

AMDD Vol.9

NEWSLETTER

December 2011

*English translation of Japanese newsletter

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Complete Prevention of Cervical Cancer Within Reach

A combination of a vaccination and two screenings has brought us closer to the goal of complete prevention of cervical cancer. We interviewed Dr. Yasuo Hirai, Associate Professor in the Department of Obstetrics and Gynecology at the Tokyo Women's Medical University, about the current situation.

In Japan, the age of women who are diagnosed with cervical cancer has become younger in the past 10 years. Women in their 20s were being diagnosed with cervical cancer, with it peaking in women in their 30s and 40s. About 8,000 women each year are diagnosed with cervical cancer, and about 2,500 of them die from it. The human papillomavirus (HPV) vaccine was authorized in Japan in the fall of 2009, and vaccination started in girls between the ages 10 to 15. However, precise screening is essential in order to prevent cervical cancer completely.

Precancerous lesions emerging in 10 percent of women

Most women are infected with HPV, the causative virus for cervical cancer, once or twice during their lifetime if they are not vaccinated. Generally, the virus is eliminated within a year by a woman's own immune system. However, the infection remains in about 10 percent of women, and cells in the cervix are converted to precancerous lesions. If infection is detected and surgery (cervical conization) is performed at this stage on precancerous lesions, the disease is cured completely without developing into cancer.

Cytology is essential for the diagnosis of cervical cancer. In the traditional method, cells in the cervix are scraped using a cotton applicator to collect specimens for cytology. In the US and other countries, the detection rate of cervical cancer has been improved by liquid-based cytology (LBC), which uses a uniquely shaped "broom" brush. Because it can capture a sample containing a large number of cells with this method, cancer detection is

more precise. As studies of LBC have already begun in Japan, it is expected that it will be covered under the Japanese medical insurance system in the near future and used widely. Other advantages of LBC are that it can also perform gene analysis of certain cells, as well as test for HPV using the same sample.

In short, if precancerous lesions can be discovered at an early stage through the combination of cytology and HPV testing, then progression of the disease is almost completely preventable.

Extremely low screening rate compared to other countries

Unfortunately, the cervical cancer screening rate is only about 24 percent in Japan, which is less than one-third of screening rates in advanced countries such as the US and Europe. The situation is serious because the screening rate is the lowest in women in their 20s and 30s, who are the likeliest to become pregnant and give birth. If the cancer progresses and requires removal of the uterus, not only will a woman not be able to give birth, but she also faces the risk of death.

Currently, the best possible method for the prevention of cervical cancer is administration of the HPV vaccine (primary prevention) in teenage girls, followed by cytology (secondary prevention) every one to two years from their 20s and on. DNA testing for HPV is provided when it is determined to be necessary at the discretion of physicians.

Furthermore, experts around the world are making advances in research to ensure the reliability of cytodiagnosis, as they aim for complete prevention. But more than anything else, the key is for all women to receive cervical cancer screening.

(This is a summary of the interview with Dr. Hirai, edited by the editorial desk.)

Dr. Yasuo Hirai
Associate Professor, Department of Obstetrics and Gynecology, Tokyo Women's Medical
University

Dr. Hirai graduated from Chiba University School of Medicine in 1976. After training at the National Kohnodai Hospital, he was on the medical staff in the Department of Gynecology and the Cytology Section at the Cancer Institute Hospital of JFCR. He pursued research in cytology at the University of Chicago. After serving as a deputy director in the Department of Gynecology at the Cancer Institute Hospital of JFCR, he was appointed as a director in the Cytology Section in 2005, and later in the Cancer Screening Center in 2009. He assumed his current position from April 2011.

