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### The Significance of Board-Certified Registered Breast Specialist of the Japanese Breast Cancer Society in Regional Medical Activities

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#### 1. Introduction

Although the mortality of breast cancer patients in the Western countries has declined due to high screening rate, the number of Japanese breast cancer patients has seen a sharp rise and the most common cause of death of middle-aged women. Since one of every sixteen Japanese women have been diagnosed with breast cancer and more than 10,000 patients die from breast cancer every year, it is a goal to reduce the mortality through detection and treatment in its early stages. Board certified breast specialists of the Japanese Breast Cancer Society have been established in 1997 to contribute for the benefit of welfare of the nation and meet the social needs. In addition, The Ministry of Health, Welfare and Labor authorized the advertisement of specialists via the home page (http://www.jbcs.gr.jp/) in October, 2004 (Sonoo, 2005). As our institution has been designated as the region-based affiliated hospital for cancer treatment since January, 2007, the significance of the breast specialists was surveyed.

#### 2. Breast specialists, board certified institutions and its affiliated institutions

#### 2.1.Breast specialists

It is the minimum requirement for breast specialists to be authorized experts or qualified doctors in any one of the fields of surgery, oncological internal medicine, radiology and gynecology. The standards for qualifying breast specialists are different depending on each field. The standards for surgeons is: (1) It is required to be specialists in surgery and authorized breast doctors whose titles can possibly be acquired 4 years after graduation. (2) It is necessary to deal with breast diseases for over 7 years and experience the treatment

and/or diagnosis of more than 100 breast cancer patients. (3) It is mandatory to be engaged in clinical works at the certified institutions. (4) Academic achievements on breast diseases ( publications or presentations ) have to exceed the compulsory score. (5) Passing the written and oral examinations is needed (Table 1). The qualification has to be renewed every 5 year.

- 1. Concerning surgeons, it is required to be specialists in surgery and authorized
- breast doctors whose titles can possibly be acquired 4 years after graduation.
- 2. It is necessary to deal with breast diseases for over 7 years and experience
- the treatment and/or diagnosis of more than 100 breast cancer patients.
- 3. It is mandatory to be engaged in clinical works at the certified institutions.
- 4. Academic achievements on breast diseases ( publications or presentations ) have
- to exceed the compulsory score.
- 5. Passing the written and oral examinations is needed.

Table 1. Standards of board-certified registered breast specialist.

The breast specialists have been registered from seven regional blocs in Japan: Hokkaido, Tohoku, Kanto, Kinki, Chubu, Chugoku-Shikoku and Kyusyu-Okinawa. The present number of the nationwide breast specialists has been still as small as 837 and 303 in Kanto bloc or eastern part of Japan, 40 in Chiba prefecture of Kanto bloc and 2 in Funabashi city of Chiba prefecture, respectively (Fig.1.)

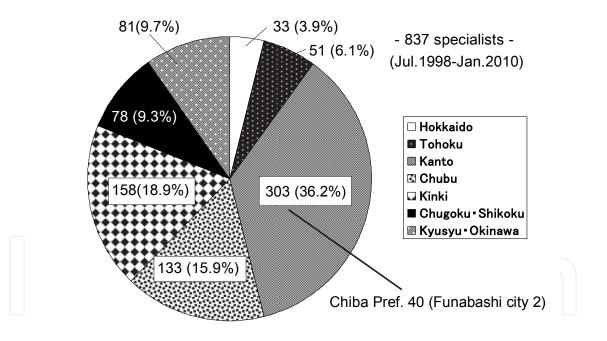


Fig. 1. Distribution of the numbers of board-certified registered breast specialists in Japan.

#### 2.2 Board certified institutions and its affiliated institutions

In1998, the Japanese Breast Cancer Society has designated certified institutions and its affiliated institutions in the seven blocs of Hokkaido, Tohoku, Kanto, Chubu, Kinki, Chugoku-Shikoku and Kyusyu-Okinawa throughout Japan and our hospital has acted as the certified institution since then. Certified institutions have to meet the following standards (Tab. 2).

