

### **JMA Policies** The Continuing Medical Education Program of the Japan Medical Association **JMA Activities** School and Community Health Project: Part 1: A community development and health project in Nepal Report A Healthcare Crisis in Japan: Criminalizing medical malpractice **Research and Reviews** What Maternity Clinics Can Do for More Reliable Perinatal Care Present Status of Obstetric and Perinatal Care and the Action Plan Issued by the Japan Society of Obstetrics and Gynecology Current Status and Future Prospects of Hospital Midwifery Departments Article 21 of the Medical Practitioners Law A Model Project for Survey Analysis of Deaths Related to Medical Treatment Medical Malpractice in Obstetrics—A look into the practice under South Korean law From the Japanese Association of Medical Sciences Management of the Open Abdomen—Usefulness of the bilateral anterior rectus abdominis sheath turnover flap method for early fascial closure Shigeki KUSHIMOTO, Hiroyuki YOKOTA, Makoto KAWAI, Yasuhiro YAMAMOTO.......272 Current Status of Musculoskeletal Disorder Care in Japan

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## The Continuing Medical Education Program of the Japan Medical Association

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#### Introduction

In 1987, the same year as the publication of the World Medical Association (WMA) Declaration of Madrid on Professional Autonomy and Self-Regulation, the Japan Medical Association (JMA) started systematized continuing medical education (CME) programs to provide systematic support to the broad-based, effective engagement of physicians in CME under the philosophy of professional autonomy based on self-regulation.

In this system, physicians voluntarily and autonomously endeavor to improve their clinical capabilities and study basic healthcare problems shared by all colleagues, so that they can build trust relationships between physicians and patients, provide high-quality health care prioritizing patient safety, and contribute to health of the people. The program is also open to non-member physicians. This article outlines this CME program, along with introductory descriptions of the school education system in Japan and the activities of JMA.

#### School Education System in Japan

The compulsory education in Japan consists of 9 years from elementary school to junior high school. After compulsory education, students must undergo 3-year high school education and then complete a university medical course to be eligible for qualification as physicians. The university medical education comprises 6 years, including basic and clinical education. The courses up to this point are under the supervision of the Ministry of Education, Culture, Sports, Science and Technology. There are 80 medical colleges and

university medical departments in Japan at the present, admitting approximately 7,500 students every year. Reflecting the shortage of physicians, the annual admission capacity is expected to increase gradually. After the 6-year medical education, students must pass the National Examination for Medical Practitioners, be registered with the Ministry of Health, Labour and Welfare, and complete 2-year postgraduate training. While this postgraduate training was voluntary in the past, it was made compulsory in 2004. In this way, new physicians are trained and allowed to perform medical acts in Japan

#### Outline of JMA

JMA is a private organization with a membership of 165,000 (as of December 1, 2006). It was established in 1916 by Dr. Shibasaburo Kitasato and colleagues, and was legally authorized as a non-profit organization in 1947.

There are approximately 270,000 physicians in Japan at the present, and about 60% of them are affiliated with JMA on a voluntary basis. Almost all self-employed hospital-based physicians are JMA members. The membership includes selfemployed physicians and employed physicians at the ratio of approximately 1:1. Figure 1 shows the trends in JMA membership. It has been growing year after year from the 50,000 at the time of establishment in 1947. Figure 2 represents the overall organizational chart of JMA. There are regional branch organizations covering various regions in Japan, which include 47 prefectural medical associations and approximately 900 municipal medical associations. Each of these associations is an independent incorporated organization.

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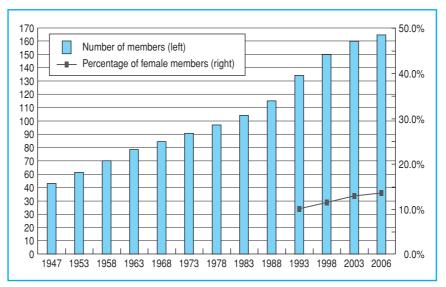


Fig. 1 Trends in the membership of JMA

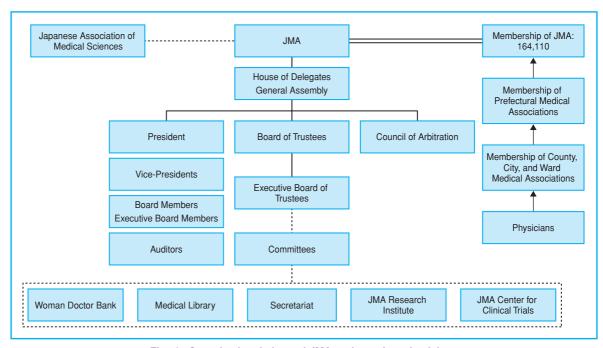


Fig. 2 Organizational chart of JMA and member physicians

To be eligible for membership in JMA, a physician first needs to join a municipal medical association and then a prefectural medical association.

Decisions at the level of JMA are made by the Board of Trustees, and the House of Delegates is the highest decision-making body.

#### Main Activities of JMA

#### Shaping national health policies

Preparing for future amendment of medical legislation and revision of medical fees, JMA is con-

stantly constructing the theoretical foundation for its basic, long-term policies and announcing its position in the Grand Design published by JMA. The Council on Health Policy has been established as an advisory body reporting to the president to materialize comprehensive measures in communities and making proposals from the standpoint of citizens.

#### **Ethical issues**

In the field of medical ethics including bioethics, JMA has the Bioethics Council and other mechanisms to study important issues relating to medical ethics, such as the attitude problems towards advanced medical technologies, end-of-life care, and informed consent, and is making proposals in these areas. In 2007, JMA published the Japanese version of the WMA Medical Ethics Manual and distributed about 220,000 copies to JMA members, medical students, lawyers, etc. at no charge.

#### **Academic activities**

In the field of academic activities, JMA is playing a leading role in the discussion of how university medical education and CME should be organized, positioning the CME system as the central axis of education. The monthly publication, the Journal of the JMA, and the radio and TV programs on medical topics produced by JMA are utilized by a wide range of people. The JMA Library, housing 71,000 books and journals, is supporting the research activities of members.

#### Medicine, healthcare, and welfare

This field pertains to all aspects of community healthcare, and JMA believes that enrichment in this field should be central to healthcare in Japan. Some issues in this field, such as the response to the aging population and patient safety policy, are extremely important, and JMA is now making great efforts in addressing these issues.

#### International activities

JMA is a member of WMA, and is also playing an active role as the secretariat office of the Confederation of Medical Associations in Asia and Oceania (CMAAO), which is an organization made up of 17 national medical associations. In addition, JMA is promoting interaction with medical associations in various other countries.

#### **Public relations**

Public relations as part of advocacy activities is important to spread the policies and opinions of JMA. With increased staffing, public relations are expected to play increasingly important parts as a core part of the activities of JMA.

#### **JMA Research Institute**

JMA Research Institute was established in 1997 as an internal body for studying medical policies. This Institute is a think tank supporting the JMA's goal of "the development of health policies for the people" through various research activities, information collection, and survey analysis. JMA carefully examines the study results and incorporates them into policy development. The Institute is currently staffed by about 50 persons, including researchers and support personnel.

#### **CME Program of JMA**

#### **Basic policy**

The CME Promotion Committee of JMA has been established to promote and support the CME of members. Local associations also have similar committees for physicians in respective regions, and JMA is working in close cooperation with these committees. The CME Committee of each local association is supporting the learning of members with programs incorporating the policies and regional characteristics. The content of learning covers not only medical science but also various fundamental issues physicians must understand in their daily practice, such as medical ethics. Respecting the self-determination of physicians, the CME activities performed by individual physicians are evaluated based on self-declaration in principle, and no penalty is imposed on physicians who fail to declare. "The CME Certificate" is awarded to physicians who declare that they have completed 10 credit units or more in a year. Physicians achieving this certificate in 3 successive years are granted "the Certificate of Recognition for Completion of CME."

#### **Curriculums**

The curriculums set the goals and show the learning directions of the physicians. The study topics in the curriculums are divided into basic healthcare topics and medical topics.

#### **Basic healthcare topics**

These include the 106 basic healthcare topics that all physicians should know irrespective of the fields in which they specialize. Examples of such topics are medical ethics, laws, welfare, social security, and health economy. This part of the curriculum is intended for the acquirement of broad knowledge related to healthcare.

#### **Medical topics**

These are the learning of medical science, comprising the 2 parts covering "important matters in medical practice" and "important diseases," respectively. The former part, "important matters in medical practice," assesses the acquirement of the knowledge, skills, and attitude related to the important matters in the process of medical practice. The latter part, "important diseases," is a curriculum that assesses the acquirement of sufficient knowledge and treatment skills for diseases commonly seen in daily practice and diseases of clinical importance.

JMA recommends the following ways of utilizing these curriculums.

- 1) The CME Committee of a local medical association may plan a CME workshop, featuring some of the themes in the curriculums.
- 2) The curriculums may be used in self-directed home learning and group learning.
- 3) It is recommended to select study topics referring to the curriculum of experience-based learning in a hospital-clinic cooperative program.

#### Main learning media

Main learning media include the Journal of JMA published in Japanese by JMA. The Journal, produced by its Editorial Committee of JMA, is published in 12 regular issues and 2 special issues every year. The JMA CME Courses refer collectively to the CME courses supported by collaborating companies reflecting the diversification of learning media. These courses are also planned by the Editorial Committee.

- The JMA website allows visitors to search and read papers in the Journal of JMA, to search titles in the video library, to view videostreamed medical TV programs, and to view Internet-based CME courses.
- In addition, journals and websites of local medical associations are also used as learning media.

Table 1 Specialty societies offering interchangeability with JMA CME programs

- 1. The Japanese Society of Internal Medicine
- 2. Japanese Ophthalmological Society
- 3. Japanese Pediatric Society
- 4. The Japanese Association of Rehabilitation Medicine
- 5. The Japanese Orthopaedic Association
- 6. Japan Radiological Society
- 7. The Japanese Urological Association
- 8. Japan Society of Obstetrics and Gynecology
- 9. The Japanese Society of Psychiatry and Neurology
- 10. The Japan Geriatrics Society
- 11. The Japanese Society of Gastroenterological Surgery
- 12. The Japanese Society of Gastroenterology
- 13. The Oto-rhino-laryngological Society of Japan
- 14. Japan Society of Plastic and Reconstructive Surgery
- 15. Japan College of Rheumatology
- 16. Japanese Dermatological Association
- The Japanese Society of Balneology, Climatology and Physical Medicine
- 18. Japanese Society of Psychosomatic Medicine
- 19. The Japanese Society of Pathology
- 20. Japanese Society of Laboratory Medicine
- 21. Japan Diabetes Society
- 22. The Japan Society of Colo Proctology
- 23. Japanese Society of Pediatric Surgeons
- 24. The Japan Society of Transfusion Medicine and Cell Therapy
- 25. The Japan Society of Hepatology
- 26. The Japanese Association for Infectious Disease
- 27. Japan Gastroenterological Endoscopy Society

#### **Learning methods**

Learners may obtain credit units defined as follows.

A learner attending a lecture meeting or a workshop receives a certificate (card, sticker, etc.) from the host organization and submits it with the declaration to acquire 3 to 5 credit units. In the case of experience-based learning (learning in a hospital-clinic or clinic-clinic cooperative program), the learner submits the theme,



Fig. 3 CME Certificate

the name of facility, and other details with the report form, and receives 5 credit units. Some professional achieve-ments may be recognized as credit units. A learner making an academic presentation or publishing a paper attaches the records of presentation title, author name, etc. to the declaration and receives 3 to 10 credit units. Home learning, such as sending an answer to a question in the Journal of JMA via mail or the Internet or answering the self-assessment in the Internet-based CME courses, is worth 1 credit unit each time.

#### **Self-declaration practice**

The acquisition of credit units is based on self-declaration in principle. Some local medical associations collect declarations from the members send them to JMA. The report form is distributed as a supplement to the March issue of the Journal of JMA every year. A person making a declaration fills in the report form, attaches the certificates of attendance to seminars and other events and records of achievements, and submits the completed form to the county, city, or ward medical association or the university medical association to which he or she belongs by the end of April every year. The submitted declaration forms are sent to JMA via prefectural medical associations and processed and managed by computer.



Fig. 4 Certificate of Recognition for Completion of CME

#### Interchangeability of credit units

The certificates of attendance obtained from the participation in the JMA CME Courses are interchangeable with the credit units needed for the renewal of specialist certification in several specialty societies. In the CME system of JMA, attendance to a lecture meeting or other events of a specialty society is counted as 3 credit units. As of 2008, arrangement for credit interchangeability has been made with the specialist physician/certificate physician systems of 27 specialty societies listed in Table 1.

#### Awarding of "the CME Certificate" and "the Certificate of Recognition for Completion of CME"

"The CME Certificate" (Fig. 3) is awarded to physicians submitting the CME declaration and documented (by certificates of attendance, records, etc.) to have achieved 10 credit units or more in a year. Physicians achieving this certificate in 3 successive years are granted "the Certificate of Recognition for Completion of CME" (Fig. 4).

Although these certificates of completion and certificates of recognition do not signify any qualification, the proof of participation in CME as indicated by the declaration rate provides a yardstick for measuring the attitude of a physi-

cian towards CME. The physician may display these certificates in the clinic, for example, as a means of building the trust relationship with patients.

#### Conclusion

The medical care system of Japan faces a crisis as a result of the government's policy of cutting expenditure and curtailing social security measures. In this difficult situation, JMA is doing everything in its power to enrich community health ensuring patient safety and to build a reliable foundation for social security. The CME program is one of the most reliable means of improving the quality and ability of individual physicians, and the importance of CME is undoubtedly going to increase in the future.

In addition, JMA has been engaged in international works through participation in WMA,

and continuing the interactions with the medical associations of various countries to exchange opinions regarding world healthcare problems. The enrichment of community health in Japan directly means a contribution to the health of people in the world. From this perspective, JMA is committed to continue its efforts to improve the health standard of the world from the standpoint of patients. JMA intends to compile records of successful cases in the solution of various problems of community health, and share the experience with the physicians of the world, so that it may be of help to physicians working in various environments.

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# School and Community Health Project: Part 1: A community development and health project in Nepal

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#### **Abstract**

This article first gives information on the School and Community Health Project (SCHP) by His Majesty's Government of Nepal, the Japan Medical Association, and the Japan International Cooperation Agency, which tried to improve the living conditions and health of the rural population in Nepal. Secondly, it describes SCHP activities as one case of a community development and health project that was implemented based on Rifkin's community development approach. To improve living conditions, SCHP conducted literacy education for adult women's and children's empowerment programs in schools. For health activities, SCHP worked with traditional healers and conducted local health manpower development through a scholarship program. As a result, the adult women's literacy rate improved from 16% in 1996 to 50% in 2000 and the majority of them formed self-help groups, made kitchen gardens, and started income-generating activities. The schools became more active in health activities through child clubs and improved hygiene facilities. Traditional healers' treatment skills and referral to government health institutions were also improved. In addition, one more achievement of this project might be the change of the local villager's consciousness from 'development as a gift' to 'development from within.' Community development and health projects can in this way contribute to improving the health and living conditions of rural people. It also has the potential to raise the consciousness of people who jointly work for community development from within. More efforts should be made to scale up these activities in a country where the rural population still suffers from poor health conditions.

Key words World health, Community health, Community development, School health, Empowerment, Nepal

#### Introduction

The Japan Medical Association (JMA) implemented a School and Community Health Project (SCHP) in Nepal from 1992 to 2006. Although several articles have been published on SCHP activities both in Japanese and English, no English paper has yet been published that summarizes SCHP's activities as a whole, in particular, as a community development and health project. This paper has two major objectives. The first is to show the background to why a community development approach was needed in Nepal after the

first democratic revolution in 1951. The second is to describe SCHP activities as one case of a community development and health project. The first part was written by using selected literature on the community development approach. The second part was written mostly using published peer review articles on SCHP.

## Why a Community Development Approach?

#### **Democratic revolution and health in Nepal**

Nepal's overall health status has progressively improved since 1951, when Nepal decided to

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open the door to the rest of the world through the first democratic revolution. It allowed foreign aid agencies to come to Nepal, and their support began in the 1950s. As a result, the infant mortality rate (IMR), once estimated to be 255 per 1,000 live births in 1951, declined to 156 in 1969 and further to 79 in 1995. The most current Demographic and Health Survey (DHS) showed that it reached 48 in 2006.

Despite a great achievement in improving health in the past half a century, there was a huge gap in IMR among the 75 districts of Nepal. In 1994, IMR in urban areas was 62, whereas that in rural areas, it was 105.3 More strikingly, IMR of the best district was 32, whereas in the worst district, it was 201 in 1991.4 A similar disparity was also visible in other development indicators such as the overall composite index of development, the poverty and deprivation index, the women's empowerment index, etc.5

Considering the declining IMR over the decades and the existing gap in IMR among the districts, it is important to know the reasons for both. By comparing district-wise IMR data in 1991, Thapa (1996), for example, revealed that female literacy was the most important factor in accounting for variations in IMR. Using the 1991 DHS data, Suwal<sup>6</sup> suggested that the most influential variables on IMR were parity, place of residence, immunization, and ethnicity.

## Need for a community development approach in Nepal

Although both Thapa<sup>4</sup> and Suwal<sup>6</sup> also considered the importance of health care-related factors, it is worth noting that they found that demographic, socio-economic, and culture-related factors were more important in reducing IMR. Knowing that such demographic, socio-economic, and culture-related factors are important to improving health, how can these considerations be put into health planning in Nepal and how can they be implemented in practice?

According to Rifkin,<sup>7</sup> health planning can be categorized into three approaches: medical, health service, and community development.

Over the five decades after the opening of Nepal, medical and health service approaches have been common in this country. In the 1950s and '60s, hospital-based and vertical programs were implemented. First, hospital upgrading was the major focus of the government. NGOs also

took the hospital-based approach. Then, vertical programs were implemented for malaria, leprosy, tuberculosis, smallpox, family planning, and child welfare. Although such vertical approaches reduced malaria, eradicated small pox, and have produced other successful outcomes, influential health sector agencies recognized that the hospital-based approach benefited only the urban population and that vertical programs were expensive to operate.

Then, as an improved method of health service approach, the concept of integration was introduced. The term "integration," however, applied only to the health sector of USAID and the Nepalese Ministry of Health.8

These medical and health service approaches have had limited success in achieving health for all in a country like Nepal for several reasons. First, despite the increased number of heath posts (HP) and sub-health posts (SHP) in rural villages, only about 45% of households can access them within a travel time (in many cases on foot) of 30 minutes.9 Even if villagers can reach HP/SHP, absenteeism of HP staff is common and the annual drug rations allocated to HP/SHP are adequate for only three to six months.<sup>10</sup> As a result, nearly three out of five households, on average, do not have adequate access to health care services. These households are disproportionately located in the western and far-western regions.10 Tailor & Tailor11 described this situation as the 'anatomic structure' of the health system, without the 'physiologic function' for it to accomplish societal goals.

It is this situation, Rifkin's<sup>7</sup> community development approach has the potential to improve health in rural settings, if it works. However, there are several problems with the practical application of this approach. According to Rifkin,7 the community development approach is different from the other two approaches in six points: views about community participation, the role of the professional, the role and the training of community health workers to support the program, evaluation of the program, and financial support of the program. Lastly, the most striking point of the community development approach is that community people take the initiative in solving health problems using health professionals as one of their resources.



Fig. 1 Map of Nepal

## **School and Community Health Project** in Nepal

#### Khopasi primary health care center

#### a) How did it start?

In 1990, the second democratic revolution took place, which allowed Nepal to start a new, democratic political system. After the revolution, the newly elected government created a new health policy based on a primary health care approach. It was in this context that the Nepalese government requested support from Japan for implementation of the new health policy.

To respond to a request made by His Majesty's Government of Nepal (HMG/N), the Japan International Cooperation Agency (JICA) sent a project formation survey team in 1991, which was headed by Dr. Toshiro Murase, then deputy president of the JMA. The mission report made

four key recommendations. 1) A healthy village approach should be taken; 2) The bottom-up function should be strengthened; 3) Community health activities should be conducted through HP/SHP; and 4) Nepal's new health policy should be supported. Dr. Tadatoshi Kuratsuji then made an additional survey in 1992, and on December 15, 1992, HMG/N, JMA, and JICA launched the SCHP in the Khopasi village development committee (VDC, the minimum local government body in Nepal, with a population 2,000 to 5,000 for each VDC in a hill region). JICA dispatched two Japanese experts for SCHP, and JMA has worked as an international non-government organization and allocated the budget for project activities.

#### **b) Target area and initial activities** (Fig. 1)

Three parties agreed to implement the project in Khopasi in response to the government need to improve rural health care in Nepal. Khopasi was located in Kavrepalanchowk, a hilly district roughly sixty-five kilometers southeast of Kathmandu.

During the initial phase of the project, SCHP completed the construction of the Khopasi primary health care (PHC) center in December 1993 and started its operation in January 2004. The center was equipped with a laboratory and an ambulance car, and provided both preventive and curative services to a population of 100,000 in the southern part of the Kavrepalanchowk district. However, mostly due to difficult geographical conditions, only residents who live around the center tended to use the center and outreach activities were also limited. That is why since 1995, SCHP started to take a community development approach conducting a pilot literacy education program for women and a pilot school health program.

## Community development and health activities in rural Nepal

#### a) Shifting focus from central to rural

While the Khopasi PHC center retained the target population of 100,000 in the southern Kavrepalanchowk district, SCHP decided to narrow down its target area from a center to ten rural VDCs, and then later, it was increased to fifteen. The estimated population of the fifteen VDCs was approximately 45,000 in 1997.12 Several different ethnic groups reside in the area, including the Tamang, Newar, Brahmin, and Chhetri. Among them, the Tamang comprise the majority. The villagers had no electricity, telephones, or vehicular roads. Reaching the nearest vehicular road required a two- to sixteen-hour walk from these communities. The area included eighty-four schools and fourteen government health institutions (HPs, SHPs) in 1997.

#### b) Major activities

SCHP had two major objectives. The first was to improve living conditions through community development activities. The second was to improve health through local human resource development for health. Both objectives were made considering Rifkin's six points for community development approach in mind.

#### **b-1) Improving living conditions**

This activity consists of two major programs. The first is women's empowerment through literacy education and self-help groups (SHGs). The second is children's empowerment through child-to-child activities.

### b-1-1) Women's empowerment through literacy education

Literacy education was taken up as part of SCHP activities based on two articles. One article showed that increasing rural female community health volunteers' literacy levels improved the quality of their services in Nepal. <sup>13</sup> The second article stated that an improved literacy level was the main contributor to reducing infant mortality rates. <sup>4</sup>

Started in 1995, SCHP's Adult Literacy Program made more than 3,500 adults literate through 170 basic literacy classes and 168 post-literacy classes. Both classes were conducted for six months per year. Among the post-literacy classes, 157 formed SHGs for launching savings and credit groups and kitchen gardening activities.