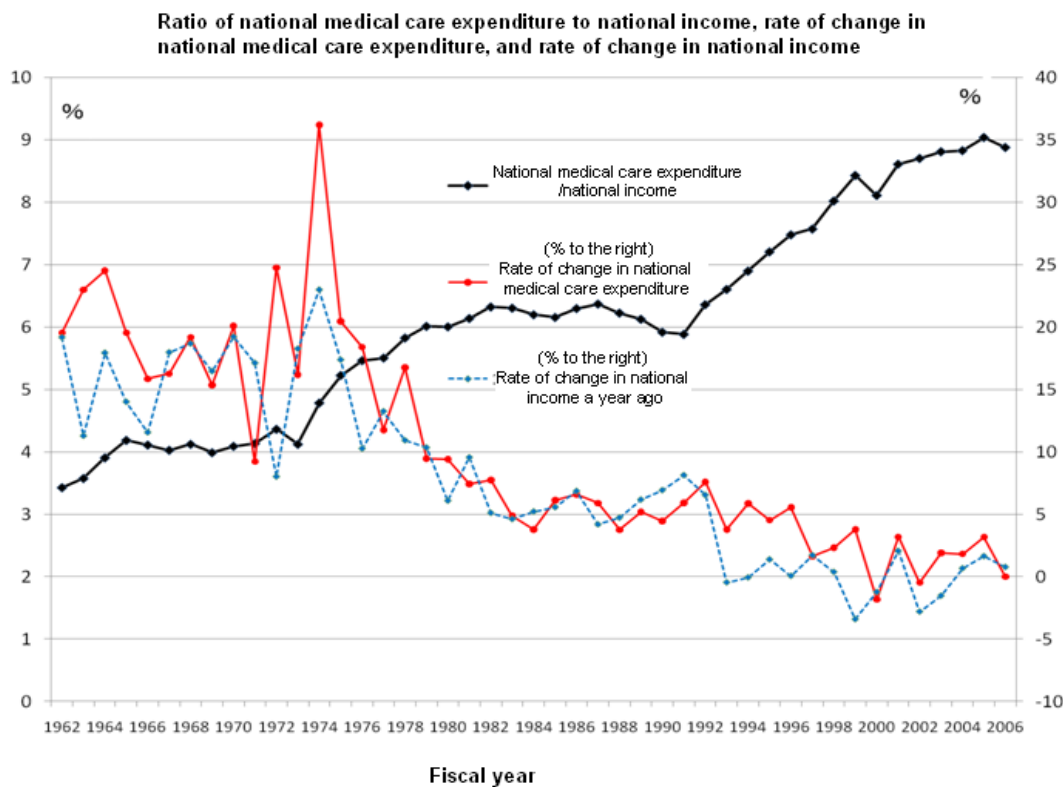
The Japanese Economy and Medical Care Policy—How to Secure Financial Resources for Medical Care

Japan is facing the world's fastest aging society, long-term stagnant economic growth, and the largest ratio of public debt to GDP among advanced countries. Under these tough conditions, it is inevitable to discuss the financial burden of maintaining a world-class universal healthcare system.

Japan's ratio of medical care expenditure to GDP is the lowest among advanced countries

Although the number of people aged 65 or older in Japan is increasing by 3 to 4 percent each year and the aging rate is the highest in the world, total medical care expenditure as a percentage of the GDP is 8.1 percent – the lowest among advanced countries. There has only been a 1.6 percent increase since 1980. The increasing rate of the ratio of medical care expenditure to GDP for the last 20 years is lower than in other advanced countries.

Why is the ratio of medical care expenditure to GDP stagnant? This is because the authorities have controlled the increase in rate of medical care expenditure so that it does not differ significantly from the economic growth rate.



Japan used medical care expenditure aggressively during the high economic growth period because the healthcare system was undeveloped. Japan entered a stable growth period in the 1980s, but eventually the economic bubble burst. Faced with a period of small economic growth, Japan experienced the “lost decades.”

During this period, the government suppressed the increasing rate of medical care expenditure according to the sluggish economic growth rate. It was necessary to find a reason to convince medical professionals to lower Japan’s medical care expenditure even further, which was already quite low among the nations of the world. The logic at the time was that the current situation of medical care in Japan was somewhat different from that in other countries, so it would be desirable to bring it closer to the international standard.

Because cost of medication took up a high percentage of medical care expenditure (30 percent), the government significantly lowered prices of listed drugs by reducing the reasonable zone (R-zone)*. However, it was difficult to lower drug prices any further. The government thus changed its policy to the promotion of generic drugs. It plans to increase the use of generic drugs to 30 percent by 2012.

Hospitals, which had long had undifferentiated facilities, were also improved. At the time, there were many patients who had been hospitalized for long periods in general beds. Beds were therefore divided into acute-phase beds and so-called long-term care beds, which were low in costs for hospitalized patients. Recently, the government has tried to divert a part of long-term care beds to nursing-care facilities.

The government also thought to reduce medical care expenditure by shortening the average length of stay in acute care hospitals, which has differed significantly from the average length of stay in other countries. In addition, medical remuneration was amended so that the income of hospitals would decrease as the length of hospital stays became longer. As a result, the average length of a hospital stay was shortened from 24.8 days in 2000 to 18.5 days in 2009. This is, however, still longer than the international standard.