- 1. It is required to have beds for surgical treatment or diagnosis and/or non surgical treatment of more than 20 breast cancer patients in a year.
- 2. Board -certified registered breast specialists have to regularly work and adequately instruct.
- 3. Laboratories and libraries are well-equipped.
- 4. Records of anamnesis are well-written and preserved in ample care.
- 5. Autopsy room is equipped.
- 6. Instructive events on breast diseases are regularly held.
- 7. Publications or presentations on breast diseases have to be continued.
- 8. It is compulsory that board-certified registered breast specialists belonged to certified institutions instruct at the certified affiliated institutions and report its contents.

Table 2. Standards of board certified institutions.

It is impossible for doctors who aim at breast specialists to be qualified although they even practice hard in the non-certified institutions where non-certified but skillful surgeons treat many breast cancer patients. Therefore, considering the present small number of breast specialists in Japan, it is necessary for non-certified institutions to be affiliated with the regional certified institutions so that the doctors could be qualified. If the number of breast specialists is large in the future, the affiliated institutions may possibly be abolished (Sonoo, 2005,2008). The standards of the affiliated institutions are shown in Table3. The number of board-certified institutions and its affiliated institutions are 357 and 410, respectively, Kanto bloc occupying most in the latter (Fig. 2).

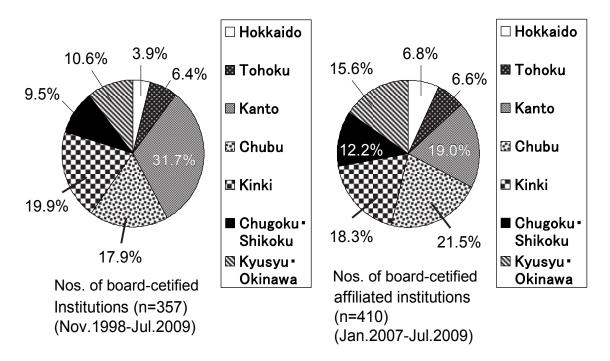


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Table 3. Standards of board-certified affiliated institution.

#### 3. Medical activities as region-based affiliated hospital for cancer treatment

Japanese government has issued an Act of Strategy for Cancer in June, 2006 to treat the Japanese major cancers of lung, stomach, liver, colorectum and breast with equal high medical quality throughout the nation. For that purpose, affiliated hospitals for cancer treatment have been designated in each region and our institution has been the hospital since January, 2007.

The present number of the hospitals is 13 in Chiba Prefecture and the qualification has to be renewed every 5 year. The main works for breast specialists in our region are raising the percentage of examinees, reducing the percentage of detailed examinations, maintaining quality control in breast cancer screening, promoting close cooperation with the board certified affiliated hospital and community hospitals or clinics, optimal team management for breast cancer, an education of trainee doctors and providing citizens with information on breast cancer including extension lectures.

#### 3.1 Breast cancer screening

As for breast cancer screening in Funabashi city, a mammography has been applied to women aged 40 and over since 2004. The percentage of examinees has annually risen from 8.9% in 2004 to 17.0% in 2009, whereas the percentage of detailed examinations has been almost constantly 6-7% exept in 2008 due to the effect of good quality control, the detection rate of breast cancer being 0.28% (Fig.3).

Although there were only four qualified doctors to read mammography when mammographic screening started, there have been 10 qualified doctors at present to form five teams in which a pair of two doctors reads alternately every week. On mammographic technics and knowledge, a qualified technologist at our hospital who plays a leading role in Japan has called a monthly meeting to educate technologists involved in screening mammography in Funabashi city. Breast cancer screening using stereotactic guided Mammotome has begun in our hospital by request of the community hospitals and clinics in March, 2011.