As a result, the female adult literacy rate in the target area increased from approximately 16% to 50% during the period between 1996 and 2000.

According to Acharya et al., <sup>14</sup> during their discussions with the women, participants valued the post-literacy classes on sanitation, immunization of children, dehydration therapy, and family planning. More specifically, they became familiar with immunization against tetanus, diphtheria, pertussis, measles, and various malnutrition problems. The discussions revealed that these programs improved awareness of the use of *Jeevan Jal* (oral rehydration solution) in diarrhea, green vegetable intake, safe drinking water, and the protection of food from dust, flies, and insects. Moreover, approximately one third of the participants began recording income and expenditure in their daily lives.

#### b-1-2) Kitchen garden training

SCHP started kitchen garden training for literacy class graduates and attendants as literacy skills themselves were not sufficient to improve living conditions and some husbands started to complain of their wives' absence at night.

At the time of the mid-term evaluation of SCHP in 2000, 2,197 participants had received kitchen gardening training, of those, 44% had already made kitchen gardens prior to the training. Encouragingly, nearly one third had just started it after receiving literacy training. Approximately two thirds had developed traditional gardens. After five years of program intervention in rural areas, nearly all the participants made kitchen gardens. However, participants expressed various problems in this activity during discussion. Disease and pests were the most frequently

Table 1 Development process of a self-help group

Steps	Dates	SHG activities		SCHP support and requests
Forming	Dec-94	Construction of classrooms for literacy education	<b>←</b>	Needs assessment meeting
		Participation for basic literacy education	←	Implementation of basic literacy education (supervision and teaching for 6 months)
		Provision of support for a literacy education campaign on nationwide educational promotion day		
		Activities other than literacy education (e.g., street cleaning)		
	May-95			End of literacy education
		Implementation of making home gardens	←	Implementation of training for making home gardens
		Requesting practical literacy education	$\rightarrow$ $\leftarrow$	Provision of technical training for facilitators for practical literacy education
	Dec-95	Participation for practical literacy education	$\leftarrow$	Initiation of practical literacy education
			←	Provision of second training for facilitators End of practical literacy education
	Jun-96	SHG establishment	$\leftarrow$	Recommendation of establishing SHG
Norming	Aug-96	Group works (e.g., rule creation, role sharing, monthly meeting)		
		Requesting training for construction of portable toilets	<b>←</b>	Provision of training for construction of portable toilets
		Constructing toilets in every SHG member's household		
		Requesting support for constructing a library	$\rightarrow$ $\leftarrow$	Provision of library construction funds
		Provision of support for a nationwide vaccination campaign	$\rightarrow$ $\leftarrow$	Requesting support for a nationwide polio vaccination campaign
	Dec-96	Requesting training in first aid	$\rightarrow$ $\leftarrow$	Provision of training in first aid
		Requesting training for income-generating techniques (SHG members invested their pocket money in a "goat bank.")	$\rightarrow \leftarrow$	Provision of training for income-generating activities (i.e., management solution for the "goat bank") Provision of partial loans for the "goat bank"
		Revision of group rules		
Performing	Mar-97	Three SHG members implemented training for construction of pit latrines in a nearby village.	<b>←</b>	Requesting training for a women's group in a nearby village to construct pit latrines
		Financial support for a critically ill mother		
		Volunteer activities for UNDP river conservation project		
		Provision of support for construction of portable toilets in nearby villages		

 $<sup>\</sup>leftarrow$  : Request from SHG to SCHP

reported problems in the community regarding kitchen gardening activities. Likewise, there were other problems such as lack of seeds, training, and information, and water for irrigation. <sup>14</sup> Still, it was effective to improve living conditions instead of simply conducting literacy education.

#### b-1-3) SHG activities

#### b-1-3-a) Development process of one SHG

A self-help group called "Khushiyali (Happy) Women's Group (KWG)" was first formed in K village after completion of the basic and post-literacy classes. The development process of KWG

<sup>→:</sup> Support or request from SCHP to SHG

<sup>\*</sup>Cited and modified from "Sato C, Jimba M, Murakami I. Adult literacy education as an entry point for community empowerment: evolution of self-help group activities in rural Nepal. Technology and Development. 2000; No.13: 35–44.

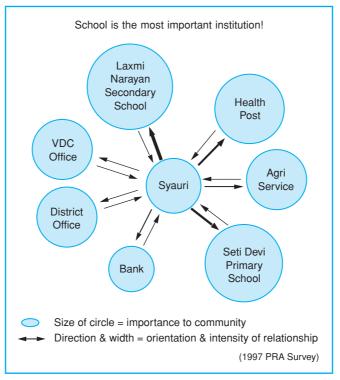


Fig. 2 Participatory rural appraisal survey about the importance of available institutions in Syauri village

and a description of the cooperative relationship between KWG and SCHP is offered in Table 1.<sup>15</sup> Below is a summary to explain the process.

#### **Step 1: The Process of Forming**

Table 1 shows the steps in the growth of the SHG in K village. A quick glance at Table 1 reveals heavy support from SCHP for KWG, which is indicated by arrows pointing to the left. It is clear that there were more approaches from SCHP to KWG than vice versa, and that most activities, during this stage, were undertaken on SCHP's initiative.

#### **Step 2: The Process of Norming**

As indicated in Table 1, the number of arrows from the right increased during this stage. This reflects SCHP's responses to KWG's requests for support. Thus, during this stage, the SHG gradually began to initiate more activities than SCHP.

### **Step 3: The Process of Storming and Performing**

Table 1 indicates that during this period, the SHG started to become more self-reliant. In keeping with this, the relationship between

KWG and SCHP moved from 'aid agency' and 'beneficiary' to 'partners' as the SHG was able to respond to SCHP's requests. Thus, in this period, a partnership between them developed.

#### b-1-3-b) Scaling up SHG

After KWG, SCHP was successful in scaling it up, and 157 SHGs were formed by the end of 2000. These SHGs initiated several activities. The example below highlights the income generation activities of four SHGs.

"... SHG funds were on an increasing trend in every community. According to a four-case study in three villages (one from Mate, two from Gairigaun, and one from Bhanjyangkhark) in the mid-term evaluation, the average annual interest income earned by group investment was Rs. 600 (Nepali rupees: 1US\$ = Rs 68.25 in July 2008), and the interest rate was 24% in all groups. In half of the cases, however, group membership was declining. According to the discussion, the major reason was the inclusion of many unmarried young women in the groups. Once they got married, they left the village and became less interested in continuing fund-

raising activities, whereas the married women were supporting these activities, as they were permanent dwellers in the community. The nature of group investment varied. According to the discussion, Mate community participants were receiving loans for household expenses, whereas in Gairigaun, money was borrowed for poultry and pig raising. Of the three people receiving loans in Bhanjyangkhark, one was producing local liquor, another was producing dalo (bamboo baskets used for household purposes) and namlo (the rope or band passed round the forehead that supports a load carried on the back), and the third was raising goats. Although small, these were also noteworthy impacts of the SHG activities.'14

#### b-1-4) Children's empowerment through a school health approach b-1-4-a) Why school health?

School health has been prioritized by donor agencies as it is cost effective,16 the target population is big,<sup>17</sup> school children are not as healthy as expected, 17 and better health can contribute to better educational achievement.<sup>17</sup> In addition to these perspectives, SCHP found out several additional reasons to justify school health activities in their target areas. A participatory rural appraisal in 1997 revealed that of twenty-eight target communities in fourteen VDCs, approximately 70% of them regarded schools as the most important institutions compared with other institutions such as government offices (district office, VDC office, and agricultural office), banks, and others. One example is shown in Fig. 2. As the villagers consider schools to be the most important institutions, they get together when they conduct mass meetings, and a school can thus be used as a center for different types of community development activities.18

To implement school health programs, SCHP initially targeted school teachers, but most of them came from urban areas and frequently took extended leave. SCHP was then obliged to target school children and their parents for their school health activities. Then, SCHP initiated the Supportive Healthy Environment Program in 1997 and the Child Initiative Program in 1998.<sup>18</sup>

#### b-1-4-b) Supportive Healthy Environment Program

This program aimed at creating a supportive environment for health in schools. Its major activities were to establish safe drinking water and toilet facilities in schools and to implement health education programs for hygiene.

For this program, first, the school children's parents and other villagers made significant contributions. To install one school toilet with a septic tank system and a safe drinking water supply system, it cost approximately US\$1,100. As many drinking water supply projects were active in the target villages, it usually required only water pipes to link them from nearby, existing pipes. Of \$1,100, the donor agencies provided 65% in cash to buy materials. The remaining 35% was provided as labor cost from the villagers. In addition to SCHP's own budget, UNICEF also supported this program.

As a result, while only 20% of all the target schools had both a functioning toilet and water supply system in 1995, 100% of them had set up this system by 2001. Every time after completion of these two facilities, a health education program was also implemented.

#### b-1-4-c) Child Initiative Program

SCHP initiated the Child Initiative Program using a child-to-child approach. This is an approach to health promotion, which focuses on the contribution that children and young people can make to their own health and well-being and that of their families and communities. Through an active learning process, children are able to participate in identifying health problems and in playing an active and effective role in providing solutions.<sup>19</sup>

In Nepal, the Save the Children Fund (UK) first adopted the child-to-child approach first in 1989 to involve schools as part of its outreach program from maternal and child health (MCH) clinics. Similarly, Redd-Barna, Hatemalo Sanchar, and other NGOs adopted this approach.

In practice, SCHP helped each of eighty-four schools to form a child club with seven to nine members and facilitated various activities, such as school toilets and drinking water management, health quiz competitions, and deworming or immunization campaigns. UNICEF also started to support this program from 1999.

As a result, whereas no such child clubs existed in any of the schools in 1998, all the schools formed a child club in 2001. The club members joined the above-mentioned health activities and have also come to work as health messengers for their families and communities.

## b-2) Human resource development for health b-2-1) Healthcare-seeking behavior survey

Improving living conditions through community empowerment may help to improve health, but it takes time. To improve health, certain kinds of health-specific activities are also necessary. SCHP conducted several health-specific activities after conducting a healthcare-seeking behavior survey.

In 1997, SCHP carried out a healthcare-seeking behavior survey for randomly selected 425 households, and obtained data from 405 of them. The results revealed that some form of illness strikes about 50% of households in rural Nepal each year. When rural Nepalese feel sick, they seek healthcare only when the sickness is moderate or severe. Mild illnesses are treated at home. When the villagers seek healthcare, it was found that rural Nepalese preferred to visit traditional healers first, before visiting other health workers. They prefer to visit traditional healers because they are highly accessible, do not charge cash, and can tell whether the diseases are caused by evil spirits according to another study of SCHP.

When health planners devise health policies, they tend to focus first on improving the hospitals, then on HP/SHP, and finally community-based health workers including traditional healers. However, these results show that the majority of rural Nepalese seek care of community-based health workers first and they use HP/SHP secondarily, only if they find it necessary. This study thus urged SCHP to work with traditional healers.

#### b-2-2) Working with traditional healers

SCHP started to work with traditional healers, also supported by further evidence of the benefits of working with them.<sup>22–25</sup>

In 1996, SCHP conducted a traditional healer training program in western medicine for fifty healers. These healers were selected from 269 healers in ten VDCs, based on the following criteria: the healers should be interested in the training, highly respected in their communities, and physically fit and enthusiastic to work anytime in their own VDCs. The first objective of the training was to give basic knowledge about common illnesses (diarrhea, stomach ache, helminthes, fever, etc.) and HIV/AIDS. The second objective was to increase healers' referrals to HPs and SHPs when the healers were unable to treat illnesses. The third objective was to provide them with a first aid kit that contained simple western medicines so that they can increase

treatment skills for common illnesses.

Using a training manual developed in Nepalese, four instructors trained the healers. One year after the training, SCHP conducted an evaluation survey with forty-eight healers (two died within a year) and thirty randomly selected untrained healers. As a result, SCHP found that the trained healers had a better knowledge of allopathic medicine, practiced modern treatment using the first aid kit, and were more likely to refer patients for HPs and SHPs.<sup>26</sup> They also improved their relationship with the governmental health workers in these institutions.

#### b-2-3) One doctor from one VDC

When referral was made, it was questionable whether government health workers were in the health institution and could indeed help these referred patients. As most health workers came from outside the target area and none of them were local, SCHP decided to give scholarship to young, local applicants who were interested in becoming skilled health workers in the future. As a result, SCHP gave scholarship to at least one to two from each VDC (eighteen in total) and trained local health manpower. They attended a fifteen-month auxiliary heath worker course (a graduate can become a SHP in-charge) or assistant nurse-midwife course; some of them became government employees and others became private physicians in their own villages.

#### c) Selected outcomes

In 2000, SCHP conducted a mid-term evaluation with support from New Era, a well-known health research institute in Nepal. In 2002, SCHP also made an internal evaluation. Although the evaluation results were not published, below are the major outcomes of the SCHP activities.

#### c-1) School health

In 1996, only 20% of schools had functioning toilet and water facilities, but in 2002, 100% of the schools had them (by 2002, target schools were increased to 103). During this period, 100% of schools formed child clubs and received a first aid kit and formed school management committees.

#### c-2) Community health

In community health, the adult literacy rate was improved from nearly 16% in 1996 to 50% in 2000 in the target area. The number of SHGs increased from zero to approximately 160, and 12,633 community people took part in several health education courses (some who attended twice or more were counted multiple times).

## Box 1 A letter from a SCHP project staff member to a Japanese public health nurse expert which shows raising consciousness after joining SCHP

'Sister, how I can express my heartfelt thanks for you. I have changed a lot in the past four to five years, which I could not imagine in the past. I feel like I am now standing on a new world. When you first came to my village, I wanted to talk to you, but could not. I had no confidence about what I would say in Nepalese. I was so disappointed.

Then later, I got a chance to attend a literacy education training course as I was selected to be a teacher of a literacy class in my community. The other participants were older than I and were highly educated. I again lost my confidence.

However, little by little, I started to feel, 'I am also the same human being, I can do as they can do.' I attended the training course enthusiastically and studied until late at night. Then the course ended. Then, I became confident in myself and could manage to run a six-month literacy course in my community.

After that, I attended more and more courses and became more confident in development activities. I graduated only from 8th grade. I am not well educated and am not rich. However, I started to realize that 'being rich' means that I have confidence within myself, and I can be being a fighter in seeking a better living.

My parents gave me birth and raised up. But it was you who have shaped my life. You showed me the way to go, too. Then I could gain a confidence and hope.

Now I am going to marry . . . . I want to still continue to work with you. Please do not forget me even after my marriage.

Please come to my wedding ceremony with the project staff members. Finally, I am sorry if I've made any mistakes in this letter.'

(Cited and modified from "Jimba M. Public health and globalization. In: Hoshi T. ed. Social Security and Health of the Individual 2: public health, Textbook for Nurses 8, Igakushoin; 2002: pp. 264–277.")

Ninety-six traditional healers were also trained and eighteen local villagers became assistant health workers or assistant nurse-midwives.

#### c-3) Conscientization

One of the hidden outcomes of this project was raising consciousness about development. In the beginning when the project started in rural villages, people used to say 'development means a gift from outside.' 'It is a hospital, it is a road, there is nothing I can do or I should do for development.' It was a common consciousness in the target area. However, in 2001, one local staff member from one target community sent a letter to a Japanese public health nurse expert, which is shown in Box 1, and which showed her internal change as a conscientized human being after her

involvement with SCHP.

#### Conclusions

SCHP conducted a variety of community development activities considering Rifkin's six points for community development approach. It aimed at improving the living conditions and health of rural Nepalese. As a result, it gained positive outcomes mentioned above. Improving the numbers is indeed important, but one letter shown in Box 1 is also precious for those who remain in development activities. Community development and health projects can in this way contribute to improving the health and living conditions of rural people. It also has the potential to raise

the consciousness of people who jointly work for community development from within. More efforts should be made to scale up these activities in a country where the rural population still suffers from poor health conditions.

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## A Healthcare Crisis in Japan: Criminalizing medical malpractice

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#### Introduction

Two types of risks related to medical disputes are creating confusion in the field of clinical practice in Japan: civil lawsuits, such as those seen in other countries, and the handling of medical disputes as criminal cases, the latter exemplified by the Fukushima Prefectural Oono Hospital case (Table 1). In the Oono Hospital case, an ob-gyn doctor was arrested and indicted for professional negligence and violation of the professional obligation to report any unusual death (i.e., violation of the Medical Practitioners Law, Article 21). The death in question was in regard to death from hemorrhage during a cesarean section. The doctor was the only ob-gyn doctor in the prefectural hospital that had assumed a significant role in community healthcare, and the doctor's arrest had a heavy impact on the medical profession. The number of medical facilities that handle childbirth, which had already decreased to a critical number because of the risk of civil litigation, decreased even further after this case (Fig. 1). Not only ob-gyn related societies but also surgical societies such as the Japan Surgical Society and the Japanese Society of Anesthesiologists concurrently posed questions in regard to this case, and medical organizations such as the Japan Medical Association and the Japanese Association of Medical Sciences issued statements objecting to this particular case. Thus, during the past few years the medical profession in Japan has been experiencing unprecedented change.

## **Are Medical Criminal Cases Increasing?** (Fig. 2)

According to an announcement by the National

Police Agency, a total of 250 medical malpractice cases were sent to the public prosecutors office during the 3 years from 2003 to 2005, while the number of those indicted was 79 during the 5-year period from January 1999 to April 2004. Eighty-four cases were sent to the public prosecutors office, with approximately 16 cases being indicted per year. Seventy-nine medical malpractice suits underwent litigation in court during the 5 years from January 1999 to April 2004; 20 cases of 36 accused were brought to trial, and summary orders were issued in 59 cases of 76 accused. On the other hand, only 137 medical criminal cases were addressed during the entire 54 years from 1950 to January 1999, indicating that criminal cases related to medical malpractice have been increasing recently.

## Why Has the Criminal Prosecution of Medical Disputes Become More Common?

Initially, the civil responsibility of doctors was defined by Supreme Court decisions in marginal cases including the decision of "high probability" issued in February 1999, the conclusion of the case of denial of blood transfusion by members of Jehovah's Witnesses in February 2000, and the decision stipulating "considerable likelihood" in September 2000.

Second, disturbing instances of medical malpractice occurred in large-scale hospitals at about the same time as the court was altering its rulings. Such malpractices included the incorrect identification of patients at Yokohama City University Hospital in January 1999, erroneous infusion of an antiseptic solution at Tokyo Metropolitan Hiroo Hospital in February 1999, an anticancer

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#### Table 1 Fukushima Prefectural Oono Hospital case

- In December 2004, a 29-year-old woman who received cesarean section at Prefectural Oono Hospital in Okuma Town, Fukushima Prefecture, died from hemorrhagic shock. In March 2005, the Investigation Committee of the prefecture published the accident report that attributed the case to medical error. The prefectural police department, which received news of the accident from news reports, initiated an investigation of the accident. On February 18, 2006, the 38-year-old ob-gyn doctor who performed the operation was arrested for professional negligence resulting in death and for violation of the Medical Practitioners Law. On March 10, the Fukushima District Public Prosecutors Office prosecuted the case at the district court level. The doctor was released on bail on March 14.
- After four sessions of pretrial proceedings, the first trial hearing was begun on January 26, 2007.
   Following the 13th hearing (prosecutors' closing arguments) in March 2008 and the 14th hearing (summation) in May, the case is expected to conclude in June.

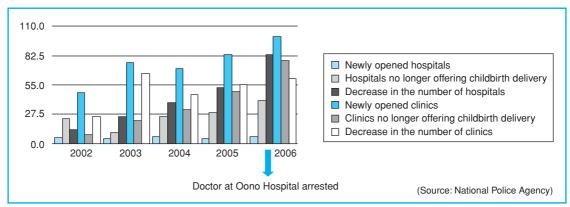


Fig. 1 Medical facilities that deal with childbirth and delivery have already decreased to a critical limit

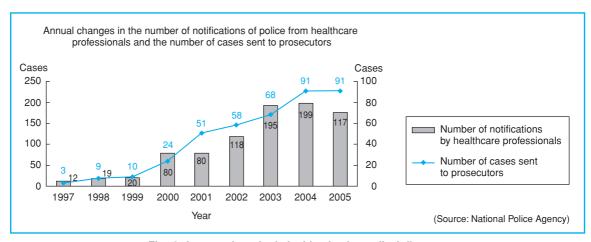


Fig. 2 Intervention of criminal justice in medical disputes

drug overdose at Saitama Medical Center, an affiliate of Saitama Medical School, in October 2000, and tampering with medical charts at the

Heart Institute of Japan, an affiliate of Tokyo Women's Medical University, in March 2001. The news media gave prominent coverage to these

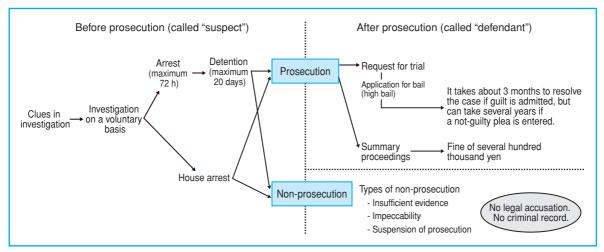


Fig. 3 Difference between prosecution and non-prosecution

cases, leading to distrust and disaffection in regard to the medical profession.

Third, the situation of the police and prosecution, who must face the emotions of patients and bereaved individuals, is involved. For example, in the Okegawa stalking/murder case that occurred in October 1999, a female college student was murdered near Okegawa station of the Japan Railway Takasaki line in Okegawa City, Saitama Prefecture, on October 26, 1999, by a man hired by her ex-boyfriend and his brother. The victim had been threatened by stalking behavior that included close scrutiny, maligning, and threatening from these men. The victim and her family consulted with the local office of the prefectural police department many times and submitted a written accusation. The police, however, ignored the accusation and did not undertake an investigation, but instead requested that the family withdraw the accusation. It was also revealed later that they tampered with the written accusation. The police officers who had been involved in tampering were given a dishonorable discharge, and eventually were convicted in court. Another influential case was the Tochigi lynching case, a case of confinement, assault, and murder uncovered in Tochigi Prefecture on December 4, 1999. The Tochigi prefectural police department failed to investigate the incident, despite the fact that the victim's parents had asked the police department nine times to search for their son. This lack of action left an emotional scar among the general populace. This case, together

with the Okegawa stalking/murder case, aroused dissatisfaction toward the authorities. After the exposure of this incident, the Tochigi prefectural police department was subjected to harsh criticism from both the public and the court. In these cases, claims for damages resulting from negligence in regard to the investigation were entered. Currently, in response to increased advocacy by victims' groups, the investigative authorities are necessarily conducting more thorough investigations. In addition, the current state of affairs is such that the prosecutor has almost no choice but to bring in indictments, although the prosecutor has the authority to conduct prosecution, representing the principle of discretionary prosecution prescribed in Article 248 of the Criminal Procedure Law (the prosecutor can avoid instituting prosecution if there is no need for legal action, considering the personality, age, and circumstances of the criminal, grade and circumstances of the offense, and the situation following the offense). It must be borne in mind that there is no difference in handling the cases of doctors and criminals once they are involved in criminal proceedings.

