 2007, this issue has been officially taken up for GCIG trial, and currently includes the participation of the KGOG. Furthermore, MRC, GINECO, MITO, etc., are expected to register their patients in this trial. Also, we are actively considering

whether clinical trials can be registered from Japan with regard to the EORTC, GOG, or other group trials. Additionally, we are making efforts to establish our own clinical trials to facilitate registration from both the GCIG and JGOG.

## International Collaboration



# Committee of Japan-Korea Relations

**Toshiharu Kamura M.D., Ph.D.** Chairperson, Committee of Japan-Korea Relations

This committee was organized with the aim of strengthening the relationship between the JGOG and the Korean Gynecologic Oncology Group (KGOG) through holding a scientific meeting to exchange opinions. We have been principally engaged in conducting the Japan-Korea Gynecologic Cancer Joint Meeting (JKGCJM), which was held for the first time in Korea in 2002 in conjunction with the annual meeting of the IGCS and has been held every year thereafter, sponsored

alternately by JGOG and KGOG. Last year, the 7<sup>th</sup> meeting was held at Hanyang University, Seoul, on November 21. Based on the exchange of opinions between both groups, international collaborative clinical trials have been planned and currently JGOG3017, DT 104 is in progress with the participation of KGOG.

In response to the recommendation made by Dr. Soon-Beom Kang, Professor of Seoul National University, President of the KGOG, the Asian Society of Gynecologic

Oncologists (ASGO) was established this year. It is clear that the JKGCJM has been most important in promoting the establishment of ASGO. I, therefore, as the Japan-side moderator of JKGCJM, strongly expect that the JGOG will support ASGO and I believe that the JGOG's cooperation will be essential in further promoting international collaborative clinical studies in Asia.

## International Collaboration



# AGOG Committee

**Eizo Kimura, M.D., Ph.D.** Chairperson, AGOG Committee

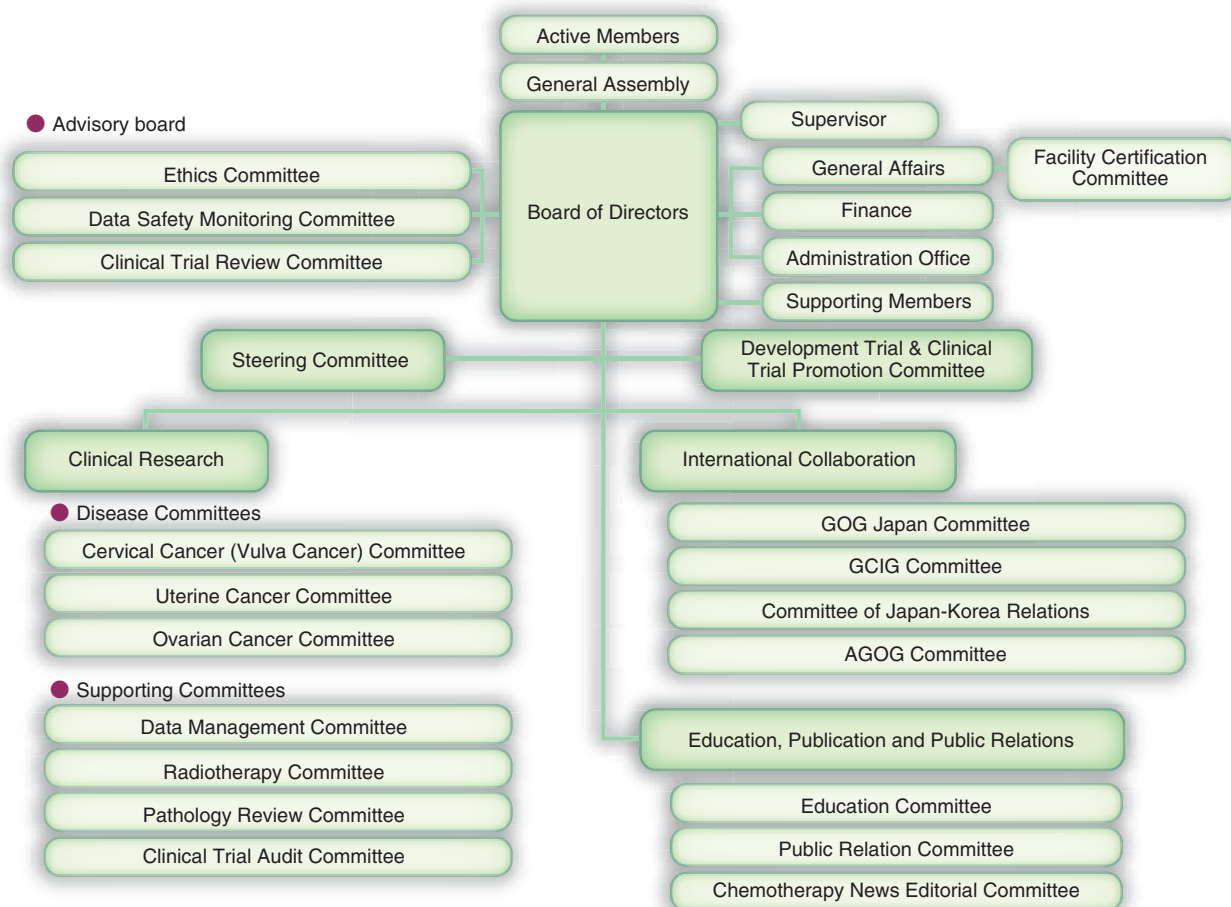
The Asian Gynecologic Oncology Group (AGOG) was established in 2005, chaired by Professor Chyong-Huey Lai from Taiwan, with the principal aim of systematizing clinical trials in Asian countries. From Japan, Dr.Kazunori Ochiai (President, JGOG) was elected as Vice-Chairperson, Dr.Toru Sugiyama (Vice-President, JGOG) and Dr.Eizo Kimura (Chairperson, JGOG-AGOG Committee) as board members, Dr.Shingo Fujii (President-Elect of IGCS; Director, National Hospital Organization Kyoto Medical Center) as a member of the Scientific Advisory Committee (SAC), and Dr.Keiichi Fujiwara (Professor, Saitama