Where should we seek financial resources for medical care?

The out-of-pocket payment amount from patients was increased in medical care insurance. In 2009, the co-payment fee (hospitalization fee) from the elderly was raised 10 percent from what was originally 300 yen a day. Co-payment from salaried workers was increased from 10 percent to 30 percent.

Recently, the most effective method for controlling medical care expenditure has been the lowering of the medical remuneration revision rate. The medical remuneration revision rate has remained at low levels since 2000, including negative revisions. In years when medical remuneration was not revised, medical care expenditure increased by about 3 percent from the previous year, which greatly exceeded the economic growth rate. The government has thus tried to fill this gap by setting low revision rates.

As the number of low-income earners is increasing under the economic slowdown, so it would be difficult to unreasonably raise the co-payment rate. There is also concern about the effect on the quality of medical care if the medical remuneration revision rate is set too low. Should financial resources be sought from public funds (taxes + deficit-covering government bonds) or insurance premiums? A consumption tax rate hike to 10 percent is being discussed, but Japan currently has a large public debt. How much money from the tax hike can be passed on to the medical care expenditure? As insurance premium rates have also been raised, the burden on the working generation and the effect it would have on employment cannot be ignored.

National medical care expenditure will continue to increase in conjunction with the aging society and the advancement of technology. It is necessary to build a national consensus on how to handle this burden. One could say that we have neglected to discuss this issue up till now and instead escaped to deficit-covering government bonds.

The importance of cost-effectiveness

Under the constraints of economic growth and demographics, the government will try to suppress the increase in medical care expenditure more strictly. Considering that it is politically difficult to limit patients' access to medical care, it is better to proceed in the direction of suppressing medical care prices, such as medical remuneration, drug prices, and insurance reimbursement prices of medical devices. Although the specifics are yet to be decided, a cost-effective approach is critical. Prices of highly effective or innovative items are set high, while those that are not are reduced. Alternatively, popularization of

items that are less innovative but inexpensive is encouraged. Such concepts will be increasingly important.

(This is a summary of the special lecture “The Japanese Economy and Medical Care Policy” from the 3rd AMDD conference [September 2011])

*Drug prices are revised by adding a certain fraction of drug prices before the revision to the weighted averages of medical institutions’ purchase prices. This added fraction is called the reasonable zone (R-zone).

Prof. Hisao Endo
Professor, Faculty of Economics, Gakushuin University

Prof. Endo was born in Tokyo in 1954. He assumed his current position in 1997. He served as the chairman of the Central Social Insurance Medical Council (Chuikyo) in the Ministry of Health, Labour and Welfare from 2008–2011. He is currently a member of the Social Security Council and serves as the chairman of the Committee on Health Insurance in the Social Security Council.

Patient’s Voice

Hopes for the Introduction of High-Precision Testing

By Ms. Hiromi Kawamura

Chairperson, Teal & White Ribbon Project Association

Chairperson, NPO Women’s Cancer Support Group Orange Tea

“Was my cancer overlooked?” Such voices are often heard in our patient group. We are Orange Tea, a women’s cancer support group. Orange Tea supports people who have experienced uterine cancer, ovarian cancer, and breast cancer.

Orange Tea was started in January 2002. Two years later, in January 2004, the group was authorized as a specified nonprofit organization. Orange Tea, which began in Shizuoka Prefecture, will celebrate its 10th anniversary next January. Our activities are performed nationwide.

The main activities of Orange Tea are group peer counseling with cancer survivors, in what is called the *oshaberi* (chatting) room, and study groups for women who have been affected by cancer. Women who have had cancer require lifelong physical and mental care because they suffer from postoperative dysfunction and have lost the symbol of being a woman. However, it is difficult for them to consult with their families or friends as it is related to their genital organs. Thus Orange Tea was established as a place where women can talk comfortably and openly.

In this *oshaberi* room, women who had their cancer detected in later stages – despite having had regular checkups – say, “My cancer was probably overlooked.” Although it cannot be determined if their cancer was actually overlooked or not, these women sometimes develop a feeling of distrust regarding the checkups they received, and have difficulties facing their own disease.