## The Flow from Medical Disputes to Criminal Disputes in Japan

The flow from medical disputes to criminal disputes in Japan is shown in Figs. 3 to 7.

If a criminal proceeding is initiated, it is important to know when to contact the lawyer. If a

It means "sending the record of interrogation and other papers pertaining to the accused person from the police to the public prosecutors office in order to help assess the propriety of prosecution without detaining the accused person." (Translated from the Daijirin dictionary, Sanseido Co., Ltd.)

→ This is not legal terminology, but rather a term used by the mass media. It is the state in which the accused person is not arrested as a result of police discretion. The accused person receives no legal disadvantages by "sending papers," but is not relieved of the possibility of future prosecution.

Investigation should be primarily by the police, and "prosecutors investigate particular crimes by themselves when they recognize it as necessary" (Article 191, Section 1 of the Law of Criminal Procedure). The police must report to prosecutors all cases that they have investigated, excluding minor offenses (Article 246 of the Law of Criminal Procedure).

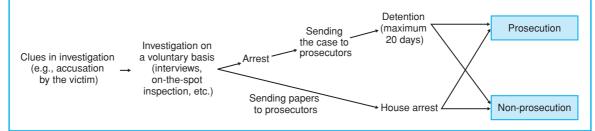


Fig. 4 What does "sending papers to prosecutors" mean?

#### Court proceedings (formal trial)

- In open court
- No limitations in type of sentence
- When the accused person is detained, he or she is kept in custody unless bail is admitted.
- If innocence is asserted, at least 2 years may be necessary. It is difficult for a single lawyer to deal with the entire case, and expenses incurred in defending may be high.
- Mass media response: Reported by national newspapers

### Summary proceedings (Article 461– of the Law of Criminal Procedure)

- · Proceedings not open to the public
- Limited to cases of a penalty or a non-penal fine of 500,000 yen or less (1 US dollar = 110 yen)
- The basic premise is that the accused person admits his or her own guilt → risk of false accusation
- Papers are prepared by the prosecutors office and the court, and a decision is given on the day of institution of prosecution or a few days later.
- Mass media response: Reported in a corner of a local news page

Fig. 5 Difference between court proceedings and summary proceedings

person is informed of the right to remain silent during questioning by a police investigator, he or she is already a suspect from the legal point of view. Therefore, the person should consult a lawyer immediately at this point. It is a disadvantage to call a lawyer after arrest. Criminal defense requires the support of evidence, but all evidence including medical charts is impounded at the time of arrest. Thus, information is sealed, and it is extremely difficult to obtain such sealed

information. When a doctor is arrested, the prosecutor is usually confident of the guilt of the suspect through consultation with a superior government agency. Therefore, it can be quite likely that the doctor will be prosecuted. Many doctors who are covered by medical compensation insurance assume that a lawyer from the insurance company will support them. Although the insurance company acts on behalf of the insured in civil cases, selection of a defense

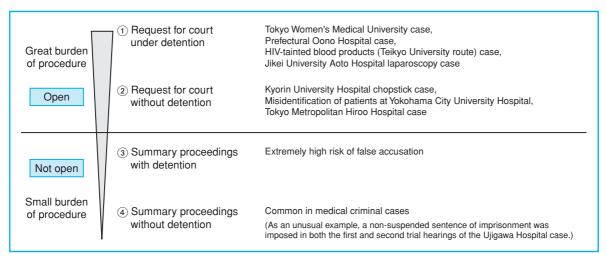


Fig. 6 Difference between detained cases and house arrest cases

In detention cases, application for bail is possible after prosecution, although bail money is necessary.

① HIV-tainted blood products (Teikyo University route) case in October 1996
② Tokyo Women's Medical University Hospital artificial heart lung clogged filter case in July 2002
② on illion yen
③ Prefectural Oono Hospital case in March 2006
⑤ 5 million yen
⑥ (1 US dollar = 110 yen)

The above three were detention cases that required high bail, although they all resulted in a decision of not-guilty. The accused doctors in the second and third cases were both hospital doctors in their 30s.

Fig. 7 Difference between detention cases and house arrest cases (bail guaranty deposits)

attorney is a separate requirement in criminal cases. Considering the time, labor, expertise, and compensation provided, not many lawyers are willing to take on this responsibility. This further increases the anxiety of Japanese doctors.

## Confusion Related to the Expanded Interpretation of Article 21 of the Medical Practitioners Law

In Japan, when a medical dispute becomes a criminal case, violation of Article 21 of the Medical Practitioners Law as well as professional negligence resulting in death are among the reasons for prosecution. However, the view that a

doctor's violation of Article 21 of the Medical Practitioners Law includes the death of a patient during treatment is an extremely new interpretation. Prosecution for this charge was unheard of a decade ago.

Article 21 of the Medical Practitioners Law has been in effect since 1874. Its legislative intent was to facilitate the discovery of crimes because abnormal deaths are more likely to be associated with crime. For instance, when a patient brought to a hospital died in spite of emergency treatment and when the administration of poison was suspected, the doctor in charge would report the case to the police. Originally, doctors were obliged to report an abnormal death within 24

hours to avoid the escape of the criminal in cases such as the above.

However, no prosecutors, jurists, or any other persons have considered that doctors who experience the unexpected death of a patient undergoing treatment and who might be accused of professional negligence resulting in death because of the death would also be under obligation to report the death according to Article 21 of the Medical Practitioners Law.

Attention was first focused on Article 21 of the Medical Practitioners Law after the Tokyo Metropolitan Hiroo Hospital case occurred in 1999. In this case, a patient died because a wrong drip infusion was confused with another drug and administered by a nurse. The attending doctor and the director of the hospital, who dealt with the incident after the fact, and the supervising Tokyo Metropolitan Government Bureau of Public Health attempted to cover up the incident by recording false information on the death certificate. The two nurses who were directly involved in this incident of malpractice were promptly assigned 1 year of imprisonment and 7 months of imprisonment, with each given suspended sentences for professional negligence resulting in death. Other persons involved were prosecuted for the preparation and exertion of a signed false public document and violation of Article 21 of the Medical Practitioners Law (failure to report an abnormal death of a patient within 24 hours after confirmation), and the suit against some of the defendants went to the Supreme Court.

Acting under the influence of this case, the Risk Management Standard Manual Committee, Department of National Hospitals of the then Ministry of Health and Welfare, prescribed in August 2000 that, in cases of death or injury from definite or suspected medical malpractice, the director of the hospital has to report the case promptly to the police station under jurisdiction. Notification of this rule was immediately sent to national and public hospitals, and was later distributed to private university hospitals and other large-scale hospitals.

In response, medical societies began to publish guidelines. Representative is the 2002 Guidelines of the Japan Surgical Society. In the statement entitled "report of death and injury of patients related to medical conduct," it is said that "it is desirable that medical accidents be reported to

a specialized organization other than police, but in the current absence of any such organization, it is desirable for the time being that, in cases of death or serious injury resulting from definite or strongly suspected serious medical malpractice, the doctor in charge report it promptly to the police station under his or her jurisdiction."

In 2004, the Supreme Court gave its final decision in the Hiroo Hospital case. It concluded that placing the obligation of filing a report according to Article 21 of the Medical Practitioners Law on the doctor who has carried out medical malpractice does not contravene Article 38 of the Constitution (infringement of right to silence).

However, since 2000, convictions for violation of Article 21 of the Medical Practitioners Law have shown distinct features in common. The defendants were not only accused of professional negligence resulting in death but also of various additional infringements. One example is the suspected intentional hiding of correspondence relating to an accusation of preparing a false medical certificate. Another is rudimentary malpractice obvious to anyone, such as death resulting from the erroneous use of an inappropriate medication as a result of error or from an extraordinarily high overdose. In contrast, no cases of the violation of Article 21 have resulted in conviction without additional reasons. Therefore, at present, violation of Article 21 serves only as a hook for the investigation of professional negligence resulting in death.

#### The Future of Institutional Design

In Japan, there is almost no effective functioning of administrative punishment by experts, and no professional organizations for extra-judicial resolution of disputes, such as offices at which to file complaints or tribunals of professions. These are cited as underlying factors for the tendency of medical disputes to become criminal cases.

Any medical action necessarily involves some risk. There is the view that civil or criminal penalty and administrative punishment represent certain measures to control the quality of medical care. However, it is not possible to restructure system errors by pursuing individual responsibility alone. The current status, which is inclined to criminal accusation, creates only a negative profile, leading to defensive medicine. It is becoming increasingly important to understand these circum-

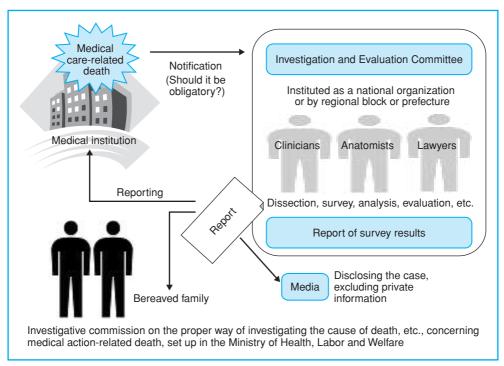


Fig. 8 Schematic image of the Medical Accidents Investigation Committee

stances and realize the governance provided by professional organizations. Institutional designs that are urgently needed include the following:

- Reinforcement of civil compensation: introduction and expansion of the no-fault compensatory system (already targeted for introduction in the case of cerebral palsy in departments of obstetrics)
- (2) Amendment of laws that serve as a gateway to criminal proceedings; particularly, improvement or elimination of Article 21 of the Medical Practitioners Law.
- (3) Setting up of independent organizations to deal with medical accidents: model projects for survey analysis of deaths related to medical actions, Medical Accidents Investigation Committee (Fig. 8)
- (4) Oversight and self-monitoring by the medical community

#### **Concluding Remarks**

Initially, medical providers in Japan conceived of an accident investigation committee that would have the main aim of preventing the recurrence of accidents. However, the current Medical Accidents Investigation Committee is an organization inside the Ministry of Health, Labor and Welfare, and the Committee members include representatives of the bereaved and lawyers. In addition, it is possible to use investigative reports in civil and criminal investigations. Surgery-related societies, in particular, have issued a statement that vehemently objects to these features of the current Committee. No resolution has yet been found for what is probably the greatest dispute in medical care in Japan since the war.

## What Maternity Clinics Can Do for More Reliable Perinatal Care

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#### **Abstract**

The collapse of perinatal care is imminent, unless measures are implemented for its smooth operation in a community care system. However, we are now faced with the prospect of the destruction of perinatal health care. The number of maternity clinics supporting childbirth is decreasing. The presence of maternity clinics supporting primary care is an essential prerequisite for maintaining the community perinatal care system. The following actions are required: (1) prompt recruiting and training of workforce including physicians and midwives; (2) revision of the medical fees for perinatal care to appropriate levels and ensuring the salaries of employed physicians to meet their work burdens; (3) realization of the community care initiative, in which general and community perinatal care centers treat high-risk patients, while normal and low-risk patients are treated at primary care facilities (maternity clinics and small/medium-sized hospitals); (4) conducting publicity activities on the medical risks associated with childbirth; (5) establishing a system to minimize the risk of medical lawsuits and creating a system for no-fault compensation and independent organization investigating medical accidents.

Key words Maternity clinic, Perinatal health care, Community health care system, Actions

#### Introduction

Japan has a history of providing the world's highest quality perinatal health care to its citizens for approximately 10 years. However, we are now faced with the devastation of health care, particularly perinatal health care. The number of maternity clinics supporting childbirth is decreasing, and childbirth centers are disappearing in many communities. Many childbearing women, reportedly 200,000 or 300,000, have become health care refugees and are having difficulty in finding childbirth services. The shortage of midwives, the functional insufficiency of secondary and tertiary care hospitals, poor work environment, and increasing lawsuits are also accelerating the devastation of health care. While this devastation is taking place in all fields, its impact is most strongly felt in perinatal health care. It is no exaggeration to say that if we can overcome this problem, health care problems in all other fields can be resolved. This article analyzes the causes of the withdrawal of maternity clinics from child-birth service, and explores what maternity clinics can do to ensure safer and more reliable perinatal health care.

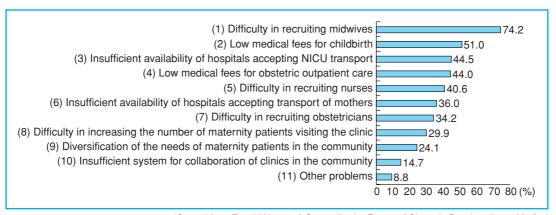
## What Caused the Drastic Decrease in Childbirth Centers, Particularly Maternity Clinics?

(1) The shortage and uneven distribution of obstetricians, NICU (neonatal intensive care unit) physicians, and midwives pushed the fatigue of physicians in obstetric practice to an extreme, and the decrease in childbirth centers and the shortage of NICU became a manifest problem. The increased burden on medical institutions still offering childbirth

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- service caused more to withdraw like falling dominos.
- (2) As a result of the introduction of the new program for the clinical training of physicians, obstetricians who had been working at hospitals associated with universities were called back to universities, and the hospitals that became unable to recruit obstetricians withdrew from childbirth service. At the same time, the number of residents and medical students aspiring to obstetrics decreased. Because the entry of new workforce has decreased, the situation is expected to worsen over a period of several years to 10 years in the future.
- (3) The system for perinatal health care proved defective. This surfaced as the failure of the community care initiative, in which health institutions were to be classified into levels from primary to tertiary according to function and scale, and a community health care system was to be established based on role sharing and collaboration. The number of health institutions accepting emergency transport of patients is decreasing.
- (4) The curtailment of the national health expenditure caused worsening of the work environment and medical fees of physicians, and induced the decrease in the number of obstetricians.
- (5) The "year 2007 problem": many obstetricians in the baby boom generation are reaching retirement age and leaving their

- jobs.
- (6) There was criminal prosecution involving medical practice, charging violation of the Medical Practitioners Law, Article 21 (reporting of abnormal death) (e.g., Fukushima Prefectural Oono Hospital) and charging violation of the Criminal Law, Article 211 (professional negligence resulting in injury and death) (e.g., Fukushima Prefectural Oono Hospital and Oyodo Town Oyodo Hospital, Nara Prefecture).
- (7) There was criminal prosecution involving obstetric practice, charging violation of the Public Health Nurse, Midwife, and Nurse Law (vaginal examination by a nurse). This forced maternity clinics without midwives to withdraw from childbirth services.
- (8) Users came to have high expectations of maternity centers (particularly of their amenities, expected to be like those of hotels). Maternity clinics that could not meet such expectations withdrew from childbirth service.
- (9) Many clinics withdrew from obstetric practice because of aging of the physicians and a lack of successors.
- (10) The devastation of the perinatal health care system and the decrease in medical institutions accepting emergency transport of patients produced a situation where maternity clinics cannot offer childbirth service with confidence.



(Quoted from Eguchi N et al. A Survey for the Future of Obstetric Practice, Japan Medical Association Research Institute Working Paper No.141, 2007.)

Fig. 1 Major operational problems (n=1,040, multiple answers)

## Analysis of Present Conditions from the Standpoint of Employed Physicians

The four elements to run a health institution are said to be persons, material things, money, and information.

- (1) The present crisis of obstetric and gynecology practice derives from a serious shortage of persons or physicians.
- (2) The burdens of overwork, low salaries, medical lawsuits, and resident training have induced a phenomenal increase in physicians leaving general hospitals.
- (3) The collapse of the medical office system has accelerated the movement of physicians from hospitals with poor working conditions to those offering better conditions. Although concentrated allocation of workforce has been proposed as a solution to the shortage of physicians, it is difficult to promote exchange of personnel among hospitals operated by different entities. The regulations on national government workers also present an obstacle.
- (4) Because the training of midwives requires time, this must be rapidly promoted. Measures should be taken to re-train and mobilize inactive midwives (which can be done on a prefectural basis). The establishment of midwifery clinics in hospitals (midwifery departments) may also be an option for coping with the shortage of obstetricians.

## Operational Problems of Maternity Clinics and Proposed Solutions

The survey conducted by Japan Medical Association Research Institute covering 1,040 maternity clinics<sup>1</sup> identified the following issues as operational problems reported in a multiple-answer questionnaire (Fig. 1).

(1) **Difficulty in recruiting midwives:** While 18% of midwives are working at maternity clinics, only 2.4% of new midwives enter employment at maternity clinics. The difficulty in recruiting midwives is expected to intensify further in the future. In fact, 75.7% of maternity clinics are troubled with a shortage of midwives. It is necessary to rapidly train new midwives. New midwifery courses should be established (within nurse schools operated by medical associations in communities) so

- that nurses working at maternity clinics may obtain qualification in midwifery.
- (2) Low medical fees for childbirth: The fees are in the range from 300,000 to less than 400,000 yen (USD 3,000–4,000) at 68.1% of clinics. The Japan Association of Obstetrics and Gynecology estimates that the appropriate range of fees is 600,000 to 700,000 yen (USD 6,000–7,000). Considering the need for equipment, the work environment of medical staff, and wages, it is necessary to secure fund sources through appropriate revision of medical fees. A precondition for securing medical staff is the appropriate revision of medical fees including the fees for childbirth service and perinatal care.
- (3) Insufficient availability of hospitals accepting NICU transport: More than 60% of transport of pregnant women is requested for conditions involving fetuses, i.e., threatened premature delivery. It is often the case that such transport is hampered by the shortage of NICUs despite the availability of obstetric beds.
- (4) Low medical fees for obstetric outpatient care: To lessen the burdens on medical institutions performing childbirth service, clinics that are not performing childbirth service are required to offer health examinations of pregnant women. It is necessary to revise fees to appropriate levels that can support the sound management of clinics.
- (5) Difficulty in recruiting nurses: The cooperation of nurses is essential to perinatal medicine. Nurses can perform internal examination only under the instructions of a physician. The cooperation of nurses is indispensable for delivery monitoring continued 24 hours a day.
- (6) Insufficient availability of hospitals accepting transport of mothers: There is a shortage of secondary and tertiary care hospitals accepting emergency transport of mothers (postnatal bleeding, abruption of the placenta, pregnancy-induced hypertension, etc.)
- (7) **Difficulty in recruiting obstetricians:** Obstetricians are generally in short supply, and recruiting them is extremely difficult. Maternity clinics with relatively few restrictions on the setting of working terms can readjust working terms to facilitate the employment of female obstetricians and obstetricians

after retirement age.

(8) Difficulty in increasing the number of maternity patients visiting the clinic: A means to increase the number of maternity patients visiting clinics is role sharing among medical institutions, such as treating high-risk patients at secondary and tertiary care facilities and normal and low-risk patients at maternity clinics.

A survey of future directions pursued by clinics showed that maternity clinics are taking various stances, including treating all cases except for high-risk delivery (56.5%), treating only normal delivery and elective cesarean delivery (19.1%), withdrawing from delivery (18.9%), focusing on obstetric outpatient care such as maternity health examinations (10%), treating only normal delivery (9.4%), decreasing the number of delivery cases (8.5%), and employing a semiopen system (7.7%) and an open system (4.1%).

- (9) Diversification of the needs of maternity patients in the community
- (10) Insufficient system for collaboration of clinics in the community

## Positions of Maternity Clinics and Actions for the Future

In Japan, most women in childbirth leave their homes after the appearance of signs of labor (beginning of labor pains) and go to a maternity center located within a 30-minute drive by private car. Small and medium-sized maternity clinics and hospitals have been the mainstay supporting perinatal care in communities. However, the roles of clinics are changing depending on the situation of the community perinatal care system. There are several patterns of practice as follows. (1) Non-participating clinics: These clinics do not participate in perinatal care. (2) Obstetric outpatient clinics: These clinics perform maternity examinations up to about 36 weeks' gestation and also cooperate in neonatal examination. (3) Semiopen system clinics: These clinics perform maternity and neonatal examinations, but patients in labor are transported to childbirth centers and physicians at childbirth centers assist with delivery. (4) Open system clinics: These clinics perform maternity and neonatal examinations, and patients and physicians at the clinics go to

childbirth hospitals for delivery. (5) Clinics offering complete care: These clinics provide complete care including maternity and neonatal examinations and childbirth service.

From the standpoint of patient safety, a prerequisite for providing childbirth service at primary care facilities is the establishment of a system for providing care through involvement of multiple physicians or a cooperation system to respond to the emergency needs of primary care facilities in the community. It is important to promote the community care initiative in perinatal medicine. In the present situation, the attempt to overcome the shortage of obstetricians and NICU physicians through concentration and prioritization at secondary and tertiary care facilities has been unsuccessful. Although maternity patients are concentrated at childbirth centers, there is a shortage of workforce to be concentrated at these centers.

In any case, the following actions are needed for the improvement of perinatal care: (1) prompt recruiting and training of workforce including physicians and midwives; (2) creation of an environment to facilitate the cooperation of nurses and total legalization of internal examination performed by nurses; (3) revision of the medical fees for perinatal care (fees for childbirth) to appropriate levels and ensuring the salaries of employed physicians to meet their work burdens; (4) realization of the community care initiative, in which general and community perinatal care centers treat high-risk patients (measures to ensure sound business operation without the need to treat normal and low-risk patients are needed), while normal and low-risk patients are treated at primary care facilities (maternity clinics and small/medium-sized hospitals); (5) conducting publicity activities about the medical risks associated with childbirth; (6) establishing a system to minimize the risk of medical lawsuits and creating a system for no-fault compensation (NFC) regarding complications that may occur in perinatal care (e.g., cerebral palsy); and (7) creation of a system to prevent undue criminal prosecution against medical professions, including the establishment of an independent organization investigating medical accidents and the amendment of Article 21 of the Medical Practitioners Law.

#### **Concluding Remarks**

The collapse of perinatal care is imminent, unless measures are taken to operate it smoothly in a community care system. If the business performance of maternity clinics does not improve and their withdrawal from childbirth service continues, secondary and tertiary care facilities will be crowded with normal delivery cases, and the function of higher-level medical institutions will be disrupted. On the other hand, if secondary and tertiary care facilities are not able to fulfill their function, it will be impossible for primary care facilities to provide childbirth services, which always involve risks. The presence of maternity clinics supporting primary care is an essential prerequisite for maintaining the community perinatal care system.

#### Reference

 Eguchi N et al. A survey for the future of obstetric practice. Japan Medical Association Research Institute Working Paper No. 141; 2007.

# Present Status of Obstetric and Perinatal Care and the Action Plan Issued by the Japan Society of Obstetrics and Gynecology

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#### **Abstract**

The recent decline of doctors in the field of clinical practice, particularly from regional emergency care services, has caused serious problems in Japan. This trend is especially problematic in the field of obstetrics, which, in comparison with other specialties, rests on a rather weak foundation and has a variety of complex structural issues. As a result, the obstetric care system in Japan is facing a serious situation that will require radical changes in order to maintain its stability.