#### 3.2 Coordination with the affiliated hospital

As far as coordination with the affiliated hospital is concerned, a conference has been held monthly to compare mammography with pathology of the postoperative cases of both

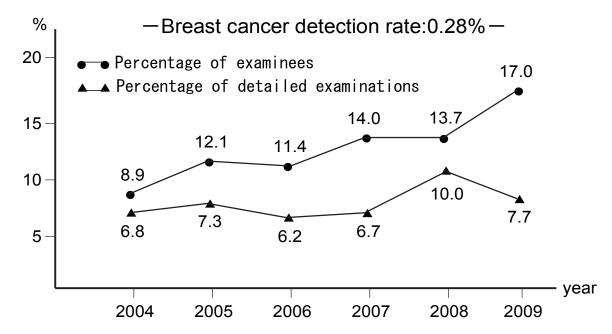


Fig. 3. Change in percentage of breast cancer examinees and detailed examinations in Funabashi city.

hospitals. Doctors including gynecologists, cytologists and technologist attend to share knowledge and information on breast cancer. In addition, breast cancer patients who want to undergo surgery at an earlier date are referred to the affiliated hospital. Those women who are indicated to screening are referred to the hospital also.

#### 3.3 Team management

In our hospital activities on breast cancer patients, patient and the family-centered team management has been carried out and comedical staffs play an important role in each field. Apart from nurses, a pharmacist not only immediately reacts to advise doctors on optimal use of drugs whenever asked but also kindly responds to the patients soon after adverse events particularly of chemotherapy are seen. She is well informed about recent drug news both domestic and abroad on breast cancer and often has presentations even in the Japanese Breast Cancer Society. An experienced cytologist who plays a leading part in Japan is specifically of great help in the diagnosis of breast diseases both on the outpatient and intraoperative basis to contribute much for the benefit of not only our hospital but also the community hospitals or clinics which ask consultations of microscopic specimen.

Education of trainee doctors contain mammography reading, academic presentation and surgery of breast cancer. On mammographic reading ability, a third-year trainee doctor in our hospital was the first successful candidate in Chiba prefecture in the nationwide examination several years ago and it was also quite rare in Japan. Six trainee doctors of 2 general surgeons, 2 lung surgeons and 2 gynecologists have been accredited up until now.

Since present team management basically requires certified nurses (breast care nurse) in particular, it is an urgent task to have the staffs in our team although the nationwide examination is relatively difficult to pass. As for the accredited pharmacist for cancer drug, The Japanese Society of Pharmatheutical Health Care and Sciences has also adopted a board-certified system since 2006 and the standards of certified pharmacist for cancer drugs are as follows (Table 4).

- 1. It is required to have a career as a pharmacist for over five years and have to be a member of the Society for over five years when applied for the examination.
- It is necessary to attend the Society or symposium of the Society more than two times.
- 3. Academic presentation on medical pharmacy has to be carried out as a coauthor over three times in meetings and one of them must be given as an author.
- 4. Publishing more than three papers on medical pharmacy is needed.

Table 4. Standars of board certified pharmacist for cancer drugs.

Strengthening a supportive system of cancer consultation is so important also that we started the team formed of a nurse who serves exclusively and three social workers in November, 2008. Concerning best supportive care, a specialist of former lung surgeon has gone into action in a newly built ward with 20 beds since April, 2009.

As the region-based affiliated hospital for cancer treatment, we will have to achieve the goal to have common clinical path of breast cancer among the community hospitals or clinics in our city and carry out breast cancer screening using ultrasound especially for the examinees aged 30-40 years.