Medical University International Medical Center) as a member of the Independent Data Monitoring Committee (IDMC). Board meetings, general assemblies and seminars are held semiannually. The JGOG-AGOG Committee handles official affairs and serves as the office to contact in Japan for international collaborative clinical trials. In Japan, the board meeting was held in Yokohama in April 2006 and in Tokyo in April 2008. A board meeting will be held in Yokohama in October 2009, during the 47<sup>th</sup> annual meeting of the Japan Society of Clinical Oncology chaired by Professor Toru Sugiyama.

Up to now, the JGOG has not officially participated in clinical trials sponsored by the AGOG. With regard to the participation in international protocols, there remain some issues to be solved in accordance with situations that each country is facing. Therefore, efforts are made by the JGOG-AGOG committee to bring about our participation. Also, we would like to make an effort to increase the number of member medical institutions from Japan by informing them of eligibility to apply as a member of AGOG and of the application procedures.

## Japanese Gynecologic Oncology Group

## Organization Chart



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Kayoko Tsujino, M.D. (Hyogo Cancer Center)

Takashi Uno, M.D. (Chiba University Hospital)

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## Editorial postscript

The Public Relation Committee constantly revises our website to provide members with up-to-date information on clinical trials and activities in progress in a timely manner and makes every effort to offer easy-to-understand information in a friendly manner to allow the public to more deeply understand and increase awareness of treatments for gynecologic cancer.

At the same time, the Public Relation Committee is now giving consideration to the issuance of an Annual Report, the creation of a membership list (management of personal information) and security measures (with new passwords), the revision of leaflets describing the JGOG (in Japanese and English), the creation of the JGOG's website in English, a collection of slides available within the webpage exclusively for registered members, including "Terminology for clinical trials", etc.

At this time, as requested by the President, we have issued the JGOG International overseas to provide information primarily about decisions made in the General Assembly and to report on activities implemented by each committee to further expand the JGOG's activities.

In the first issue, we have mainly introduced our activities relating to overseas cooperation and public relations. In the second issue, we plan to describe the clinical research we are committed to, and in the third issue, we will report on our activities in relation to education, publicity and publication areas.

**Kazushige Kiguchi M.D., Ph.D.**  
Chairperson, Public Relation Committee



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