Recent years have seen rapid changes in obstetric practice in Japan, including an aging population of doctors, an increasing proportion of female ob-gyn doctors, and the influence of a new clinical training system. Introduction of the new clinical training system has caused a delay in the supply of newly minted ob-gyn doctors and a decline in the number of doctors who are entering this specialty. These factors have resulted in a significant decline in the clinical workforce and have been followed by the closure of many regional childbirth facilities. In addition, a defensive attitude toward medical practice has recently emerged as a precautionary measure against civil suits and criminal prosecution for malpractice. To solve these problems, the Japan Society of Obstetrics and Gynecology has formulated an action plan for obstetric care reform and has initiated a variety of activities.

Key words Shortage of doctors, Pressure of lawsuits, Support for doctors in clinical practice

#### Introduction

One of the serious problems in Japan's health-care is the withdrawal of doctors from the field of clinical practice, particularly from regional emergency care services. This trend is especially prominent in the field of obstetrics. The area of obstetrics in Japan rests on a weak foundation compared with other specialties, creating many complicated structural issues. As a result, fundamental reform is required in this particular specialty so that a stable and sustained structure can be ensured.

The author presented an outline of the current status of obstetric care in Japan at an educational

session on maternal and child health supported by the Japan Medical Association in March 2007 [Journal of the Japan Medical Association 136; 4 (supp.):48–55]. This paper describes some of the changes currently taking place in the field of obstetric practice and includes additional data obtained after the session. The direction of reform under consideration and the action plan of the current year designed by the Japan Society of Obstetrics and Gynecology (JSOG) will also be addressed.

#### **Current Status of Obstetric Practice**

#### An aging population of doctors

Although the number of doctors as a whole is

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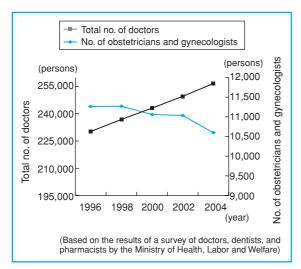


Fig. 1 Changes in the number of ob-gyn doctors

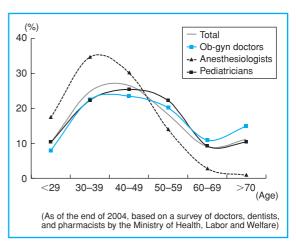


Fig. 2 Age distribution of doctors

Proportion of those aged 60 or older: 26.0% among ob-gyn doctors, 19.6% among pediatricians, 3.7% among anesthesiologists

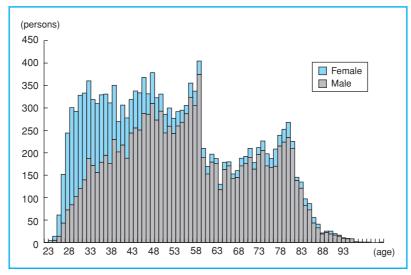


Fig. 3 Number of members of the Japan Society of Obstetrics and Gynecology by age and sex (as of November 2006)

increasing in Japan, the number of obstetricians and gynecologists is decreasing (Fig. 1). Aging is another factor that differentiates obstetricians and gynecologists from doctors in other specialties. Physicians in their 60s or older account for about 20% of all doctors, whereas the percentage of doctors in this age group is 26% among obstetricians and gynecologists (Fig. 2). Current obstetric practice is sustained by doctors recruited in the 1950s and '60s, when obstetrics

and gynecology were often chosen as a specialty by young doctors.

#### Increasing numbers of female ob-gyns

The number of female doctors has been increasing among ob-gyn doctors as a whole over the past two decades. Prior to that, the percentage of female ob-gyns was only about 10%, whereas now female ob-gyns account for about 50% of all ob-gyns in their 30s, and the corresponding

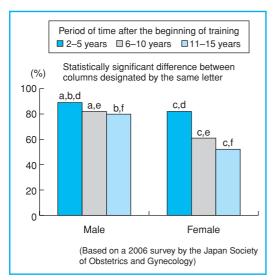


Fig. 4 Proportions of doctors working for delivery and childbirth facilities within 15 years after beginning obstetric training

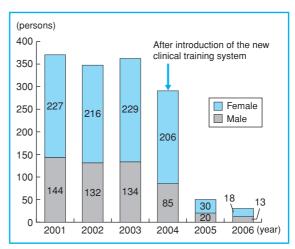


Fig. 5 Number of members of the Japan Society of Obstetrics and Gynecology by year of graduation from medical school (graduates in 2005 estimated at 304)

percentage is at least 70% among those in their 20s (Fig. 3).

The increase in female doctors in the field of obstetrics and gynecology is considered to be related to an increase in female doctors overall as well as to changes in social mores associated with progress in the medical sciences focused on gender differences and the growth of womenonly outpatient services. However, further details of the reasons for change remain unclear. As a result, there has been a fundamental change in the male/female composition of doctors who provide obstetric and gynecological services. In particular, since advanced or emergency care at university hospitals and regional core hospitals is largely conducted by doctors of the younger generation, structural changes in manpower in this particular field have had a serious impact on local sites of secondary and tertiary care.

In 2006, the Committee for the Support of Female Doctors in Their Careers, a subgroup of the Japan Society of Obstetrics and Gynecology (JSOG), conducted a survey concerning the current work sites of doctors who had begun training in obstetrics and gynecology at university hospitals over the past 15 years. The results showed that more than 80% of male doctors were working in facilities that handled delivery and child-birth, whereas female doctors tended to leave

such facilities after 6 years; the percentage of female doctors remaining in delivery and child-birth facilities was just 60% at 6–10 years and 50% at 11–15 years (Fig. 4). This generation corresponds to those in their 30s, and it is apparent that the changes in gender composition among doctors has had a direct influence on the work-force in clinical practice. Since younger female doctors, who currently account for 70% of all younger ob-gyns, will soon be in their 30s, measures to retain them at childbirth and delivery facilities appear to be essential to securing the workforce at sites of secondary and tertiary medical care.

## Influences of the new clinical training system on the clinical practice of obstetrics and gynecology

Innovations in the clinical training system have presented two serious issues in the field of obstetric and gynecologic care.

Since the compulsory training for two years after passing the national board examination was introduced in 2004, the supply of junior doctors entering clinical practice has been suspended for two years. In the field of obstetrics and gynecology, most young doctors used to be sent from medical schools to hospitals for clinical training in a rotation program of a relatively short period

of time. In small-scale hospitals with limited manpower, disruption of the supply of young doctors resulted in a significant decrease in the workforce, and this change has been too great to be overcome by the efforts of people involved in the local areas. (The number of members of JSOG decreased by 450 from 2004 to 2005, whereas there had never been a decrease in excess of 40 members per year, although a gradual decrease had been noted.)

Second, the new training program requires all second-year residents to be engaged in obstetric and gynecological care. This program also requires ob-gyn doctors in clinical training facilities to be in charge of resident education in addition to their daily clinical activities, although in fact any of the training facilities could afford to secure additional personnel for education or clinical services. Thus, an additional burden has been placed on the working conditions of ob-gyn doctors, making working conditions in this specialty more difficult than those in other fields. On the other hand, it became possible for residents to have the opportunity to work in a department of obstetrics and gynecology prior to making a final decision as to their choice of specialty.

An important event was the withdrawal of obstetric and gynecological services from university-affiliated hospitals, which occurred just prior to the introduction of the new clinical training program. According to a survey conducted by JSOG, at least 117 hospitals closed their departments of obstetrics and gynecology in 2003–2004.

Among all medical graduates in 2004, a total of 291 residents chose obstetrics and gynecology as their specialty in 2006 after completion of the training program. As shown in Fig. 5, the number was around 350 prior to 2006, and the number of new JSOG members decreased about 15–20%. This decrease was largely attributable to the fact that the residents had experienced the difficult working conditions in the actual hospital settings of obstetrics and gynecology during their initial residency program. The main cause of these problems may have been due to the fact that the new clinical training system was introduced to facilities that were not prepared to improve their working environment.

#### **Decreases in childbirth facilities**

Figure 6 presents historical changes in the num-

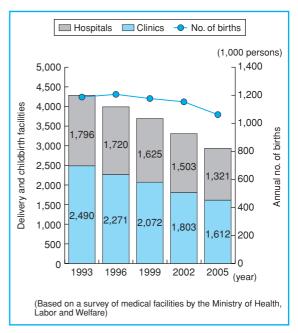


Fig. 6 Decrease in delivery and childbirth facilities

ber of facilities that handle childbirth and delivery in Japan. In the 12 years from 1993 to the autumn of 2005, the number of facilities handling delivery and childbirth decreased from 4,286 to 2,933. This represents an annual decrease of 100 hospitals and clinics. The number of childbirth facilities per se is not related to introduction of clinical training program or the health policy of the Ministry of Health, Labor and Welfare. Rather, the decrease reflects a structural problem in obstetric and gynecology services in Japan. The decrease in the number of childbirth and delivery facilities not only limits the access of pregnant women to such facilities, but also imposes a greater burden on doctors working for these facilities because the decline in facilities is greater than the decline in childbirths. It seems that a steady decrease took place up to 2005, prior to the Government's policy of consolidation.

## Influence of the Oono Hospital case on obstetric practice

Obstetrics is the specialty that receives the largest number of malpractice suits per doctor, as indicated by the figure of 12.4 lawsuits per 1,000 doctors in 2004. High compensation damages are often awarded in the case of lawsuits related

to newborn central nervous system damage, such as cerebral palsy. Although these facts are not readily made public, they can be an important factor in discouraging young doctors from taking obstetrics and gynecology as their future specialty.

The clinical practice of obstetrics today is efficiently managed, and the results of childbirth are generally favorable. Still, unexpected complications resulting in poor outcomes occur and cannot be avoided. It is natural for a married couple and family to expectantly await the birth of a new family member, but when they are faced with a poor outcome, it is extremely difficult for them to accept the reality.

Medical disputes are more common in the field of obstetrics, not only in Japan, but also in other countries worldwide. Disputes in this field probably occur more often than in other specialties because it deals with life processes like pregnancy, delivery, and childbirth. It is necessary to decrease the pressure of lawsuits on obstetric departments through an institutional approach. Otherwise, obstetric services will come to an impasse as a result of a decrease in service providers.

In the Fukushima Prefectural Oono Hospital case, a doctor was criminally accused of the intra-operative death of a pregnant woman with placenta previa accreta who had a history of cesarean section. The charge levied against the doctor was professional negligence resulting in death. This case had an extremely strong impact on not only ob-gyn doctors but also all other clinicians, because of the fact that an unfortunate incident that occurred in the process of ordinary medical practice had been linked to criminal prosecution. As is commonly known, the Japan Medical Association, Japanese Association of Medical Sciences, and various other healthrelated organizations expressed their strong concern regarding this kind of judicial action.

The case is currently (as of October 2007) undergoing trial at the Fukushima District Court. It is important in regard to future health care activities for the court to clarify its rulings in regard to judicial intervention in medical care.

In regard to the influence of this case on obstetric practice, the most substantial change has been that secondary care hospitals or regional core hospitals have been referring a larger number of high-risk patients, who otherwise would have been treated at their facilities, to tertiary care facilities. For example, cases of placenta previa or low-lying placenta accounted for 0.88% and 1.13% of all obstetric cases in 1974–1978 and 2001–2005, respectively, at Kitasato University Hospital. This indicates no significant difference between the two periods. However, the corresponding percentage increased significantly to 2.44% in 2006. Similar changes were noted at other hospitals such as the University of Tokyo Hospital, Jichi Medical School Hospital, and the National Defense Medical College Hospital.

This trend is not limited to placenta previa, but to a wide range of high-risk pregnancies. These changes seem to result from an oversensitive reaction on the part of medical facilities to the possibility of criminal intervention and excessive coverage by the media when the results of treatment prove to be unfavorable. Although the concentration of high-risk cases in advanced-care facilities may be reasonable, the problem is an increase in the number of patients while medical resources lag behind. Tertiary care facilities also face the problem of a lack of doctors. An excessive concentration of high-risk patients increases the burden on tertiary care facilities, leading to the possible flight of doctors.

Since the spring of 2006, hospitals that have withdrawn delivery and childbirth facilities have increased to more than 100. Although there have been no detailed data on changes in clinics since 2005, it seems clear that an increasing number of clinics are withdrawing delivery and childbirth.

#### Obstetric Care Reform

## Discussion of the JSOG Study Committee on the Ob-Gyn Care System

The Committee on the Ob-Gyn Care System, which was set up in November 2005, proposed suggestions for ob-gyn care in its final report issued in April 2007 (Table 1). The full text of this report is available from the website of JSOG in Japanese as follows: (http://www.jsog.or.jp/news/pdf/iryouteikyotaisei\_last12APR2007.pdf).

The fundamental premise is that any further damage to the current regional obstetric care system needs to be avoided, and that the current system be transformed to a new system that ensures stable, sustained provision of obstetric care. Given the marked increase in female doctors, it is absolutely necessary to carry out efforts to secure and retain them in the field of delivery

### Table 1 Final report: Future prospects of obstetric and gynecologic care in Japan and specific measures proposed to establish them (summary)

Recognition of the current situation: the obstetric care system in Japan is currently in crisis owing to a number of complex reasons

Issues of human resources

- Shortage and further decline in ob-gyn doctors as a whole as well as those engaged in childbirth and delivery
  - Harsh working conditions and poor treatment at hospitals
  - Aging of doctors and increasing numbers of female doctors among younger ob-gyn doctors
  - Introduction of a new clinical training program
- (2) Shortage of midwives and their uneven distribution among facilities
- (3) Limited capacity to handle childbirth and delivery among clinical departments that may involve childbirth and delivery, such as general medicine
- (4) Shortage of pediatricians and anesthesiologists who also assume responsibility for perinatal care

#### Institutional issues

- (1) Inadequacy of system to resolve medical disputes
- (2) Legal problems related to Article 21 of the Medical Practitioners Law and Article 30 of the Public Health Nurse, Midwife, and Nurse Law
- (3) Application of criminal law to medical errors

Future prospects of the obstetric and gynecologic care system: The current system should be transformed into a new system that allows for the stable provision of obstetric and gynecologic care in an atmosphere of well-established safety

Proactive formation and maintenance of a hierarchical network in the obstetric care zone, and positive administrative support and guidance for the network

- (1) Development of an obstetric care system that can respond promptly to emergency cases
- (2) Groups of regional childbirth delivery facilities where prompt instrumental or operative delivery, including cesarean section, are always available
- (3) Regional obstetric and gynecologic centers that offer 24-hour services
- (4) Establishment of a perinatal emergency-care system

#### Improved working conditions and treatment of doctors

- (1) Provision of working conditions that facilitate the retention of female doctors
- (2) Better treatment of hospital doctors by improving the flexibility of employment conditions: provision of rewards suited to the actual work provided

#### Specific measures for achieving the future vision. In regard to obstetric care:

It is necessary to prepare conditions that will ensure existing obstetric care providers remain and work as long as possible to prevent future crises in obstetric practice. As long as there is shortage of midwives in the clinical field, nurses should be permitted to perform pelvic examinations as assistants in medical treatment.

After the current situation of clinical practice stabilizes, transfer to a better, safer system should be attempted through policy making. In this process, regional obstetric and gynecology care centers and core hospitals should be rebuilt to larger size. Decreasing the number of childbirth delivery facilities will be unavoidable.

Development of a medical dispute-resolution system by the national government

- (1) Alternative dispute resolution for medical disputes
- (2) Organization to determine the cause(s) of medical errors
- (3) A no-fault compensation system for medical errors

Ob-gyn doctors should play a proactive role in the establishment of obstetric care zones and in the growth of groups of regional childbirth delivery facilities and regional obstetric and gynecologic centers. The government should provide active support for these activities.

Ob-gyn doctors should make proactive efforts to achieve better working conditions and treatment, and thereby attempt to increase the number of new ob-gyn specialists and to maintain and develop obstetric and gynecologic care. The ob-gyn profession should actively help to resolve problems that female doctors encounter.

(April 12, 2007, Exploratory Committee on the Ob-Gyn Care System of the Japan Society of Obstetrics and Gynecology)

#### Table 2 2007 JSOG obstetric care system-related action plan (summary)

### Activities of JSOG

- (1) Provide information and education
  - Enhance public relations activities to facilitate the public's understanding of obstetric and gynecologic practice (obstetric care system and ethics issues)
- (2) Support clinical practice from the standpoint of medical sciences
  - Develop practice guidelines
  - Reinforce specialist training
- (3) Stress the appeal of obstetrics and gynecology to recruit more medical students and trainee doctors
  - Recruiting DVDs
  - Summer school
  - Encourage more male medical students and doctors to enter the ob-gyn profession
- (4) Support doctors in clinical practice
  - Provide perinatal emergency doctors with a proper allowance for emergency care and childbirth delivery care
  - Ensure good working conditions
  - Ensure that the work environment does not result in Karoushi (death from over-working)
  - Ensure that the work environment enables female doctors to continue working
- (5) Develop regional obstetric and gynecologic centers
  - Consolidate core hospitals with the aim of enhanced functioning
  - 24-hour emergency services to meet the needs of the local community
  - Create facilities that provide good working conditions and enable female doctors to continue working
  - Improve hospital management such that it creates an environment in which doctors and other medical staff wish to continue working

### Approach government and administrative authorities

- (1) Establish a system to handle medical disputes
  - Organization for Alternative Dispute Resolution (ADR)
  - Organization to identify the causes of medical errors
  - Development of a no-fault compensation system
- (2) Enhance perinatal care promotion projects
  - Review the general framework of obstetric care
  - Resolve the shortage of neonatal ICUs
  - Intensify cooperation between regional medical facilities
  - Problems involved in the operation of projects (e.g., modification of cases subject to "additional charges for maternal and fetal ICU" in the medical fee system)
- (3) Add payment to the "additional charge for management of high-risk pregnancies" in regional medical centers and core hospitals
  - Additional charges for management of high-risk pregnancies and deliveries
- (4) Stabilize conditions surrounding childbirth and delivery
  - Increase the lump-sum allowance for childbirth and nursing
  - Secure regional childbirth delivery facilities
  - Provide information about childbirth delivery facilities
- (5) Intensify regional healthcare cooperation
  - Revise the medical fee for cooperative management of high-risk pregnancies and parturient women

and childbirth. Thus, reform is indispensable. Reform will be necessary to improve working conditions and the level of care through much closer cooperation among regional perinatal care facilities and the restructuring of existing core hospitals into more modern, up-to-date facilities.

### Action plan related to the obstetric care system

In 2007, JSOG formulated an obstetric care system-related action plan as a specific action program and initiated activities to support health care providers in the field of obstetric practice (http://www.jsog.or.jp/news/pdf/actionplan\_H19\_06\_16.pdf) (in Japanese). Table 2 presents a summary of the action plan. In particular,

JSOG intends to address the issue of providing doctors with a proper allowance for emergency care as well as delivery and childbirth care services in the field of perinatal emergency care, thereby supporting ob-gyn doctors practicing under the severe working conditions of understaffed facilities.

### Postscript:

In August 2008, Fukushima District Court declared the Ob-Gyn doctor was not guilty in all the charges, and the prosecutor abandoned to appeal to a higher court. The doctor is going to resume Ob-Gyn clinical practice. The long-term influence of this case needs to be clarified by future investigation.

# **Current Status and Future Prospects of Hospital Midwifery Departments**

JMAJ 51(4): 255-257, 2008

Kyoko YOKOO,\*1 Mayumi OKANAGA,\*2 Masayo AWANO\*3

### **Abstract**

Although the recent shortage of obstetricians in Japan has resulted in the closure of obstetric wards at a number of hospitals, various countermeasures are being developed to deal with the problem. The Midwifery Professional Committee of the Japanese Nursing Association has prepared a guidebook entitled "Midwives at Hospitals and Clinics: Toward a System of Independent Care." The guidebook advocates a system that would allow midwives to independently assess whether the conditions of the mother and child are normal or abnormal and to provide care during pregnancy, delivery, and the postpartum period, while taking into consideration the preferences of the parturient woman and her family, as well as cooperating and apportioning duties with doctors. We believe that establishing such a system would adequately compensate for the current shortage of obstetricians. To facilitate midwives in undertaking a more independent role, it is necessary to establish systems of re-education and training of midwives, to obtain better understanding from obstetricians and pediatricians, and to define the distinctive role of the midwife.

Key words Hospital midwifery departments, Shortage of obstetricians, Midwives, Independence

### Introduction

A shortage of obstetricians has resulted in the closure of obstetric wards at a number of hospitals in Japan, and countermeasures are being developed to deal with this problem. The Midwifery Professional Committee of the Japanese Nursing Association set up a subcommittee in 2004 and in March 2006 developed a guidebook entitled "Midwives at Hospitals and Clinics: Toward a System of Independent Care." This system proposes a new approach to providing care of both mother and child in addition to making good use of midwives' expertise. We believe that the establishment of this system will be able to adequately compensate for the shortage of obstetricians. In regarding a midwifery department at hospitals as a unit of the entire

system, in which midwives would provide midwifery care independently, this paper discusses the current status and future prospects of the midwifery department.