#### 3.4 Clinical path

A clinical path is useful for low-risk postoperative breast cancer patients in shortening time to visit and wait for receiving the same standard treatment without concentrating only in the region-based affiliated hospital . It is also beneficial for the region-based affiliated hospital to have more ample time on treating more seriously ill patients with metastases or recurrence. When the patients are operated on at the region-based hospitals and found to be at low risk (i.e. node negative, positive hormone receptors for prescription of oral medicines alone and no chemotherapy or no therapy ), they are treated there with or without hormonal medicines for 1- 6 months, then are referred to community hospitals or clinics if they consent the use of path. They are checked up only with prescription and blood collection and then return to the region-based affiliated hospitals every 6-12 month for detailed examinations like mammography, ultrasound and CT or bone scan if required. If some emergencies, recurrence and/or metastases happen, the region-based affiliated hospitals have to respond immediately not only for the patients but also the community physicians (Fig. 4).

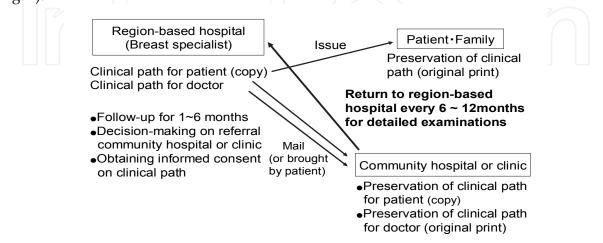


Fig. 4. Flowchart of clinical path for postoperative breast cancer patients.

#### 3.5 Extension lectures

Together with the affiliated hospital, community hospitals and clinics, we have held fourtime extension lectures for citizens on breast cancer each with certain theme at every other year since 2006 (Tab. 5.). Specifically, a lecture on liaison clinical path was given for the first time in October 2010, and the majority of the audience including men was in their 40s and 50s, younger than the age group at the previous lectures.

Year	Sponsored organization	Attended institutions
Sep. 2006	A private enterprise	Our hospital and three community hospitals
Mar. 2008	Funabashi city	Our hospital
Jun. 2008	A private enterprise	Our hospital, two ommunity hospitals and a breast clinic
Oct. 2010 *	A private enterprise	// //

Table 5. Extension lectures ever held. \* A theme 'clinical path ' was included.

#### 4. Discussion

Quite different from Western countries, Japanese specialist system has been privately established to improve and maintain the quality of the members in each society. In 1962, specialist system for anesthetists started for the first time in the Japanese Anestheology Society followed by those for radiologists and brain surgeons in 1964. Since around mid-1970, the Japanese Society of Internal Medicine has taken the iniative not only to let the board-certified doctors and specialists be socially accepted but also to enable them to advertise in April, 2004 (Sakai, 2005). Health, Welfare and Labor Ministry has also authorized the advertisement of breast specialists through the home page in October, 2004. Although the field of breast cancer is related to not only surgery but also radiology, gynecology and oncological internal medicine, surgeons occupy 95% of breast specialists in Japan, quite unlike Western countries. Therefore, Japanese breast specialists are busy working even for rapidly-advancing chemotherapy, however, they can possibly acquire a broad range of knowledge and experience through medical activities in team management. Since there are few emergency patients, even woman doctors including surgeons and gynecologists could work by taking advantage of being female while they rear children. As the number of breast specialists is still small in Japan, they will turn out to be important human resources for Japanese breast cancer patients who have continued to rise in number (Sonoo, 2007, 2008).

Before applying to the examination for breast specialist, the following curriculum has to be finished; 1) to master general knowledge on breast diseases, clinical judgement, the ability to

solve problems without regard to each expertise, 2) to master basic knowledge on anatomy, physiology, hormonal environment, epidemiology, pathology, biology of the mammary gland and breast cancer screening and to be able to clinically respond, 3) to master basic treatment technics on diagnosis by imaging modalities, aspiration cytology, core needle biopsy, biopsy using Mammotome, surgical biopsy , sentinel lymphnode biopsy and treatment with surgery, radiation, anticancer drugs, hormonal medicines, best supportive care and postoperative rehabilitation, medical ethics including informed consent, second opinion and clinical trials. 4) to master special treatment technics on breast diseases required for each expertise. 5) to actively attend conference or academic meetings, research or treat via evidence based medicine and give academic presentations on case reports or clinical study. 6) to understand the importance of medical administration involving risk management, medical cost, team management, etc. for carrying out practical medical activities (Sawai, 2006).