## Creating a System in Which Midwives Would Provide Midwifery Care Independently

The subcommittee initially attempted to develop a guide for setting up an in-hospital midwifery clinic to promote such clinics within hospitals. However, there was concern that the name "in-hospital midwifery clinic" in Japanese might infringe on Article 3 of the Medical Care Law that prohibits the use of the term midwifery center and similar terms for facilities that do not correspond to defined midwifery centers. In addition, this expression has been used commonly

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Table 1 Model cases of the system in which midwives provide midwifery care independently

	Saiseikai Utsunomiya Hospital	Fukaya Red Cross Hospital	Sano Hospital
Motive for setting up the system	To aim at practicing an obstetric department chosen by parturient women in spite of decreasing cases of delivery	To realize the ideal vision of midwives under the current situation of the shortage of full-time doctors	Simultaneous pursuit of feeling secure in the hospital environment and feeling homey in a midwifery center
Basic data			
Number of beds in obstetric ward	32 in obstetric ward	42 in mixed ward of ob-gyn and internal medicine	33 in mixed ward of ob-gyn and other specialties
Annual number of deliveries	1,000	700	520
Affiliation of midwives	Obstetric ward staff belongingto the Nursing Department	Obstetric ward staff belonging to the Nursing Department	Clinical Technology Department (Midwifery Division)
Mode of providing nursing care	Module-type (partly by function) two-shift system	Primary nursing (in combination with module-type) irregular two-shift system	In-hospital midwifery care system (team midwifery care: two-team formation, on call at night)
Childbirth expenses	420,000-450,000 yen	400,000-450,000 yen	300,000-350,000 yen
Midwifery outpatient clinic			
Scale	Open once a week from 14:00 to 17:00. 30 min per person	Open 5–6 days a week from 8:30 to 15:00. 15–20 min per person	Open 6 days a week from 9:00 to 16:00. 45 min per person
Target	Applicants who are at 20–40 weeks of gestation	Pregnant women with established due date who are not at risk (applicants are seen by a doctor)	Applicants who are at or after 24 weeks of gestation and who fulfill eligibility criteria
Evaluation by a doctor	Early gestation to 20th week, at 34 or 35 weeks (once), and after 40th week	From the initial examination until the due date is established	Until the 24th week of gestation, at 28 weeks, and one month after delivery
Delivery			
Attendance by a doctor	Present even in cases of normal delivery	Absent in cases of normal delivery	Absent
Mode of delivery	Freestyle delivery, delivery in water	Freestyle delivery	Freestyle delivery, delivery in water
Fetal monitoring	Intermittent auscultation	Intermittent auscultation	Intermittent auscultation
Vascular access	Implementation as needed.	None	None
Medication	When judged necessary by a doctor.	None	None
Hospital care in puerperal period			
Evaluation by a pediatrician	At birth, at discharge, one month after birth	Neonates are managed by the Department of Pediatrics	Once on admission, one month after birth
Maternal care provider	Midwife	Midwife and doctor	Midwife
Mode of hospital stay of the mother and neonate	24-hour rooming-in	Rooming-in	Rooming-in
Examiner at discharge	Doctor	Midwife and doctor	Midwife

[Prepared from "Current status of midwifery systems in midwifery center models (1)–(3). Japanese Journal for Midwives. 2006;60(4):295–306."]

without a clear definition of its meaning or a social consensus in regard to it. Considering these circumstances, the subcommittee discussed a system in which midwives would provide midwifery care independently, without using the specific term "in-hospital midwifery clinic."<sup>1,2</sup>

This system, in which midwives provide midwifery care independently is defined as a one that allows midwives to independently assess whether the conditions of the mother and child are normal or abnormal and to provide care during pregnancy, delivery, and the postpartum period, while considering the preferences of the parturient woman and her family, and while cooperating and apportioning duties with doctors in a medical institution capable of emergency treatment.<sup>1</sup>

## **Current Status and Future Prospects of Hospital Midwifery Departments**

Three model cases of a system in which midwives would provide midwifery care independently are shown in Table 1.3-5 Even among these cases, there is a difference in the degree of independence of midwives' roles, as reflected in variations in the timing of reference to the midwifery outpatient clinic, presence or absence of a doctor in cases of normal delivery, and consultation with the puerperal woman and neonate at discharge. In order to cope with the shortage of obstetricians, it is indispensable for midwives to carry out their role and uphold their responsibilities. However, under the current situation, midwifery practice is necessarily under the supervision of doctors. To achieve greater independence of midwives at work will require re-education and training of midwives, better understanding from obstetricians and pediatricians, and a definition of the distinctive role of midwives.

The formulation of functional structures is also

an important issue. What should be noted when we refer to the midwifery department at a hospital is the affiliation of midwives. At Sano hospital, one of the model cases in Table 1, two separate systems (the in-hospital midwife care system managed by midwives and the doctor care system managed by ob-gyn doctors) are functioning to realize the initial target, i.e., simultaneous pursuit of safety, security, and comfort. The in-hospital midwife care system is independent of the nursing department; midwives in this system belong to the Midwifery Division of the Clinical Technology Department, which also includes Pharmacy and the Division of Nutrition.<sup>5,6</sup> We believe that it is desirable for the midwifery division to become a midwifery department independent of the clinical technology department, and that thereby midwives can play a more independent role in providing midwifery care and compensate for the shortage of obstetricians, responding to pregnant women who wish to give birth to their babies at home or at a midwifery center.

#### Conclusion

Given the current trend promoting the consolidation of obstetric facilities, we think that birth centers affiliated with hospitals, but not restricted to a narrowly-defined "midwifery departments at hospitals," are necessary to serve the needs of pregnant women and to support the health of mothers and children and their families. Such birth centers represent a modern-day version of the "maternal and child health centers" (prescribed by the Maternal and Child Health Law in 1965) that used to be an important base for regional maternal and child health, and they seem to correspond to the system that would ensure that midwives provide independent midwifery care.

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### **Article 21 of the Medical Practitioners Law**

JMAJ 51(4): 258-261, 2008

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#### **Abstract**

Since 2000, attention has been focused on the professional obligation to report any unusual death to the police, a requirement based on Article 21 of the Medical Practitioners Law. However, facilitation of its enforcement has caused confusion in the field of clinical practice in Japan. In 1999, an incident that occurred in the Tokyo Metropolitan Hiroo Hospital became a major social issue. In this case, a patient died because an incorrect drip infusion was confused with another drug and administered by a nurse. Following the incident, some of the persons involved attempted to cover it up. With this incident serving as an incitement, a movement was initiated to improve medical practice by reporting medical errors to the police to inquire into the criminal responsibility of medical providers. However, several years after this movement was initiated, it has become apparent that this policy is not working well.

First, it is unclear whether the original concept of Article 21 of the Medical Practitioners Law (obligatory reporting of unusual deaths within 24h) included medical care-related deaths. Second, examining the criminal responsibility of medical providers does not necessarily lead to disclosure of the cause of medical errors or to the prevention of recurrence, nor does it help to eliminate mistrust in the arena of medical services. Rather, it places a heavy burden on the medical care system. It appears that the time has come to abandon dependence on the criminal justice system and to formulate a mechanism that will offer an improved form of patient safety.

Key words

Patient safety, Medical errors, Article 21 of the Medical Practitioners Law, Report to the police, Medical care and law

#### Introduction

On February 18, 2006, newspapers reported that a doctor in Fukushima Prefectural Oono Hospital was arrested. The doctor was accused of professional negligence resulting in death and violation of the Medical Practitioners Law in regard to the death of a pregnant woman who died from excessive bleeding because of improper medical care during a cesarean section. However, the Japan Society of Obstetrics and Gynecology and the Japan Association of Obstetricians and Gynecologists raised serious questions as to the actions of the police, for the following reasons: it was difficult to attribute the death to the fault of the doctor since placenta accreta, as in her case, is extremely difficult to diagnose preoperatively.

Further, the hospital promptly set up an investigative committee, illustrating its lack of intention to cover up the incident. One of the reasons for the arrest was violation of Article 21 of the Medical Practitioners Law. This article specifies "doctors who examine a dead body or a stillborn baby at a gestational age of 4 months or more and recognize an abnormality must report the case to the police station in charge of jurisdiction." Violators of this regulation are subject to a fine of 500,000 yen or less, as prescribed by Section 2, Article 33, of the Medical Practitioners Law.

This paper discusses the significance of Article 21 of the Medical Practitioners Law, which had attracted almost no attention until approximately 10 years ago, and considers how the criminal justice system should deal with medical incidents.

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### Past and Present of Article 21, Medical Practitioners Law

### History of Article 21, Medical Practitioners

Article 21 of the Medical Practitioners Law has been in existence since 1874. The article obligates the medical reporting of unusual deaths by doctors to facilitate the detection of crimes, because unusual deaths are likely to be associated with crimes. A typical case would be one in which a patient who was brought to a hospital died despite efforts to save his or her life. If the doctor in charge suspected poisoning, he or she would report it to the police. If a crime were indicated, the criminal might be at large and might escape or carry out repeat criminal offenses. Because of the need to initiate an investigation as soon as possible, doctors are required to report the case within a period of 24h. Although cooperation in an investigation normally should be a voluntary action, it is imposed on doctors as a legal obligation because they are more likely to come into contact with unusual deaths that may be associated with crimes, such as the above example. Criminal sanction for violating this obligation, however, remains at the level of a monetary penalty.

As indicated by this specification, unusual deaths should be understood in the broad sense. The prewar Supreme Court advocated that an unusual death meant a death in any situation that caused doubt as to simple death by disease (p.1226 of the report of court decisions, vol. 24, issued September 28, 1918), and opinions from the academic circle have upheld this opinion.

However, it is questionable whether the court would have assumed the following cases: 1) Doctor A intentionally administered poison to Patient B on the occasion of medical treatment. In this case, does Doctor A have an obligation to report this as prescribed under Article 21 of the Medical Practitioners Law? Article 38 of the new Constitution formed after the war admits that any person is free from coerced confession (the right to remain silent). Therefore, it is unreasonable that only doctors who commit murder are obliged to surrender themselves. 2) Doctor B mistakenly injured an artery outside the affected site of a patient, causing the patient to die as a result of excessive bleeding. The doctor admitted fault, and explained what had happened and apologized to the bereaved family. In this case, would the obligation to report unusual death as prescribed by Article 21 of the Medical Practitioners Law be applicable? If this case is a criminal case, the charge is professional negligence resulting in death. However, under the present constitution, obligation to report unusual death by Doctor B may be inconsistent with Article 38 of the constitution, the same as in the aforementioned case. In addition, it is questionable whether these cases were assumed at the time the law was formulated. The administrative governmental agency that holds jurisdiction over the Medical Practitioners Law held a clearly different view. According to "Interpretation of the Medical Care Law and the Medical Practitioners Law/Dental Practitioners Law" issued in 1981 under the head of the General Affairs Division, Health Service Bureau, the then Ministry of Health and Welfare, Article 21 of the Medical Practitioners Law was explained as follows:1 "Since dead bodies or stillborn babies sometimes show signs of crimes including murder, assault resulting in death, damage to a corpse, and criminal abortion, for the convenience of the police, obligation to report such unusual cases has been prescribed." Note that there was no reference to cases of professional negligence resulting in death where medical malpractice caused by the doctor him- or herself was involved.

The situation, however, has changed greatly in recent years, following a series of actions taken after 1990 by the then Ministry of Health and Welfare and forensics experts based on the scarcity of autopsy cases in Japan, as well as two triggering major medical errors that occurred in 1999.

### **Recent changes**

In January 1994, the Japanese Society of Forensic Medicine developed guidelines concerning "unusual deaths." In their guidelines, "any unexpected death related to medical action and any suspicious case" were considered cases of unusual death, regardless of whether or not there was negligence. In addition, in 1995, the Health Policy Bureau of the then Ministry of Health and Welfare issued a note clearly stating that these guidelines be used as reference.<sup>2</sup>

In January 1999, an operation was performed on a wrongly identified patient at Yokohama City University Hospital. In February of the same year, a patient died in Tokyo Metropolitan Hiroo Hospital because a wrong drip infusion was confused with another drug and administered by a nurse, and there was a movement to cover-up the matter by the persons involved. Two nurses who were directly involved in this case were promptly assigned 1 year of imprisonment and 7 months of imprisonment (each with suspended sentences) for professional negligence resulting in death. The director of the hospital and other persons were prosecuted for the preparation and execution of a signed false public document (recording of false information on the death certificate) and violation of Article 21 of the Medical Practitioners Law (failure to report an unusual death of a patient within 24 h after confirmation), and the suit against them was sent to the Supreme Court.

As a result of these circumstances, the Department of National Hospitals of the then Ministry of Health and Welfare prescribed in August 2000 that, in cases of unusual death, the director of the hospital has to report the case promptly to the police station under its jurisdiction, and sent notification of this rule to national and public hospitals throughout Japan. In July 2002, guidelines of the Japan Surgical Society were published, ruling that the doctor in charge promptly and voluntarily report cases of death or serious injury to the appropriate police station. In 2004, the Supreme Court concluded in the case of the Hiroo Hospital that application of Article 21 of the Medical Practitioners Law to doctors who have carried out professional negligence does not contravene the Constitution.

### **Patient Safety and Criminal Justice**

### Role of criminal justice

Robert Leflar, a law professor at the University of Arkansas, states in regard to the legal control and support of patient safety in Japan that the most important difference between Japan and the US is the magnitude of the role of criminal justice.<sup>3</sup> According to him, both the Fukushima Prefectural Oono Hospital case and the Tokyo Metropolitan Hiroo Hospital case, and even the case involving the incorrect identification of patients at Yokohama City University Hospital would not be dealt with as criminal cases in the US. Although civil litigation does occur, and the nurses and doctors involved are subject to administrative punishment, medical providers in the US are seldom involved in criminal proceedings.

Professor Leflar explains this difference between

the two countries in terms of two reasons peculiar to Japan. First, a charge of "professional negligence resulting in death and injury" is part of the Japanese Criminal Code, and it is understood that even simple negligence can constitute a crime. Although the US also has a charge of negligence resulting in death, it is restricted to serious negligence and demands a higher level of criminal intent as a subjective requirement. Second, in Japan, there is no choice but to rely on the criminal justice system because no other mechanism functions to respond to and sanction medical errors.

However, he also points out that criminal prosecution in several cases has clearly served as an effective "alarm" to the Ministry of Health, Labor and Welfare and to health professionals, but continuously placing emphasis on the criminal justice system in the regulation of medical activities has resulted in obvious problems and adverse effects.

First, criminal intervention may result in covering up the truth, rather than uncovering it. Criminal responsibility is characteristically focused on a particular individual, and is therefore not suitable for, or rather in opposition to, the recent recognition of medical malpractice as an issue of the system as a whole.

Second, criminal intervention enhances mutual distrust within the medical institution. In contrast to today's trend that stresses team medical care, bringing a serious criminal charge against a doctor or nurse who made an error has repercussions among teams of health professionals. Targeted doctors and nurses may suffer a sense of isolation, which then can interfere with their cooperation in the peer review process or other approaches to the prevention of recurrence of errors in the hospital.

Third, since medical errors are within the scope of medical practice, to leave cases to the police, who do not have specialized medical knowledge, seems to deviate from the pursuit of professional responsibility of medical providers. Such an attitude cannot rebuild trust in the medical profession. In the first place, medical errors are different in character from traffic accidents and other recent accidents in Japan in which the manufacturers of elevators and water heaters have been held accountable for violating safety precautions.

Unfortunately, medical providers cannot promise cure to their patients. The current situa-

tion of medical care is that certain success cannot be guaranteed. In addition, even if people tend to distrust health care, they still have to rely on it. It is also difficult for police officers, who are unfamiliar with medicine, to determine the presence or absence of negligence. It should be noted that administrative punishment, such as that of suspending a driver's license, for instance, is unlikely to have a profound impact on most drivers who cause traffic accidents. In contrast, forfeiture of one's medical license undermines the foundation of a doctor's life, thereby imposing sanctions on the doctor without instigating criminal punishment. In fact, if all unusual deaths and unusual stillbirths under the definition of "unusual death" as determined by the Society of Forensic Medicine were reported to the police, they would exceed the ability of the police to function, thereby limiting police capacity to pursue criminals.

#### **Future Directions**

In recent years, criminal justice has played a major role in the control of medical errors and patient safety in Japan. However, it is a serious problem to regard medical errors as crimes under Article 21 of the Medical Practitioners Law and to assign every case to criminal justice. To reduce medical errors and regain trust in health services, the use of Article 21 of the Medical Practitioners Law in its current form should be abandoned. Procedures to this end should be formulated promptly.

To realize truly patient-oriented health services, it is necessary for medical societies and the Ministry of Health, Labor and Welfare to amend current guidelines and to establish a new system that is independent of the police and that secures the transparency of health care and prevents the recurrence of medical errors.

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### A Model Project for Survey Analysis of Deaths Related to Medical Treatment

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### **Abstract**

A model project for the survey analysis of deaths related to medical treatment has been in operation since September 2005. When a death related to clinical practice occurs, an investigative report is prepared through the following procedures: 1) submission of an application based on the consent of the bereaved family and the medical institution; 2) autopsy by a pathologist, forensic doctor, and witness clinician; 3) preparation of a draft report of the evaluation results by doctors in charge of clinical evaluation; and 4) discussion in an evaluation committee that includes legal professionals and an overall coordinating doctor. Then, the results of the survey are reported at a briefing session where both the bereaved family and representatives of the medical institution are in attendance. Problems currently recognized include the following: an average period of 7 months is required until the briefing session is held, and confusions in the application and acceptance of cases under the enforcement of Article 21 of the Medical Practitioners Law. Another problem is that a heavy burden is placed on each member of the committee, but this can be overcome through the cooperation of academic societies of clinical medicine and by addressing institutional design. Autopsy and medical survey in this model project approximate the function of a clinicopathological conference. If a national consensus is reached as to the "unusual death reporting system," this project can serve as a model of a new system aimed at ensuring better medical care.

**Key words** Medical treatment-related death, Medical evaluation system, Model project, Clinicopathological conference, Article 21 of the Medical Practitioners Law

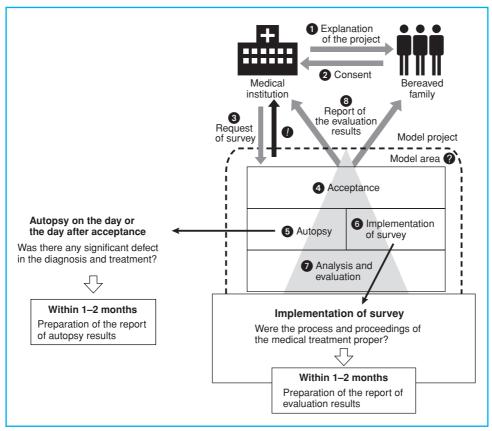
### Introduction

The model project for survey analysis of deaths related to medical treatment, in which autopsy, analysis, and investigation of medical treatment-related deaths are carried out in a neutral setting to determine the cause of death and to prevent the recurrence of similar cases, was begun in September 2005, with a grant from the Ministry of Health, Labor and Welfare (http://www.medmodel.jp/). Applications of 40 cases had been made in 7 areas by January 19, 2007. In the Tokyo area, 23 cases were accepted, 8 of which had already been evaluated, and the results were reported to the bereaved families and the medi-

cal institutions. Summary reports about limited number of cases are available on the above website.

This model project is a new system of medical evaluation (Fig. 1). Although the system currently has many problems, we believe that most of them can be overcome. More specifically, we believe that it is possible to formulate a system of medical evaluation that addresses medical treatment-related deaths in a form that approximates the autopsy and clinicopathological conference (CPC) that has been used in cases of death from illness (Table 1). However, the basic premise is that a new consensus as to the definition of unusual deaths and a proper system of reporting such deaths needs to be formed.

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[Adapted from the website of the model project for survey analysis of deaths related to medical treatment (http://www.med-model.jp/flow.html)]

Fig. 1 Model project for survey analysis of deaths related to medical treatment

Table 1 Comparison of the types of autopsy in clinical practice

	Autopsy in model project	Pathologic autopsy	Judicial autopsy	Administrative autopsy
Subject	Unexpected death during the process of medical practice	Death from illness	Death suggestive of crime	Death of unknown cause
Purpose	Elucidation of the cause of death, prevention of recurrence	Elucidation of the cause of death and the disease state	Criminal investigation	Public health
Executive body	Model project (third-party organization)	Medical institution	Police and prosecution	Tokyo metropolitan government, etc.
Autopsy doctor	Pathologist, forensic doctor, witness clinician	Pathologist, doctor in charge of the patient	Forensic doctor	Forensic doctor (medical examiner)
Involvement of clinician	Witnessing, evaluation	CPC	Comments	_
Form of disclosure of information	Issuance of repot to the bereaved and the medical institution Summary report to the public	Report to the bereaved  Case report	Expert opinion in writing	Attestation
Person briefing the bereaved	Regional evaluation committee	Doctor in charge of the patient or pathologist (rarely)	None	_
Legal force	None	None	Present	None

(Cited from Fukayama M, Kaji K. Jurist. 2006;1323:48-53.)

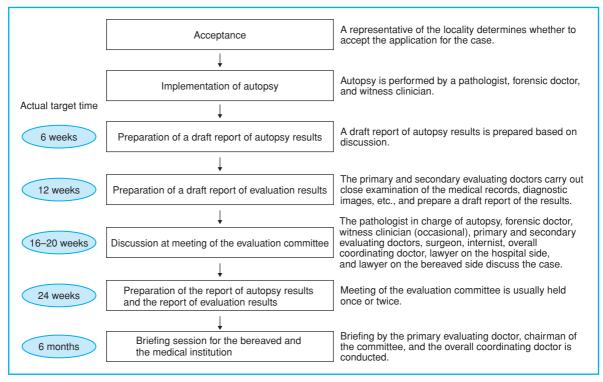


Fig. 2 Practical processing of the case

## Flow of Procedures in the Model Project (Tokyo Area) (Fig. 1)

### The process from application to autopsy

When the unexpected death of a patient has occurred during the process of medical care, or a patient's death has occurred as a result of medical treatment (medical treatment-related death), an application of the case is filed on the basis of consent of both the bereaved family and the medical institution.

Most of the cases that are handled by this model project have been those that hospitals have reported to the police in their jurisdiction as unusual deaths and were determined as deaths from illness or to be suitable for the model project rather than judicial autopsy.

### Flow of case evaluation in the model project

After autopsy of the case has been carried out by a pathologist, forensic doctor, and witness clinician, a draft report of the autopsy results is prepared by the doctors involved in the autopsy. Then, based on the results of the autopsy, the doctors in charge of clinical evaluation prepare a draft report about the results of evaluation of the medical treatment. Usually, two doctors are in charge of the clinical evaluation, each having been recommended by the relevant academic society. Using this draft report as material for discussion, a meeting of the evaluation committee consisting of about 10 members is held. Such meetings generally include two sessions. Through deliberation in committee, the final report is then prepared.

In the final stage of the project, a briefing session is held to provide information to the bereaved family and the medical institution. An outline of the case is then published, based on consent from the bereaved family and the medical institution (see http://www.med-model.jp/kekka.html).

### Composition of the evaluation committee

The evaluation committee is composed of 9 or 10 individuals including a pathologist in charge of the autopsy, a forensic doctor, a witness clinician (occasionally), primary and secondary evaluating doctors, an internist and a surgeon, a lawyer on the side of hospitals, a lawyer representing bereaved families, and a doctor from the local community

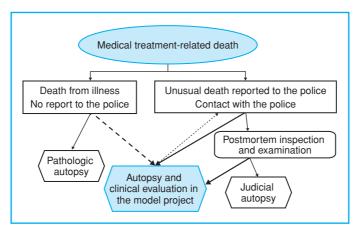


Fig. 3 Model project and Article 21 of the Medical Practitioners Law

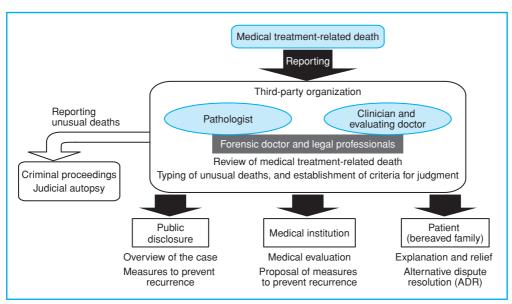


Fig. 4 Future perspective on measures for medical treatment-related death

who serves as coordinator. The internists and surgeons in the committee, knowledgeable professors or directors of hospitals, and solicited by the coordinating doctor.

### **Problems Involved in the Model Project**

It has become apparent that the model project has the following problems.

- (1) It was initially expected to take 3 months till the briefing session from acceptance of the application, but in actuality has taken a
- mean of about 7 months per case (Fig. 2). The amount of time required varies among cases depending on the autopsy, evaluation, and preparation of the case report.
- (2) A large burden is imposed on each member of the committee, particularly on the primary evaluating doctor who prepares the final report.
- (3) The greatest problem is the confusion as to the distinction between cases subject to criminal proceedings and those amenable to the model project, when they have not been

reported as unusual deaths to the police station (Fig. 3). In addition, some of the cases that were transferred to criminal proceedings may have been better addressed by the model project, because assessment as to the details of medical conduct from a clinical viewpoint was required. (In actuality, 2 of 23 accepted applications and 6 of 21 counselling cases were subjected to judicial or administrative autopsy in the Tokyo area.)

### **Future Prospects of the Model Project**

### Unusual death and death related to medical treatment should be handled separately

Based on current experience with the model project, the Ministry of Health, Labor and Welfare and other related government ministries and agencies are discussing the amendment of Article 21 of the Medical Practitioners Law and revision of the operational rules, and are considering the establishment of a third-party organization.

It is important to improve the reporting system (Fig. 4) as well as to introduce the alternative dispute resolution (ADR) and the no-fault compensatory system in the field of obstetrics, in order to formulate a more effective system. At the same time, it is required for medical providers to make a public appeal for such a system. In addition, efforts of medical providers in daily practice are also important to having such a system accepted. One of such efforts should be aimed at maintaining a high level of autopsy and CPC in cases of "death from illness," and at properly disclosing the results of evaluation to the bereaved family.

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# Medical Malpractice in Obstetrics— A look into the practice under South Korean law

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In the U.S., the number of medical malpractice cases generally has begun to fall each year. However, in obstetrics medicine, this decrease also corresponds to a falling number of practicing obstetricians in the United States. A 2002 USA Today article reported that the increased cases of medical malpractice and the concurrent rise in insurance premiums for doctors were causing a significant shortage of obstetricians in certain states where damage awards were akin to "lottery prizes." The American Council of Obstetricians and Gynecology (ACOG) reconfirmed this trend, reporting that disruptions to obstetrical care are now prevalent in nearly half of the states within the United States.<sup>2</sup> Politicians spear-heading an agenda of "tort reform" in Washington D.C. often reference this impact in the field of obstetrics to emphasize the need for changes in the system.

While the high insurance premiums and costs associated with malpractice cases have had a significant impact in the United States, in South Korea malpractice in obstetrics medicine has also had negative effects. A 5-year study compiled by the "Medical Citizen Consumers Association" found that medical malpractice suits in the area of obstetrics were a significant problem, ranking second highest of all malpractice cases after orthopedic surgical malpractice.<sup>3</sup> The study looked at the number of cases from 2003 through 2007 and found that obstetrics malpractice comprised 15.6% (or 1,248 out of 7,977 cases) of the total number of medical malpractice cases.

Recently, the Korean Consumer Protection Unit (KCP) reported that the damage awards in

obstetric malpractice were a necessary side effect to protecting consumers against obstetrics malpractice.4 Obstetricians in Korea, however, are likely to disagree with such conclusions. Instead, like their U.S. counterparts, doctors here are more likely to point to disruptions in medical care and in particular, an exodus of doctors from the practice. In fact, in a 2006 survey of 116 hospitals, a report found that the field of obstetrics had the highest rate of attrition of any field of practice in South Korea (16%); coming far behind in second was chest/breast medicine, which had a 10.6% rate of attrition.\*2 While this rate may be shaped by the recent dramatic decrease in birth rates in Korea,\*3 undoubtedly the threat of civil suits and the corresponding rising insurance premiums play a role like in the U.S.

Nevertheless, there are significant differences with malpractice actions in the United States. Despite the changing face of obstetrical medicine in Korea in part resulting from malpractice suits, Korea generally has fewer malpractice actions. While other cultural differences may weigh in, a key reason stems from the significant differences between the legal systems of the two countries. Based on a tradition of civil law, South Korea's legal system does not create the same set of incentives and low-entry barriers to raising a successful malpractice case as in the U.S. system, where pro-plaintiff evidence collecting procedures and potentially enormous damage awards have converged, turning malpractice actions into its own separate industry.

This memorandum examines some of the

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<sup>\*2</sup> Quite notably, the Korean National Statistical Office confirmed in 2006 that South Korea had the lowest birth rate in the world.

<sup>\*3</sup> The CIA World Factbook notes that the population growth in 2007 was a meager 0.394%. The UN Division on Population also notes in a 2006 survey report that the Korean population will be smaller in 2050 than the population in 2005. World Population Prospects Report by UN Division on Population.

most significant differences in the treatment of malpractice, and also looks at how the South Korean legal system has handled malpractice suits in obstetrics medicine. In particular, I will explore the consequences of Korea's civil law system and the lack of precedent, which has affected evidence-collection procedures and other logistical issues, including the possibility of concurrent civil and criminal actions. I further examine the role of South Korean criminal law, which penalizes professional negligence, on any potential civil suits including the effect on damage awards and evidence-collection.

### Civil Law vs. Common Law

South Korea has adopted much of the Continental European Civil Law system, but also has mixed in some elements of Anglo-American common law. The most notable distinction from the common law is the lack of precedent. Precedent is the binding power of previous decisions of superior and/or previous courts.\*4 As such, courts in South Korea are not required to adhere to prior decisions, even those decisions by the Korean Supreme Court. While there is deference to superior court decisions, particularly to the Korean Supreme Court, a lower court may choose to base its rulings without being restrained or controlled by prior decisions. Instead, the primary source for decisions rests upon the actual language of the legislation or statute. Consequentially, judges operating within this system have latitude in rendering their decisions, bound only to the language of the statute, and not, as in the common law, to the decisions of prior courts and any relevant statutes.\*5

For those in a common law jurisdiction, such a description naturally raises concerns that the decisions and awards will vary wildly. Despite these first impressions, the truth is that the outcomes of cases do not vary widely. There is a strong sense of respect and deference to the decisions of judges. Instead, and most significantly, the impli-

cations of the civil law system manifest in the timing and logistics of the proceedings. Without precedent, it is conceivable that a criminal action and civil action may occur concurrently. A single defendant could be subject to a private civil action at the same time that a criminal suit is pending. While in practice this is unlikely, it does, nevertheless, highlight an important consequence: prior fact-findings and/or decisions have no binding power on another court.\*6 They exist in different spheres. Moreover, such a system has important tactical consequences for would-be plaintiffs, who utilize the criminal system for evidence-collecting purposes in their private civil action.

### **Criminal Negligence**

Article 268 of the South Korean Criminal Code punishes "professional or gross negligence" which causes death or injury.\*7 The statute punishes such acts by either imprisonment for not more than 5 years, or by fine not exceeding 20 million won (or roughly \$20,000). Thus the crime is considered more than a minor offense. As a cause of action, criminal negligence parallels the elements of medical malpractice civil action in the United States, which is based in the common law of torts. The elements for finding guilt under Article 268 also mirror the necessary elements in a civil action by a South Korean plaintiff; the primary distinction, as would be the case under U.S. law, is that the burden of proof in a Korean civil action is a "beyond a reasonable doubt" standard.\*8

To prove criminal professional negligence, the prosecution must show that: 1) the professional had knowledge of the bad result; 2) the professional did not exercise good judgment, based on a comparison with other professionals who work in the same field or same circumstance; 3) the bad result was caused by the care/treatment of the professional; and 4) that there were actual damages. Distinguishably, the standard of care for all professionals, including doctors, is a national standard, and also requires consideration of the

<sup>\*4</sup> Black's Law Dictionary defines precedent as "the making of law by a court in recognizing and applying new rules while administering justice." Black's Law Dictionary, 8th Edition, Bryan A. Garner, ed.

<sup>\*5</sup> Lower courts are, however, bound to the Supreme Court's decision if the case has been remanded back to the lower court. From "The Korean Judiciary System," www.korealaw.com

<sup>\*6</sup> Under the common law, the term is titled "res judicata" or an issue already decided by the court. The term encompasses both fact-finding (or collateral estoppel) and final decisions (or issue preclusion). Black's Law Dictionary, 8th Edition, Bryan A. Garner, ed.

<sup>\*7</sup> South Korea Supreme Court webpage translated decisions, case # 2005Do3832, delivered on June 29, 2007.

<sup>\*8</sup> For a criminal action, the burden is on the prosecution to prove guilt beyond a reasonable doubt; in a civil action, the standard is generally guilt by a preponderance, or majority of the evidence.

time and place where medical treatment was provided (i.e. hospitals, clinics or private offices). This is slightly different from the U.S., where the standard of care for general practitioners is based on a local standard, while for specialists like obstetricians it is a national comparison of other similarly-practicing specialists. In essence, however, by factoring in considerations of time and place of treatment, the Korean standard becomes very similar to the U.S. standard of care.

Illustratively, the Korean Supreme Court in 2006 dealt with the issue of criminal negligence in obstetrics, delineating the necessary elements.5 The Court found the obstetrician not guilty, reasoning that the obstetrician did not cause the death of the fetus. In this case, the prosecution charged the obstetrician with negligence after he failed to discover that the fetus was inverted within the mother's womb, which caused the fatal complications during childbirth. The Court held on behalf of the obstetrician, finding that the fetus died not because of the doctor's negligence, but because the fetus suffered complications from being premature and because the expecting mother was already in poor health. These were the primary causes of death, not the obstetrician's care. The Court went on to say that the obstetrician had actually exercised reasonable judgment in light of the circumstances of the case and had actually provided sufficient care. His decision not to administer an ultrasound test and to disregard the mother's early labor pains were deemed reasonable decisions, and well within the bounds of his reasonable medical judgment.

## Criminal Negligence and Evidence-collection

While the criminal action is, in and of itself significant, it carries even greater consequences in the Korean system, where an individual plaintiff has virtually none of the evidence-collecting powers conferred to a U.S. plaintiff in civil litigation. More specifically, Korea lacks a true discovery system, leaving would-be plaintiffs without the enforcement means to depose witnesses and parties. This includes expert witnesses, who are often critical components to a malpractice action. Also significant for medical malpractice cases, the Korean system leaves plaintiffs without the

critical power to compel production of evidence. Civil litigation, in this respect, is a "come-as-youare" system.6 To compensate for these shortcomings, plaintiffs turn to, and build their cases from, the evidence collected during the criminal case by the prosecution. In the Korean system, the prosecution has significant powers, including confiscation of evidence and the ability to compel document production. These investigation records may later be used by civil courts. While under Korean civil procedure it is the judge who is empowered to collect facts and sift through evidence, it is a major advantage for a plaintiff to have such a record in existence. Thus, it is in the victim's best interests to raise malpractice issues to the Supreme Prosecutor's Office, which has the discretion to file a criminal negligence action and commence an investigation. Adding to the importance of this evidence is the high evidentiary burden in civil cases. Whereas the U.S. employs a "preponderance of the evidence" standard of proof for determinations in a civil litigation, the Korean system employs the heavier "beyond a reasonable doubt" standard normally reserved for only criminal actions in the U.S. Without the means to thoroughly gather evidence, would-be plaintiffs look instead to the evidence gathered by the prosecution during the criminal investigation. In this respect, the Korean government bears a substantial share of the costs for a plaintiff's civil action.

### Korean System of Damages

It is perhaps an equitable trade-off to have government resources fund a large portion of the litigation expenses in light of the actual damage awards. The fines and penalties resulting from the criminal action go directly to the state and not to the victim. While Korea has a system of deposit money that is used in criminal actions as an indemnity for the victim, the victim never collects directly from the fines issued by a criminal court. The system is unique, however, in that any settlement agreement reached between the victim and professional prior to the final verdict of the criminal action bears upon the sentencing meted out by the criminal court judge.\*9 Moreover, if there is no stipulation within the settlement agreement to the contrary, a settlement amount could be

<sup>\*9</sup> This creates an incentive for the criminal defendant to reach an agreeable settlement with the victim in order to mitigate criminal penalties.

deducted from any civil action awards.

As a recent New York Times article reported, the U.S. has one of the most unique damage award systems in the world, with punitive damages conferring substantial windfalls to plaintiffs.<sup>7</sup> In the U.S. system, the potential profit of a civil suit counterbalances the equally burdensome litigation expenses borne by a plaintiff. In contrast, under Korea's system, the inability to independently gather evidence coupled with the lower damage awards institutionalizes certain disincentives, dissuading many who would normally seek civil compensation.

Despite the discrepancy in the amounts awarded for malpractice, like damage awards in the United States, in South Korea damages are calculated to include both compensation for the actual damages suffered, any consequential costs for care required as a result of the injury, as well as mental pain and suffering. The end figure, however, is much less than the average in the U.S. The typical civil litigation actions award plaintiffs with actual compensatory damages for the injuries sustained and for any resulting treatment required as a result of the injury. Damages also include pain and suffering automatically awarded to the immediate family, which includes parents and grandparents. For other relatives, such as siblings, compensation for "grief" requires some proof of suffering. Pain and suffering, however, are often minimal amounts. Moreover, general award amounts are low. This is in part results from the use of a table of money damages, which a judge turns to in a civil proceeding for guidance. This table not only systematizes but also limits the total damage amounts. In calculating these numbers, the table factors in the nature of the job of the injured party, which serves to calculate lost wages/earnings. For obstetric malpractice actions in particular, where an infant is often the injured plaintiff, the damage awards are calculated to consider not only how long the infant has been living, but how much the infant could have potentially earned. Accordingly, these numbers are small.

In a 2002 case heard by the Korean Supreme Court, the court dealt with this issue of damage calculations. There, the infant suffered shoulder dystocia, which resulted from the obstetrician's failure to identify and treat the mother's sugar diabetes. The Supreme Court found on behalf of the mother and injured infant, reasoning that the

infant's injury directly resulted from the obstetrician's failure to provide proper medical care. The Court reasoned that any obstetrician exercising proper care would appreciate the dangerous complications resulting from the mother's diabetes. In addition, the doctor failed to administer an ultrasound, which would have revealed the enlarged size of the fetus, further increasing the chances of complications from shoulder dystocia. In this case, the obstetrician failed to take appropriate precautionary measures to prevent this dangerous and likely complication. However, despite finding on behalf of the plaintiffs, the Court reduced the amount of damages awarded to half the amount asked by the plaintiffs. Guided by the table of money damage awards, the Court examined the length of the injured child's life in order to determine the amount that the infant could have potentially earned. Instead of the granting the original 85 million W (or \$85,000), the Court awarded the infant 43 million W (or \$43,000). For the mother and father's pain and suffering, the Court awarded each 3 million W (or \$3,000) instead of the original 5 million W asked for each parent.

#### Conclusion

An examination into obstetric malpractice laws in Korea not only highlights important differences and fundamental similarities in the two legal systems, but perhaps is also a helpful guide for U.S. tort reform measures, especially in the area of malpractice. The objectives of the Korean system, similar to many other legal systems around the world, distinguish and separate retributive justice from compensatory justice. It is a system that punishes through action by the criminal system and compensates under the civil litigation system. Like many other jurisdictions in the world, the civil courts in Korea provide compensation to victims, and generally are not used to mete punishment (vis-à-vis punitive damages); that is a job for the state in criminal proceedings, where there are certain protections are built in to protect the defendant. Victims should not be allowed to receive a windfall from punitive damages. From this perspective, criminalizing negligence seems not only reasonable but necessary.

As a growing segment of the U.S. population push for limits to the damage awards conferred in medical malpractice actions in particular, it is illuminating to look beyond the actual dollar amounts of punitive damages, and examine other legal systems where the problem is approached from a different angle. While punitive damages and generally large damage awards are likely a mainstay to the U.S. system, it is important to

examine the underlying purpose and theories involved when considering reform programs. By comparing and learning from the differences with the Korean approach to malpractice, there may be a better understanding of how to improve the U.S. approach in the future.

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Japanese Association for Acute Medicine

### Management of the Open Abdomen— Usefulness of the bilateral anterior rectus abdominis sheath turnover flap method for early fascial closure

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The development of the concept of damage control and improved understanding of the pathophysiology of abdominal compartment syndrome have been great advances in both trauma care<sup>1-3</sup> and nontraumatic surgical conditions.4 However, these approaches require open abdominal management for a considerable period. We developed the anterior rectus abdominis sheath turnover flap method for early fascial closure in patients requiring open abdominal management who cannot undergo standard abdominal wall closure.<sup>5</sup> To the best of the authors' knowledge, this is the first report of this method being used as a technique for abdominal wall reconstruction in the early stages. The method may reduce the need for planned ventral hernia, in which the abdominal contents are covered with only a skin graft and abdominal wall reconstruction is required at a later date.

## What Are Damage Control and Abdominal Compartment Syndrome?

In conventional trauma care, definitive control and repair of all injuries is accomplished in the immediate postinjury setting. However, the physiologic derangement of the massive shock state often leads to a fully repaired but dead patient. In response to these catastrophic challenges, the concept of "damage control" has arisen as a treatment merely to control but not definitively repair injuries. Although control of hemorrhage and contamination is mandatory, the time required for performing formal surgical

procedures may aggravate the vicious cycle of coagulopathy, acidosis and hypothermia.<sup>1–3</sup>

The practice of damage control includes three separate components: 1) abbreviated resuscitative surgery for rapid control of hemorrhage and contamination, as well as for temporary abdominal wall closure; 2) ongoing core rewarming, correction of coagulopathy and hemodynamic optimization in the ICU; and 3) reexploration for definitive injury management and abdominal wall closure. However, prolonged open abdominal management is required if visceral edema continues for more than several days after damage control surgery.

Abdominal compartment syndrome (ACS) is an increasingly recognized clinical entity which occurs when intra-abdominal pressure is abnormally high in association with organ dysfunction. Although the most common cause of ACS is blunt abdominal trauma associated with massive hemorrhage, ACS can also occur in cases of burns and other non-traumatic conditions such as complex major abdominal surgery and severe acute pancreatitis requiring massive fluid resuscitation. 4,6,7 When a sustained increase in intraabdominal pressure is observed despite medical management (i.e. sedation, neuromuscular blockade, evacuation of abdominal fluid collection), decompressive laparotomy is required to treat the increased intraabdominal pressure and improve abdominal visceral perfusion and systemic cardiovascular/respiratory derangement.<sup>7</sup> However, this abdominal decompression procedure leaves the abdomen open.

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## Conventional Approach to Open Abdomen

In typical management scenarios for patients requiring open abdominal management who cannot undergo early standard fascial closure, many patients require prolonged open abdomen because of visceral edema. During this interval, the musculofascial structure of the abdominal wall contracts laterally, leaving patients with a large midline defect where standard fascial closure is not possible. Many patients have a large ventral hernia for a period during which the granulated abdominal contents are covered with only a skin graft, requiring subsequent complex abdominal wall reconstruction. To reduce the need for an intermediate period with a large ventral hernia that requires abdominal wall reconstruction at a later date, several techniques such as vacuum-assisted wound closure and application of a Wittmann patch have been employed as methods of achieving temporary abdominal wall closure.9-11

### Risk of Enterocutaneous Fistula

Enterocutaneous fistula formation is a devastating complication of open abdomen and has been reported to occur in 5% to 25% of cases. 10,12–14 Although lower fistula rates have been reported using vacuum-assisted wound closure, patients requiring prolonged mesh application have high risk of enterocutaneous fistula. The risk of enterocutaneous fistula may increase as the duration of open abdominal management is prolonged. 12 Moreover, the development of 3 of 14 fistulae after skin grafting of the granulated open wound has been reported, 10 suggesting the importance of early definitive wound closure to prevent fistula formation.

### Reconstruction of Abdominal Wall after Planned Ventral Hernia

Several methods have been proposed to accomplish late reconstruction of the abdominal wall for patients after a period with a planned ventral hernia following open abdominal management, such as component separation, <sup>16</sup> rectus turnover flap, <sup>17</sup> and modified component separation techniques. <sup>12</sup> Although use of the "open-book" varia-

tion of component separation as a technique for abdominal wall reconstruction after 6 to 12 months from initial operation has been reported, <sup>18</sup> application of such techniques in the early phase of open abdomen has not been evaluated.

### Application of the Bilateral Anterior Rectus Abdominis Sheath Turnover Flap Method for Early Fascial Closure and Prevention of Enterocutaneous Fistula<sup>5</sup>

### Management of open abdomen

In our institution, patients who required temporary abdominal wall closure underwent either Bogota bag closure (suturing of a sterile opened intravenous fluid bag to the skin edges) or a vacuum pack closure using the modified method described by Garner et al.<sup>9</sup> Recently, the latter

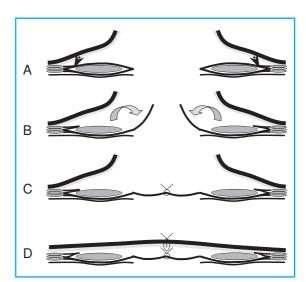


Fig. 1 Cross-sectional schematic diagram of the technique for creating a turnover flap from the anterior rectus abdominis sheath

The procedure is begun by separating the skin and underlying adipose tissue from the anterior rectus sheath to create a flap, with a base several centimeters beyond the lateral border of the rectus sheath (A). The turnover flap is then fashioned from the anterior sheath by longitudinally incising the sheath along the entire length of its lateral border. The site of this incision must be chosen carefully to avoid entering at the conjoined point of the internal oblique aponeurosis and the external oblique aponeurosis (B). The anterior sheath then is dissected from lateral to medial, freeing it from the rectus muscle. The linea alba is kept intact to serve as a medial hinge. The anterior rectus sheath turnover flap is approximated using interrupted sutures (C), and the skin is closed primarily (D) (from reference 5).

has been the preferred technique in all cases except for initial damage control surgery where aggressive resuscitation is ongoing and visceral edema therefore may increase after surgery. Dressings were changed every 48 to 72 hr until fascial closure or the decision was made to perform skin grafting over an intentional ventral hernia. If the abdominal fascia could be fully approximated under no tension, standard fascial closure was performed. After 10 to 14 days following initial laparotomy, use of a turnover flap constructed from the anterior rectus abdominis sheath was considered instead if the distance to be closed with fascia was less than 15 cm in patients unsuitable for standard fascial closure because of prolonged visceral edema. Formation of a planned ventral hernia using a skin graft over granulated abdominal contents was chosen in patients without edema resolution 3 weeks or more after the initial laparotomy who were not candidates for either method of fascial closure.

### Surgical procedure for the anterior rectus abdominis sheath turnover flap method

The procedure is begun by separating the skin and underlying adipose tissue from the anterior rectus sheath to create a flap. Next, creation of a turnover flap from the anterior sheath is begun by incising the anterior sheath along the entire length of its lateral border. The anterior sheath then is dissected from lateral to medial, freeing it from the rectus muscle. Kept intact, the linea alba serves as a medial hinge to mobilize the flap (Fig. 1). The fascial flap is then reflected medially with care so as not to damage the anterior sheath.