The number of board certified institutions and their affiliated institutions has seen a gradual rise and the largest number is centered on Kanto bloc or eastern part of Japan as well as breast specialists. There have been only two breast specialists in Funabashi city with a population of 600,000, therefore it is essential to increase the number of breast specialists for treating the steadily increasing breast cancer patients.

Under a guidance of The Ministry of Health, Welfare and Labor, nationwide mammographic breast cancer screening for women aged 50 and over has been introduced at intervals of two years since April, 2000 followed by the screening for women aged 40-49 since 2003 (Ohuchi, 2007). However, the percentage of examinees aged 40 and over has still been as low as 20.3% in Japan and the percentage of mammographic screening at the age of 50-69 was 23.8% compared to 60-90% in Western countries in 2006 (OECD Health Data 2009). According to the Japanese government statistics in fiscal year 2008, the nationwide average percentage of examinees is as low as 1.5% at mammography screening alone and 7.6% at combined mammography screening with palpation. The Ministry of Health, Welfare and Labor has started to distribute free coupons to raise the percentage up to 50% since October, 2009. The average rate of using coupons has been approximately 30% at the age of 40-69 (Japanese government bulletin, 2009). There have been some reports showing the effect of distributing free coupons to improve the percentage of examinees (Komoto & Ishiyama, 2010). Similarly, the percentage of examinees was raised from 81% to 88% in some age groups after the introduction of free of charge in Finland (Kauhava, 2008). Whereas the percentage was improved from 18.8% to 40.7% in Sendai, 2011's quake and tsunami-hit Miyagi prefecture, northern part of Japan through not using coupons but making various efforts of increase in consultations with universities or institutions to exchange views, women's cancer screening promotion project and distribution of application form to all houses (Satake, 2011). The percentage of detailed examinations and the detection rate of breast cancer screening in 2008 in Japan is 8.6% and 0.32%, respectively (Japanese government report, 2010). Our series have shown almost same as the nationwide data.

In order to maintain a quality control not only on facility but also personnel qualification of mammography reading ability for doctors and mammographic skills for technologists, The Central Committee on Quality Control of Mammographic Screening was launched as a non-profit organization in November, 1997 and has offered nationwide training

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seminars frequently including examinations since November, 2000 (Tsunoda, 2008 & Endo, 2009).

The examination of reading mammography includes 100 cases half with two views and candidates have to fill out the marksheets for judging categories within a limited time of 100 minutes. The results of examinations are classified into the ranks of A, B, C, D and A+B are certified. Rank A is accepted as the ability of reading and teaching of screening mammography. The possibility of obtaining rank A in a review of rigorous testing is less than 10 percent of the total candidates. The Committee has not only accredited the doctors and technologists involved in breast cancer screening program but also given the members examinations every five year for the renewal of accreditation. Futhermore, the lecturer's and staff member's meeting has also been held once a year for keeping the knowledge and information about mammography Screening system (Tsunoda, 2008). Although there has been legally-authorized Mammography Quality Standard ACT (MQSA) of the United States, the Japanese committee is considered the pioneer system in the world to evaluate the ability of individuals who engage in mammographic screening (Ohuchi, 2007).