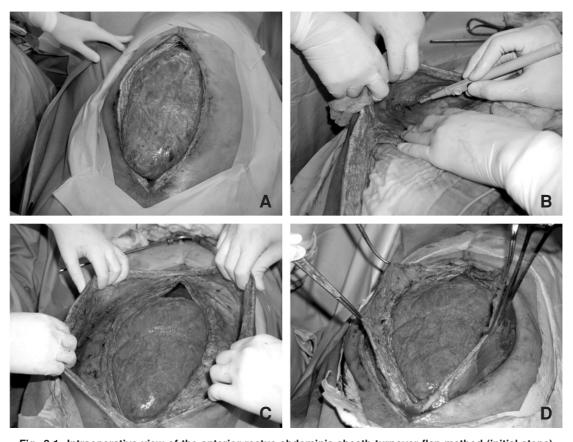


Fig. 2-1 Intraoperative view of the anterior rectus abdominis sheath turnover flap method (initial steps)

A: View just after vacuum packing removal (11th day of open abdomen). B: First, skin and underlying adipose tissue are separated from the anterior rectus sheath to create a flap. C: Skin and adipose tissue is completely dissected from the anterior sheath

from the anterior rectus sheath to create a flap. C: Skin and adipose tissue is completely dissected from the anterior sheath bilaterally beyond the lateral border of the rectus sheath. D: The anterior rectus sheath flap is reflected medially by dissection from lateral to medial, freeing it from the rectus muscle. The linea alba is kept intact as a medial hinge (from reference 5).

After creating bilateral turnover flaps, we approximate the flaps to cover the abdominal contents using interrupted sutures. Thereafter, the skin and underlying adipose tissue are approximated (Figs. 2 and 3).

### Results of our approach for open abdominal management

Fifty-four patients (21 trauma, 33 non-trauma patients) who required open abdominal manage-

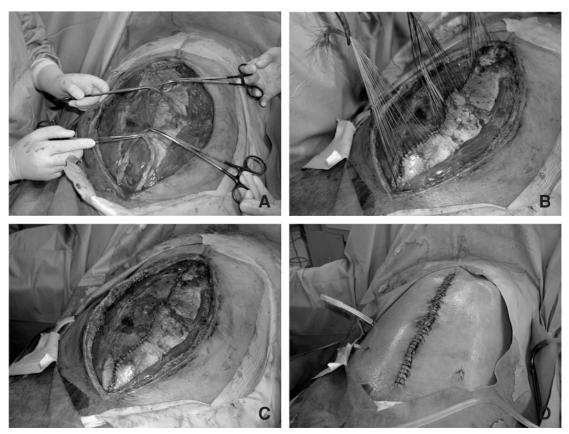


Fig. 2-2 Intraoperative view of the anterior rectus abdominis sheath turnover flap method (later steps)

A: Approximating the bilateral turnover flaps. B and C: Turnover flaps from the anterior rectus sheaths are approximated using interrupted sutures. D: Skin and subcutaneous tissue are sutured primarily (from reference 5).



Fig. 3-1 Open abdominal management in a pediatric patient with severe torso trauma

An eight-year-old girl with lung contusion, left diaphragmatic rupture, mesenteric injury, pelvic fracture and bilateral femur fracture. A: The abdomen was covered temporarily using Silo closure (3 days after initial laparotomy). B: Vacuum pack closure 10 days after initial surgery. C: The abdomen was covered using vacuum pack closure 30 days after laparotomy.

ment between April 1997 and August 2007 were treated. Patients with an acute abdominal wall defect arising from necrotizing fascial infection, or who died despite resuscitation within 48 hr of open abdominal management were excluded. Most patients had developed massive intestinal edema with coagulopathy secondary to large volumes of fluid resuscitation, precluding primary abdominal closure without undue tension after the initial laparotomy.

The mean duration of open abdomen was  $13.9 \pm 21.2$  days for all study patients. Of 33 nontrauma patients, 15 survived, as did 12 of the 21 trauma patients. In nontrauma patients, the time from initial laparotomy to standard fascial closure was 1 to 5 days in 8 patients; to turnover flap closure was 1 to 31 days in 10 patients; and

to skin grafting over a ventral hernia was 49 to 69 days in 3 patients. In trauma patients, the time to standard fascial closure was 1 to 5 days in 8 patients; to turnover flap closure, 6 and 30 days in 2 patients; and to skin grafting, 78 to 89 days in 3 patients. During the study period, no enterocutaneous fistulae or abdominal abscesses occurred.

## Fistulae and complications in patients treated with a turnover flap constructed from the anterior rectus abdominis sheath

No fistulae developed in 12 patients. Wound infection developed in 4 patients, with 1 infection being major. In that patient, the midline skin closure dehisced, but the approximated fascial flap remained intact. The skin was closed secondarily.

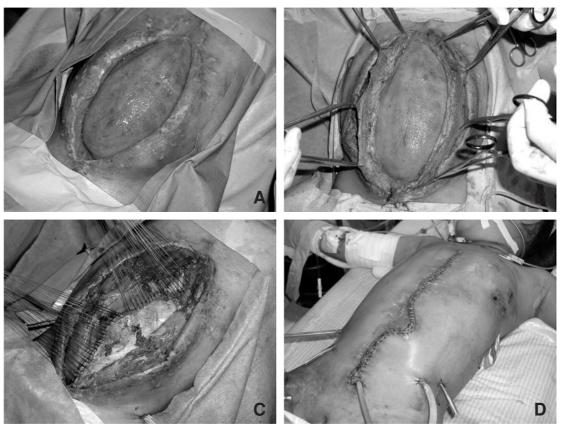


Fig. 3-2 Intraoperative view of the turnover flap method using the anterior rectus abdominis sheath carried out 30 days after initial laparotomy

A: View just after vacuum packing removal (30th day of open abdomen) showing granulated abdominal contents and retracted musculofascial structures of the anterior abdomen. B: The anterior rectus sheath flap is reflected medially, dissected from lateral to medial to free it from the rectus muscle. C: Bilateral turnover flaps from the anterior rectus sheaths are approximated using interrupted sutures. D: Skin and subcutaneous tissue are sutured primarily (from reference 5).

Although midabdominal bulging was observed in more than half of patients who underwent anterior rectus abdominis sheath turnover flap closure, no abdominal wall hernia requiring secondary reconstruction developed up to 80 months after the procedure.

In many patients requiring conventional open abdominal management, the granulated abdominal contents are covered only with a skin graft, which carries with it the risk of enterocutaneous fistula. These patients ultimately require complex abdominal wall reconstruction at a later date. Early abdominal wall reconstruction in noncandidates for standard abdominal wall closure has received little attention. Early fascial closure using the anterior rectus abdominis sheath turnover flap may reduce the need for skin grafting and subsequent reconstruction. This approach can be considered as an alternative technique for the early management of patients with open abdomen.

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The Japanese Orthopaedic Association

# **Current Status of Musculoskeletal Disorder Care** in Japan

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Kazuo YONENOBU\*1

Japan has entered the era of the aging society, with the 65-74 age group comprising 11% of the total population in 2005 and the 75 and over age group comprising 9%—a demographic composition in which 1 out of 5 people are elderly. Moreover, 1 out of 7 of these elderly people requires nursing care or support in their daily lives. Reasons for requiring nursing care or support (Fig. 1) overall include cerebrovascular disease, debilitation due to advanced age, falls/bone fractures, dementia, joint disorders, and heart disorders, with musculoskeletal disorders such as falls/bone fractures and joint disorders comprising a large proportion of these. In particular, musculoskeletal disorders were the reason for requiring support in more than one-quarter of cases, and since debilitation due to advanced age may also be included in deterioration of musculoskeletal skills, the proportion of people requiring care or support due to musculoskeletal disorders is in reality extremely high. In 2004 the Japanese Government formulated the "The New Health Frontier Strategy" and has been working to improve all kinds of health indices. In face of the facts outlined in the previous paragraph, the government's efforts include promoting prevention of nursing care and extending healthy life expectancy. In view of this social situation, the Japanese Orthopaedic Association has proposed the concept of "Musculoskeletal Ambulation Disability Syndrome" (Table 1) and has been conducting clinical studies and research on the medical examination system with the aim of extending healthy life expectancy and preventing an increase in the number of people requiring nursing care or support. The diagnostic indices for Musculoskeletal Ambulation Disability Syndrome are (1) single-leg standing with eyes open

and (2) 6-meter walking test. The former measures the length of time standing on one leg. If the person can stand on one leg stably for 15 seconds or more, there is deemed to be no problem. The test mainly examines balance capacity. The latter measures the time for a person sitting on a chair to stand up and walk to a point 3 meters away, then turn around and walk back to the chair. If this can be achieved within 11 seconds, there deemed to be no problem; nursing care is deemed necessary for daily life if the task takes 30 seconds or more to complete. In addition to these two indices, if the person is evaluated as Rank J or A (requiring support + requiring nursing levels 1, 2) on Index of Independence in ADL (Activities of Daily Living) for the nursing care insurance, Musculoskeletal Ambulation Disability Syndrome is diagnosed.

Using these methods screening is implemented and further testing is carried out if problems are found. A patient's clinical condition is analyzed and treatment appropriate for that condition (drug therapy, musculoskeletal rehabilitation, surgical treatment) is carried out. Such screening aims to restore mobility capability in order to extend healthy life expectancy and avoid the need for nursing care.

The Japanese Orthopaedic Association is a large medical society with approx. 23,000 members, of which approx. 16,000 are board-certificated orthopaedic surgeons. Activities range broadly, from the gerontological field to pediatric orthopaedics, and also include basic medicine.

In basic research, study in the field of regenerative medicine is particularly active. Basic research is advancing at a remarkable pace in the fields of cartilage regeneration, spinal regeneration, and disk regeneration, with some research at or near

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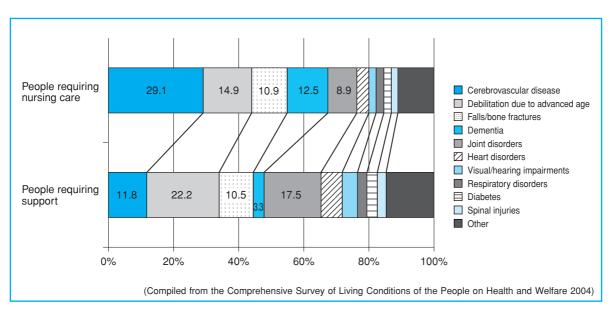
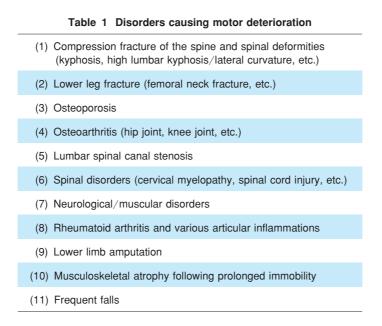


Fig. 1 Reasons for requiring nursing or support



the stage of clinical testing. Incidentally, Professor Nobuya Yamanaka of Kyoto University, who is drawing attention for his successful development of induced pluripotent stem cell (iPS cells) from human skin cells which have equivalent capacity to embryo-stem cells (ES cells), began in orthopaedics before switching to basic research.

In Japan, biomaterial research is also actively pursued; in particular, a wide variety of research is being conducted with success on the development of ceramic-based biomaterials due to the existence in Japan of a long-flourishing ceramics industry. Through the development of such biomaterials, combined with the above-mentioned advances in regenerative medical technology, function rebuilding technologies for treating musculoskeletal disorders are expected to improve more and more.

Returning to the clinical field, the following are characteristics of orthopaedics in Japan. First of all is the high standard of spinal surgery care. Because in the past Japan had a high incidence of tuberculous spondylitis, which was treated by orthopaedic surgeons, it became traditional for orthopaedic surgeons to treat spinal disorders. The incidence of tuberculous spondylitis dropped dramatically with the introduction of antituberculosis drugs, but even after this a broad range of activities in this field—from the development of cervical spine surgery techniques to research on cervical spinal cord pathology—were carried out due to the prevalence of conditions such as ossification of the posterior longitudinal ligament of the cervical spine and cervical spondylotic myelopathy. Amidst this trend, microendoscopic surgery techniques have advanced and increasingly are being partially applied to not only lumbar disorders but also cervical spine disorders.

Orthopaedics includes specialized treatments and research being carried out in many subspecialties, such as bone and joint surgery, trauma surgery, sports medicine, hand surgery, and bone tumors—so many in fact that there is not enough room here to mention them all. Through such activities, international exchange is flourishing. Begun in 1991 and expanded with the addition

of Europe, the Combined Meeting of Orthopaedic Research Societies (the United States, Canada, Europe and Japan) will next be held in Kyoto in 2010. Japan also has active exchange with countries throughout Asia, and lecture topic applications for symposiums and conferences are also increasing.

The government has been attempting to implement policies in response to the increase in the aged population and accompanying increase in medical expenses, as well as changes in the healthcare content and standards required by the public, but there is not necessarily agreement on these issues. Thus Japanese medical societies are in difficulties. As one of these societies, the Japanese Orthopaedic Association is also facing many problems such as difficulty in maintaining the number of orthopaedic surgeons to keep up with the increasing number of orthopaedic patients with the aging of society. However, we intend to bring together the wisdom of many orthopaedic surgeons in order to overcome this situation. Once we have successfully achieved this, we believe that Japanese orthopaedic surgeons will be able to apply their useful experience to the aging society-related musculoskeletal disorder issues in other countries that have yet to experience these.

### A Regional Medical Association That Works

JMAJ 51(4): 281-282, 2008

Hidenori TORIZAWA\*1

### A Regional Medical Association That Works

Every autumn the President of the Gifu Medical Association (GiMA) leads its full board members on a tour of the five districts in Gifu prefecture (the prefecture is divided into five communities and medical districts) to communicate and gather information, provide collective leadership to physicians qualified to treat health insurance patients and seek closer relations with district medical association members. We call this "a regional medical association that works."

### An Overview of Gifu Prefecture

Situated roughly in the middle of Honshu, Gifu prefecture is the center of gravity of the Japanese population. Running 120 kilometers east to west and 160 kilometers north to south, the prefecture is the seventh largest in Japan with an area of 10,598 square kilometers. An inland prefecture bordering on Aichi and Mie to the south, Nagano to the east, Shiga to the west and Fukui, Ishikawa and Toyama to the north, Gifu has a population of some 2.1 million people.

The prefectural capital of Gifu city is located in the center of the Nobi plain and is home to some 400,000 people. Mt. Kinka, on which Oda Nobunaga's\*2 famed Gifu Castle stands, is located in the center of the city, known for its scenic beauty as the location of cormorant fishing in the Nagara river flowing along the foot of the mountain. The city of Nagoya may be reached in 17 minutes by the shortest route on the JR railway. In the west is Sekigahara, renowned as the site of the decisive battle, and in the north mountains rise to heights of 3,000 meters in the Northern Alps



along the border with Nagano in the mountainous forested region famed for its cypress stands. Well-known sightseeing destinations include Hida Takayama, the Gero hot springs and the Shirakawago UNESCO World Heritage site. The prefecture is divided into the five community and medical districts of Gifu, Seino, Chuno, Tono and Hida.

#### Features of the Five Districts

Gifu District: Gifu district has the largest proportion of physicians to population in the prefecture, and Gifu city in particular has such a high concentration of physicians as to contest for the first and second positions nationally. In addition to Gifu University Hospital, the district is also home to numerous public and private hospitals and enjoys sufficient numbers of ob-gyn and pediatrics practitioners. However, depopulation, population aging and physician shortages are emerging in mountainous areas.

**Seino District:** Bordering Aichi and Mie prefectures in the south, the Seino district reaches from Kaizu city in the Waju river basin to Ibi county in

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<sup>\*2</sup> A famous feudal warlord in the 16th-century Japan.

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the north, a mountainous area bordering on Fukui prefecture. Healthcare conditions vary widely from urban to mountainous areas.

**Chuno District:** The Chuno district straddles the center of Gifu prefecture east to west. It is made up of five cities and two counties, from Gujo city in the north bordering Fukui and Ishikawa prefectures to Kani city in the south bordering Aichi prefecture and serving as a bedroom suburb for Nagoya. This district too encompasses both mountainous and urban areas, and healthcare conditions vary widely among them.

Tono District: Lying along the JR railway's Chuo Line and the Chuo Expressway, the Tono district borders Aichi prefecture in the south and Nagano prefecture in the north and is made up of five cities. The southern part serves as bedroom suburb for Nagoya and also features the ceramics town of Tajimi, and in the north Magomejuku, a way-station on the Nakasendo route bordering Nagano prefecture made famous by the early 20th-century author Shimazaki Toson, is now the city of Nakatsugawa. Healthcare conditions vary widely from urban to mountainous areas.

Hida District: Made up of three cities and one county, the Hida district is home to numerous sight-seeing destinations of national renown, including Hida Takayama, the Shirakawago UNESCO World Heritage site, the Oku Hida hot springs and the Gero hot springs. Among its hospitals are the Gero Onsen Gifu Prefectural Hospital and the Takayama Red Cross Hospital, but even relatively large hospitals in the district have problems securing physicians. As the greater part of the district is mountainous, it suffers severe shortages of emergency medical services and ob-gyn and pediatric practitioners.

### **Issues Arising from District Conditions**

Gifu district is the one that enjoys a sufficient supply of healthcare services, including even two perinatal centers. However, these two are the only perinatal centers in all of Gifu prefecture. Hospitals capable of treating acute myocardial infarctions are likewise concentrated in Gifu district, and although the prefecture has two dispatch helicopters, they cannot be dispatched at night or in poor weather. There is severe

depopulation and aging among the residents of the mountainous areas that make up the greater part of Gifu prefecture, healthcare backwaters except where pediatric and ob-gyn practices are concerned.

### **Activities of the Gifu Medical Association**

In 2006 the several district medical associations held events such as training courses and round tables. The topics covered by these events were complaints against medical practices, law suits, death with dignity, efforts underway in hospital-clinic partnership by the district medical associations, and district healthcare issues such as the inadequacy of attending physician opinions in long-term care insurance, guidance on checkups and healthcare for the newly insured, obstetric care and physician shortages.

Participants attending social gatherings with district medical association boards also raised issues such as the shortage of physicians in ob-gyn and other practices, long-term insurance and the Law for Support of Independence among the Disabled. Those of the district medical associations' questions that could be answered immediately were provided with replies on the spot, and the others were provided with considered replies several days afterwards. The boards are deliberating their requests and proposals, and considering what directions ought to be taken.

### Proposals to Local Governments and Political Leaders

Issues and proposals studied by the Board are communicated to the prefectural governor, its representatives and committees convened by the prefecture as opportunities arise. Under current conditions many problems, including those of ob-gyn and pediatrics practices and the uneven allocation of physicians, will take time to resolve, but we consider the roles of the GiMA to be to state our opinions and proposals to local government and political leaders at the prefectural level and to provide Gifu residents with security in their lives through cooperation in healthcare and medical treatment, and we are working daily to achieve these goals.

The Aichi Medical Association and Community Healthcare Provision System

JMAJ 51(4): 283-284, 2008

Akio FUJINO\*1

People say that Aichi is on fire now economically and socially. In 2005 the prefecture hosted the Aichi Expo, welcoming over 22.05 million domestic and international visitors, and human interaction with countries around the world is thriving thanks to the opening of Chubu International Airport in this area. This means that our community is continuing to grow and remains economically vibrant. The themes of the Aichi Expo were the development of modern societies and the prevention of global warming, literally the preservation of our global environment. Our local prefectural authorities and residents are united in ongoing efforts in these areas, and it's thanks to their efforts that Aichi prefecture is home to both an ample natural environment and modern advanced industrial society.

The new airport has made a gateway for products, culture and international human exchange.

Aichi prefecture is in fact basis for a key industry such as Toyota, the world-famous automaker. Also prominent in the prefecture is Mitsubishi's aerospace systems manufacturing operations and the many manufacturers clustered around them, said to be the largest such cluster in Japan. The full economic benefit derived from their presence is beyond measure.

The movement inwards and outwards of both goods and people has therefore grown dramatically in recent years, and while people's lives have thus become more active, their social milieu is also growing more complex.

The Aichi Medical Association (AiMA), located in the Chubu region of Japan, is one of the 47 prefectural medical associations which make up the Japan Medical Association.

With a population of 7.3 million people, Aichi prefecture is home to four medical universities,



and the AiMA has a membership of 8,700, the third largest among the local medical associations in Japan.

The AiMA is also honored to be the leading medical association of the Chubu region.

We are fully aware that our responsibility to this community as the local medical association is to provide healthcare and welfare services responsive to the rapidly changing needs and social environment of the prefecture's residents.

Our activities as community physicians are fundamentally grounded in the prefecture's community healthcare plan. The basic element of the prefectural plan currently is to build a systematic framework to reduce the incidence of in particular lifestyle-related diseases in an effort to cooperate with the nationwide campaign goal of securing limited financial resources for healthcare.

The prefecture's community healthcare plan divides the prefecture into 11 medical regions and establishes an individual healthcare plan for each region that may meet with the requirements of its local culture. These plans is subject to review within 5 years.

The role of the medical association is to provide backup for these healthcare and welfare services suited to the needs of the community, while the

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hospitals and medical institutions of local members coordinate to provide those services to local residents. The distinguishing feature that has emerged is the construction of a framework for the provision of "comprehensive healthcare services" that include trends in prevention, healthcare, rehabilitation and home medical care suited to particular complaints associated with lifestyle-related diseases.

Against the foregoing social background, the AiMA continues to provide public service.

The medical association's operational plan for this year comprises 38 individual elements. Below I discuss briefly those attached especial priority this year and some that are especially distinctive of the AiMA.

- (1) Patient safety measures: A mandatory program imposed at the national level in 2004, this includes programs to provide residents with safe medical care of higher quality. It covers complaints and disputes and physician training and handles some 830 cases annually.
- (2) Information technology: Although the medical field has adopted these advanced information and communications technologies to a considerable extent, we have yet to achieve the level indicated by national calls for a basic e-japan strategy and it cannot be denied that we are behind other industries and fields in this respect. We appreciate the significance of this matter, exhort efforts on the part of our members and are making steady progress annually.
- (3) Measures for emergency and disaster medicine and communicable disease prevention: The AiMA now hosts an emergency medical information center, which employs a staff of 23 and the Internet to exchange information with prefecture residents. Perhaps due to population growth and changes in the social environment, the number of emergency calls annually has risen to 195,000 in recent years.

We work continuously with regional disease control authorities and health research institutes to prepare against the incursion of communicable diseases, and especially emerging and re-emerging communicable diseases with the increasing international exchange. Both historically and geographically, Aichi has suffered extensive flood and earthquake damages, and we have been

warned that a major earthquake may occur in our Pacific coastal region in the near future. We are creating a system for exchanging information over the Internet and wireless networks.

- (4) Measures for securing physicians: Japan faces extremely severe circumstances in terms of both a shortage of hospital physicians and their uneven distribution. The phenomenon is a national one, not confined to remote rural areas but also notable in urban locations, and is an extremely serious issue for local residents. Its cause lies in the breakdown of the system by which universities have supplied physicians. The AiMA has established a "doctor bank," but it has unfortunately not been able to cope with the needs of hospitals.
- (5) Clinical trial program: The Japanese system of clinical trials is considerably behind those of other advanced countries, in terms of both its economics and time to approval.

This may be due to the excellent Japanese universal heath insurance system. Citizens who enjoy coverage for many high-cost drugs through health insurance lack motivation to participate in these clinical trials. This constitutes a waste of healthcare expenses.

A further disadvantage to Japanese citizens results from the lack, according to national law, of insurance coverage for pharmaceuticals that have received approval abroad. In order to resolve this problem, the state must call for both physicians and citizens to participate. The AiMA is one of the few regional medical associations successfully participating in this program.

(6) Formation of the AiMA Research Institute (including reconstruction of community medicine [ROC]): Published statistics relating to various healthcare systems deriving from the research of national and prefectural authorities tend occasionally to lapse into national or extensive regional reports and often fail to reflect seen in reality the local areas.

To open the bottleneck, the AiMA has begun conducting its own studies and research and formulating healthcare policy proposals for presentation to the various organizations concerned on the basis of conclusions reached. The institution engaged in this work was established and began operation in 2006.

### **Osaka Medical Association Activities**

JMAJ 51(4): 285-286, 2008

Yasuyuki TAKAI\*1

The Osaka Medical Association (OMA) was relaunched as a new democratic medical association on 1 November 1947 and last year celebrated its 60th anniversary. The OMA is the second largest medical association in Japan.

The OMA is based in the Osaka prefecture comprised of 64 city-level medical associations. As of June 2007 it had a total membership of 17,552, of which 7,917 member doctors are practicing at their clinics and 9,605 doctors are working for the hospitals.

The OMA has pursued a wide range of activities with the objectives of "giving prominence to medical ethics, the development of medical science and technology, the improvement of public health and contributing to the advancement of social welfare."

## Community Healthcare Promotion Council for Osaka Prefecture

Established in 1973 aiming at "expanding and enhancing health and welfare policy in Osaka prefecture and actively promoting community healthcare in order to achieve advances in healthcare and improve welfare of residents of Osaka prefecture," the Council is comprised of 30 organizations, including the three leading prefectural medical groups (the OMA, the Osaka Dental Association and the Osaka Pharmaceutical Association), other medical organizations, women's groups, the confederation of senior citizens clubs and other groups of local residents.

Its activities include efforts to make the local residents aware of difficulties which are faced by health professionals and protect the universal health insurance. In order to eliminate its financial distress, the Japanese government has recently been attempting to implement healthcare reform that focuses only on reducing medical expendi-



tures. The Japanese universal health insurance, which allows all citizens in Japan to receive quality healthcare services anytime and anywhere with impartiality, is now on the brink of crisis. In order to avoid the breakdown of the universal health insurance and strengthen the social infrastructure of healthcare, health professionals must joint with the general public to assert the need for increased public health expenditures, and the Community Health Care Promotion Council for Osaka Prefecture has a major role to play in achieving these goals. An assembly of prefecture residents was held in January 2007 at which over 1,700 people assembled to adopt the appeal. We have submitted requests to the Osaka Prefectural and City governments for appropriate budget to enhance the level of community healthcare.

### Female Physicians and Gender Equality

Recent years have seen a marked increase in the number of female physicians. They are playing a rapidly growing role in healthcare in Japan. In 2005 the OMA started a Female Physicians Council to address the issues currently faced by female physicians and discuss what roles they should play and how to reflect their opinions on

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the activities of the OMA. In 2006 the council was renamed the Gender Equality Study Committee and is now examining measures to improve the work environment of female physicians to support and promote their employment.

Discussions are underway on measures to support childbirth and child-rearing for female physicians, and efforts have been initiated towards the construction of a network of day care centers located within medical facilities.

### **Medical Issues Study Committee**

The OMA established Medical Issues Study Committee in 1998, composed primarily of young mid-career members who are potentially competent to create a future OMA, this committee is responsible to study a wide range of health issues and bring a fresh air to the OMA.

City level medical associations nominate one promising member each and the hospital-based physicians group nominates two members to the committee. The nominees are expected to be less than 50 years of age. They meet regularly on the second Wednesday of every month to discuss such issues as the health insurance system and community healthcare. They hold debates on topics of timely interest, thus training debate skills and enhancing their interaction skills as well. This committee has 59 members.

The committee members constantly consider what physicians and medical associations can do to improve and strengthen the healthcare system as one of the most important components of social security and develop community healthcare. They also are expected to be engaged in the committee activities with a strong sense of mission to enhance the health status of prefecture residents and public health as well. At the board meetings of their local medical associations, the committee members report the committee activities. These actions will lead to further improvement of local activities of the medical associations using by the acquired knowledge and human networks.

Activities in the first year of the committee have generally focused on lectures provided by OMA officers, followed by debates based on those lectures in workshops during the second year. Topics covered in 2006 included the following items:

- (1) Partial revisions to the Medical Care Law and Health Insurance Law and their implications
- (2) Home healthcare in the future
- (3) Activities of the medical association The themes of the debates are as follows.
- (1) Whether or not the medical association membership should be mandatory?
- (2) Whether or not an insurance exemption should be adopted?
- (3) Whether or not family doctors should be institutionalized?

Once a year, the committee also invites well-known researchers of health economics and health policy for special lectures to nurture their knowledge.

### **Designated School Physician Program**

In April 2004, the OMA introduced its unique program of the designated school physician, the first such a trial in Japan, for improved quality of school physicians in its efforts to meet with the increasing requirements according to the changes in social environment.

In addition to school physicians' primary duties of performing checkups and follow-up measures, there are increasing demands from schools for health education. The OMA Designated School Physician Program is the avenue through which we seek to upgrade the qualifications of school physicians and play a role in coping with different school health issues. JMA is also planning to introduce JMA Designated School Physician Program (tentative), but this has yet to be implemented.

The major activities of the OMA have been introduced as above. I would like to add that the OMA also runs a nursing school and healthcare center in its activities.

# Task Shifting: Necessary practice or dangerous precedent?

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Yoram BLACHAR\*1

Recently, we have been a witness to increased instances worldwide of tasks, traditionally performed by physicians, transferred to the purview of nurses and other medical (or sometimes non-medical) professionals.

In many countries, this is due to a shortage of doctors. These countries face the very real question of whether to provide medical treatment via nurses or not at all.

### Reforms at the Expense of the Patients

Where a country has an insufficient number of doctors, there will either be patients waiting weeks or months for treatment or left untreated altogether. Alternately, or in addition, physicians will be forced to work extra shifts and ultimately collapse under the superhuman workload. However, if the solution to the physician's heavy workload is the transfer of authority to perform certain procedures to nurses, how will we solve the problem of the nurses' increasing workload? The logical outcome would be to transfer their workload onward, to paraprofessionals and orderlies.

In Israel, the media has dealt over the last 6 months with the memo issued by the Director General of the Ministry of Health (the "Director"), which transfers authority to nurses to perform procedures legally allowed to be performed only by physicians. Many philosophical statements have been thrown about, slogans that don't reflect reality. I would like to set things straight and explain why the IMA opposes this trend and fears that it will seriously endanger public health.

The decision of the Director, which took effect at the beginning of June, transfers to nurses pro-

cedures and authority granted heretofore by law to physicians by renaming them "nursing procedures." These procedures have historically been part of the medical profession because of their inherent medical nature and the need to exercise professional discretion in their regard.

The legislator created a mechanism in the past whereby the Director could grant an individual permit to a specific nurse to perform "exceptional procedures" that are basically technical in nature and don't presume to replace the professional discretion of the doctor. Nonetheless, the Director decided, without any legal authority and without bringing the matter to a discussion in the advisory committee, as the law requires, to create a process whereby the power to make medical decisions requiring discretion would be broadly transferred to nurses.

Since the decision was publicized, various parties have taken advantage of the IMA's opposition to create a rift between the physician community and the nursing community. This will not work. Doctors and nurses have and will continue to work as a team, whose success arises from the fact that each party contributes a specific aspect to patient care and neither can function without the other. Physicians see in nurses a vital part of the medical team and recognize their great contribution. However, we must be careful not to blur the distinction between the training received by doctors and that received by nurses, who are trained for different tasks altogether. Physicians learn medicine for a period of 7 years, followed by an average of 6 years of residency and often an additional 2 to 3 years of sub-specialties or fellowships. This lengthy period of training allows for the broad professional dis-

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cretion, including the analysis of various factors, data and scenarios regarding the patient's condition and the continuation of care, so essential to the practice of medicine. For instance, a doctor must weigh factors that may have caused a patient to react poorly to a medication and to understand the implications of prescribing a new drug. Only the comprehensive and lengthy training received by physicians allows them to make complex decisions and give optimal care. If the decision making process is transferred to nurses, as indicated in the Ministry of Health memo, they will be able to deal only with the symptoms without the ability to investigate the reasons behind such symptoms. Moreover, intervention on the part of the nurse may prevent the doctor from being able to exercise his or her own professional discretion. As an example, if a nurse gives Petidin to a woman in labor, the woman may become disoriented and the anesthesiologist may then be unable to give her an epidural, although the situation might have warranted such.

Let us make no mistake: the IMA recognizes that in an era of rapid technological development and change the function of nurses has been greatly expanded, and nursing skills have become more complex. Nurses take advanced courses and undergo specialized training in areas such as intensive care, operating rooms etc. We have no objection to this; on the contrary, it is a welcome and essential process. However, this has nothing to do with the move to allow nurses independent discretion in medical decision making. Any training they receive, other than formal medical training, will not help them view the whole picture and enable them to reach a well thought out, educated medical decision.

The Ministry of Health memo has aggravated the current situation; not only does it transfer authority from doctors to nurses, it even states that training will be offered by nursing personnel, a designation that is difficult to understand, as how can members of one discipline be expected to teach and train topics related to another discipline. This point was conveniently absent from the array of slogans tossed around in recent months, and it is no wonder why.

There are those who have criticized the IMA, subtly alleging that we are actually looking out for the interests of the doctors under the guise of concern for patients. Such arguments have no connection to reality and don't even make sense

—if our entire purpose were concern with the rights of the physician, we should praise the Ministry memo for transferring procedures from doctors to nurses and thus lessening the workload and the responsibility of the doctors.

But this is not the case. Specifically because of our concern for public health, we have decided to act forcefully against the memo, which we have no doubt has the potential for real, tangible damage. For instance, the power given to nurses to stop treatment for high blood pressure because of the accompanying side effects is potentially life threatening to that patient. The physician is the one best suited to weighing the severity of these side effects and the only one who can make a decision regarding alternate treatments.

As to the argument that in other countries nurses have been given duties and responsibilities of physicians, I would note that these countries have for the most part done so because of a severe shortage of physicians. They faced the dilemma of giving treatment through nurses or not at all. The State of Israel, at least in the short term, does not face such an acute shortage of doctors, one that would justify such compromises to the public health.

There is no question that doctors deal with a heavy workload, but the path chosen by the Ministry of Health to deal with this problem is strange, to put it mildly. Instead of increasing the amount of positions for doctors in the public system, it has decided to transfer medical authority to nurses as a convenient, readily available and most importantly, cheap solution. What then is the next step? According to this logic, when the nurses become overburdened because of the increased responsibilities, will the Ministry of Health decide to transfer medical functions to paraprofessionals or orderlies? In addition, we have recently been witness to claims of a growing shortage of nurses in this country. If so, it is difficult to understand how nurses will be able to fulfill their traditional functions while at the same time taking upon themselves additional medical duties.

We can only conclude that the puzzling, hasty decision of the Ministry of Health, which grants medical authority to nurses, will in the end cause great harm to the unique professional relationship that currently exists among all members of the medical team and will negatively impact the quality of care, even to point of endangering life.

The IMA has petitioned the High Court of Justice to nullify the decision; they in term have requested the Ministry to delineate and justify why the memo should stand as is. If they are not

able to do so to the satisfaction of the court, the memo will be cancelled. As of the writing of this article, we await a final decision on the matter.

# Ethics at the World Medical Association: From policy to practice

JMAJ 51(4): 290-293, 2008

John R. WILLIAMS\*1

#### Introduction

In October 2004 the World Medical Association (WMA) held its General Assembly in Tokyo. The theme of the scientific session at the Assembly was "Advanced Medical Technology and Medical Ethics." The program featured presentations by prominent Japanese experts¹ as well as international guest speakers. The event reinforced the longstanding commitment to medical ethics of both the Japan and the World Medical Associations.

This article will describe the roles and activities of the WMA in medical ethics, from its beginning in 1947 to the present. Its main focus will be the relationship of ethics policies to medical practice.

### **History of WMA Ethics**

The WMA was established shortly after the end of the Second World War. Physician leaders in many countries saw the need to re-establish the good reputation of the medical profession in reaction to the widely publicized breaches of medical ethics committed by physicians in Nazi Germany and elsewhere. The first task of the newly established Association was the reformulation, in modern language, of the Hippocratic Oath by which physicians would commit themselves to high ethical standards. The new oath was named the Declaration of Geneva after the city where it was adopted. The next task was the development of an International Code of Medical Ethics, which elaborated the principles of the Declaration of Geneva. Both these documents have been revised recently in keeping with developments in medicine and society.

The Declaration of Geneva and International Code were just the first, although arguably the most important, of a long list of WMA policy statements on a wide variety of medical and health topics. Despite a small staff and fluctuating membership, the Association proved capable of international leadership on difficult and controversial issues such as the ethics of research on humans (Declaration of Helsinki, 1964), medical participation in torture (Declaration of Tokyo, 1975), patients' rights (Declaration of Lisbon, 1981) and abortion (Declaration of Oslo, 1983).<sup>2</sup> That physicians from many different countries were able to reach agreement on these issues, which have proved so politically and socially divisive, can be explained by their shared commitment to the fundamental principles of medical ethics and their friendship and respect for one another as they work together at WMA meetings to search for the best solutions to the issues.

Beginning in the late 1960s in the USA and somewhat later in other countries the medical profession was joined by other health professions and academic disciplines in its concern for ethics. Medical ethics expanded into bioethics and rapidly became an 'industry', with full-time salaried practitioners, national and international associations, conferences, journals, legislation and regulations. The WMA was no longer the only international association dealing with medical ethics; other, much larger and better funded, bodies such as the Council for International Organizations of Medical Sciences (CIOMS), WHO and UNESCO began to issue statements on medical ethics issues that were generally, but not always, consistent with WMA policies. Moreover, the WMA lacked legal authority to enforce its policies, even among its member National

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Medical Associations. These factors have posed major challenges to the WMA as it strives to define its role among the many voices speaking on ethics.

The WMA has risen to this challenge in numerous ways. It has more than doubled its membership in the past decade, welcoming new National Medical Associations in Latin America, Africa and Eastern, Central and Southern Europe. These new members have enabled the Association to speak with greater authority on behalf of all the world's physicians, not just those from the highly industrialized countries. The WMA has also refined its policy development process to ensure that its policies are always up to date. Each policy is reviewed at least every ten years to determine whether it should be reaffirmed, revised or rescinded and archived. Finally, the WMA has developed educational and advocacy programs to promote the implementation of its policies.

### The WMA Medical Ethics Manual

The WMA has for many years promoted ethics education in medical schools. One of the obstacles to such education, particularly in countries with limited resources, was the lack of a basic text for students. In 2003 the WMA decided to develop and distribute such a text. An international group of advisors was constituted whose first task was to comment on a proposed outline of the text. On the basis of their comments a first draft was written and circulated to them for review. A second draft followed and the advisors once more provided comments. One of them, a medical student in Egypt, asked ten fellow students to review the draft and mark words that they did not understand. The most frequently marked words were either changed to simpler ones or else were defined in the text or in a glossary. The final version was then sent to the publisher for design work and printing. The official launch of the English version of the WMA Medical Ethics Manual took place in January 2005.

In order to make the Manual widely and freely available, the WMA put the text on its website in its three official languages, English, French and Spanish. Two copies of the English print version were distributed to most of the world's medical schools, one for the library and the other for the faculty member responsible for medical

ethics education. The WMA invited its member National Medical Associations to translate and distribute the Manual in their own languages, and many of them responded positively. The Japanese version was published by the Japan Medical Association in 2007. Twelve other translations, including Chinese, Korean, Indonesian, Arabic and Russian, are available either in print or online, and others are in progress.

The Manual is based to a large extent on WMA policies and is therefore one means, although an indirect one, of putting these policies into practice. It provides medical students and practising physicians with a basic knowledge of the principles of ethical decision making and behaviour. Of course, this knowledge needs to be supplemented by the development of ethical skills and attitudes, which is a task for others than the WMA.

The success of the Manual prompted the FDI World Dental Federation to ask the WMA for permission to adapt it for dentists. Permission was granted and the FDI World Dental Federation Dental Ethics Manual was published in 2007 and has already received widespread distribution and requests for translation.<sup>3</sup>

### **Online Ethics Course**

In recent years the WMA has formed partner-ships with other organizations to produce online continuing medical education/continuing professional development (CPD) courses. In 2006 a CPD course on medical ethics was launched.<sup>4</sup> Based on the Medical Ethics Manual, it is available free of charge and is accredited by the Norwegian Medical Association. Although its primary intended users are practising physicians, it is especially useful for medical school faculty who are involved in ethics education.

### Declaration of Helsinki (DoH)

The DoH is perhaps the best known and most influential of all the WMA's policy statements. Adherence to its principles is a requirement for research on humans in many countries and it is widely used by research ethics committees to determine whether or not proposed research projects should be approved. However, it is no longer the only international ethics guidance for medical research as it was for some time after its

adoption in 1964. In order to maintain the DoH's pre-eminence among all the other documents on research ethics, the WMA has undertaken the following activities:

- The DoH has been revised periodically to take account of developments in medical research and social changes. In 1975 a requirement for ethics committee review of proposed research projects was added. In 1996 placebo-controlled trials were mentioned for the first time. Between 1997 and 2000 a major revision process took place that resulted in a significantly reorganized and expanded version. Notes of clarification to this version were added in 2002 and 2004. Currently (2008) another review is underway, which is expected to result in a new version to be recommended for adoption by the WMA General Assembly in Seoul in October 2008. An extensive consultation process has resulted in widespread awareness of and participation in this review.
- WMA representatives have spoken at numerous conferences and meetings on research ethics where they have promoted the DoH and invited other parties to adopt its principles.
- The WMA has played an active role in several programs designed to strengthen research ethics committees in developing countries, including NEBRA (Networking for Ethics on Biomedical Research in Africa)<sup>5</sup> and TRREE-for-Africa (Training and Resources in Research Ethics Evaluation for Africa).<sup>6</sup> These programs have proved very useful for promoting the DoH.

### **Torture**

The WMA has been a strong advocate for the abolition of torture wherever it is practised and has worked closely with other organizations to implement the Declaration of Tokyo and related WMA policies on this topic. It maintains close links with the International Committee of the Red Cross, which has provided valuable input to WMA policies and which uses these policies in its fieldwork in prisons and disaster situations. The WMA joined with the International Rehabilitation Council for Torture Victims in the

design and testing of a manual to assist physicians and lawyers to detect evidence of torture. WMA officials participated in five national training workshops in which the draft of the manual was field tested.<sup>7</sup>

### Conclusion

Ethics is both a theoretical and a practical activity. The WMA documents are strong theoretical statements about how physicians should act and what public policies on ethical issues should be adopted. However, unless the documents are made known and implemented, they do not serve any useful purpose. Realising this, the WMA has increased its efforts to have its policies incorporated in practice.

As noted above, the WMA's implementation activities include education and advocacy. Since it is not an educational organization, it works indirectly by developing and distributing educational resources such as the Medical Ethics Manual and the online ethics CPD course. Its advocacy activities are more direct, for example, intervening with national governments on behalf of physicians whose human rights are threatened and supporting the efforts of the WHO to reduce tobacco use. In order to increase its effectiveness in both education and advocacy, the WMA joins with other organizations to develop programs and materials and strategies for intervention.

It is easier to evaluate policy development than practice. The former can be determined by the number of policies approved, the time it takes to complete them and the reception they are given by the intended users. Changes in practice are usually of longer duration and involve multiple variables. The WMA does not have the resources to measure the effectiveness of its educational and advocacy activities, even if this could be done. Nevertheless, it is committed to continuing and even expanding these activities, in the hope that they will contribute to the realization of the WMA's mission, namely, to achieve the highest possible standards of medical care, ethics, education and health-related human rights for all people.

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### Visit to Sao Paulo

I recently had two opportunities to visit Sao Paulo in Brazil. The first occasion was the "Congresso Médico Do Centinário Brasil-Japão" commemorating the centennial of Japanese immigration to Brazil which was hosted by the Brazilian Medical Association, and the second was the "Declaration of Helsinki (DoH) 2008 São Paulo Conference," a forum organized for the purpose of revising the World Medical Association (WMA) DoH.

At the "Congresso Médico Do Centinário Brasil-Japão," held in June, very impressive papers on various activities related to community health issues, which were being carried out by Japanese and Japanese-Brazilian doctors in areas throughout Brazil, were passionately presented over two days. The congress was held at a special moment in history when Japan's Crown Prince Naruhito was visiting Brazil to celebrate the centennial of Japanese immigration to Brazil. Accordingly, a few participants attended other events held in honor of Crown Prince Naruhito. I noticed that the spirit of traditional Japan still exists among the Japanese community in Brazil, certainly more strongly than in Japan today. Moreover, the memory of former JMA president Taro Takemi and his successors, who promoted the global contribution of the JMA after World War II and also took part in the establishment of a new hospital for the Japanese community and all the people of Sao Paulo as well, remains strong in the



Stone memorializing the arrival of Japanese immigrants in Santos Harbour in 1908



Presentation at the Medical Congress of Brazil-Japan

minds of leaders of the medical field in Brazil.

The second visit was for the "DoH 2008 São Paulo Conference," which was held in August at the head office of the Paulista Medical Association. The meeting was attended by participants from the region and throughout the world, who actively discussed their ideas about the DoH over two days. In the Latin American manner, the discussions were carried out in an enthusiastic and passionate fashion. The meeting was a precious moment for promoting understanding of the DoH in the South American region and for the members of the WMA working group to gain a better understanding of the positions and opinions of doctors in the region. We became confident of finding a way to achieve a final version of the DoH, which will be discussed at the up-coming WMA General Assembly in Seoul in October, 2008.

Brazilian culture with people from all over the world and wonderful food and products was most impressive to me. I was also touched by the rich musical variety that spices the Brazilian lifestyle with the sophisticated cords of Bossa Nova, joyful rhythmic patterns of Samba, classical symphony orchestra and opera performances, and contemporary MPB (Musica Popular Brasileira) at a live house in Sao Paulo. I enjoyed all of these experiences during my short stay in Brazil.

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