Although ultrasound screening has been strongly recommended for examinees with dense breast particularly in their 40s or younger (Hashimoto & Ban 2010), there has been no worldwide evidence to prove whether ultrasound screening would have a potential to reduce the mortality of breast cancer for women aged 40-49. Therefore, in order to clarify sensitivity, specificity and detection rate as primary endpoint and cumulative advanced breast cancer incidence rate as secondary endpoint, 5-year Japan Strategic Anti-Cancer Randomized Trial (J-START) (http://jsrtfall.umin.jp/) has been conducted between the two groups of mammography combined with ultrasound and mammography alone in the respective number of 100,000 examinees in their 40s since 2006 with the initiative of The Ministry of Health, Welfare and Labor and the outcome will be shown in 2012. If effectiveness of ultrasound is confirmed, ultrasound screening would start in Japan for the first time in the world and we will have to prepare for the screening to especially secure a certain number of well-trained breast sonographers in Funabashi city also.

As far as clinical path in Japan is concerned, The Ministry of Health, Welfare and Labor authorized the payment for using paths for neck of femur fracture for the first time in 2006. Then, the Ministry issued Stragetic Anti-Cancer Promotion Project in 2007 to oblige the use of clinical paths of the five major cancers of stomach, colorectum, liver, lung and breast. According to the Ministry's survey in 2010, the number of the clinical paths used and patients enrolled has been larger in a comparison between before-2008 and 2009. Specifically, breast cancer patients increased even five-fold, largest in number compared to the other cancer patients. However, questionnaires to 410 hospitals by Health, Welfare and Labor Ministry in 2010 revealed that those patients including their families who understand paths have occupied only 30% even in the hospitals using paths. In other words, hospital staffs seem unlikely to give ample explanation or enlighten on paths considering that there actually have been many other path-using community hospitals throughout Japan. Likewise, the number of Chiba prefecture-based common paths used has been still as small as four, similar to lung cancer (1) and liver cancer (4) from April 2010 to January 2011. According to the other questionnaire by a certain group formed of breast cancer patients and their families, there have been the following anxieties for patients; 1) Whether the physicians of the community hospitals or clinics can treat enough or not, as well as the breast specialists in the region-based hospitals. 2) When clinical path is suddenly mentioned under treatment, some patients feel like losing a relationship of mutual trust. 3) Without

close communication between the breast specialists and the community physicians, patients may possibly think to forcedly be sent out.

Region-based affiliated hospitals for cancer treatment have now been required to more closely cooperate to promote coordination with the community hospitals or clinics using clinical paths for the purpose of improving and maintaining treatment quality (Ando, 2004 & Aogi, 2008).

Since The Ministry of Health, Welfare and Labor revised the score of payment for treatment in fiscal year 2010, the region-based affiliated hospitals and community hospitals or clinics can get a certain additional score if the patients requiring a 10-year follw-up are treated using the common clinical path. Apart from the low-risk breast cancer patients, a path for postoperative chemotherapy using trastuzumab has been applied in Kitakyusyu city, Fukuoka prefecture, southern part of Japan (Ohno, 2008). For success of the path, Ohno et al stress the importance and benefit of close communication with the community physicians by holding regular meetings three times a year before starting its use.

We have had regular meetings since 2009 like Ohno et al to start Funabashi city-based clinical path in April, 2011. In addition to the meetings, it is required for success to fully inform the patients both before and after admission for surgery and citizens through regular extension lectures like ours, bulletins or website.

#### 5. Conclusion

It is essential to have a more number of breast specialists in order to treat the steadily increasing Japanese breast cancer patients. To raise the percentage of examinees in breast cancer screening, the efforts must be continued including various campaigns by non-profit organization or consecutive distribution of free coupons by the government. Mammographic reading ability for doctors and mammographic skills for technologists have to be renewed every five year as before to maintain quality control. Evidence-based ultrasound breast cancer screening may possibly start in Japan for women aged 30-40. Clinical path has to be popular for low-risk breast cancer patients via adequate information before and/or after admission for surgery, regular extension lectures for citizens and bulletins or website.

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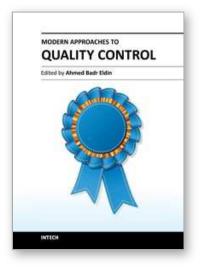
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