While liquid-based cytology (LBC) has been introduced in 90 percent of cervical cancer screenings in the US, this technique has only been partly introduced in Japan. High-

precision testing will not only contribute greatly to early detection, but it will also significantly reduce the number of women will have been affected by cancer.

Orange Tea will continue to encourage relevant organizations to introduce high-precision screening methods for the lifelong health of women.

Activity information

- Regular meetings: The first Saturday in March, June, September, and December
 - *Oshaberi* room
- [Shizuoka] east (third Saturday), center (first Saturday, not held during regular meeting months), west (second Saturday)
[Tokyo] Ochanomizu (fourth Sunday)
[Chiba] Chiba City (fourth Saturday, starting from January 2012)

Contact Info for Orange Tea

2-17-49, Nishi-atami-cho, Atami-shi, Shizuoka 413-0038
Orange Tea Liaison Office
Tel: 090-3588-5841 (8:00 a.m. to 9:00 p.m.)

Medical Journalist Viewpoint

Suppressing Medical Care Expenditure by Using Medical Devices Efficiently

By Mr. Morio Hibino

Professor, Tokyo Healthcare University

Editorial Writer for *Tokyo Shimbun* and *Chunichi Shimbun*

In September 2011, Japan's elderly made up 23.3 percent of the population. In the same month, the Ministry of Health, Labour and Welfare published "National Medical Care Expenditure in 2009," showing that national medical care expenditure had reached 36 trillion yen – 1.2 trillion yen more than the previous year.

Japan's aging society contributes largely to the increase in medical care expenditure, but this is not the only factor. According to the Ministry of Health, Labour and Welfare's "Analysis of Contributing Factors to the Increase in Medical Care Expenditure," the increase rate was 2.4 percent per person from 2005 to 2009. When this percentage was broken down by causes, "Effect of the aging society" accounted for +1.6 percent, "Revision of medical remuneration" accounted for -0.8 percent, and "Other" accounted for +1.5 percent (because the data were rounded off, the total is not exact). "Other" includes "Advances in medical care" and "Review of patient burden."

In fiscal years when medical remuneration was not revised and the patient burden was not reviewed, the large effect from "Advances in medical care" is evident. For example, the increase rate of medical care expenditure was 3.1 percent per person in fiscal year 2005. Of this percentage, "Effect of the aging society" accounted for 1.9 percent and "Advances in medical care" accounted for 1.2 percent.

In fiscal year 2007, the increase rate was 3.1 percent, with “Effect of the aging society” and “Advances in medical care” accounting for 1.6 percent and 1.4 percent, respectively. In fiscal year 2009, the increase rate was 3.6 percent, with “Advances in medical care” accounting for 2.1 percent, while “Effect of the aging society” was lower, at 1.5 percent.

Advances in medical care are increasing medical care expenditure more than we may think. Although advancement of technology lowers production costs in general industrial production, it is the opposite for medical technology.

With this in mind, the efficient use of medical devices will be strongly required in the future. It is certain that advances in medical care are useful for maintenance and improvement of health. However, the number of CT and MRI units per one million people is remarkably large in Japan compared to other OECD countries. The number of CT and MRI units is about 3 times and 1.7 times as many as those in the US, which ranks second behind Japan for the number of CT and MRI units. Such large numbers of CT and MRI units may not be necessary.

Medical institutions should find a way for shared use. This will allow for the early introduction of new devices, and ultimately benefit patients. The Ministry of Health, Labour and Welfare should lead in this direction to suppress unnecessary inflation of medical care expenditure.

Unlike drug prices, sales prices of medical devices are not transparent. This issue has often been pointed out by the Central Social Insurance Medical Council (Chuikyo) and other committees.

In addition to the gap between domestic and foreign prices, the unclear distribution method of different delivery prices from hospital to hospital for what is the same exact device is still going unchallenged. This will eventually lead to an increased burden on the population. I hope that the AMDD aims for a transparent distribution system that can gain credibility among the Japanese people, as well as championing the development of more advanced devices.

Overview of the 21st and 22nd Media Lectures

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held the 21st Media Lecture on August 2, 2011. The theme of the lecture was “Questioning the Competitiveness of Japan’s Medical Device Industry.” Japan has brought innovations to various industrial sectors, including automobiles and electric appliances. It has been pointed out, however, that Japan’s support system for innovations in medical technology is very weak.

The first lecture, entitled “Problems and Measures for Medical Device Innovations,” was given by Dr. Christopher Wasden, Global Healthcare Innovation Leader at PricewaterhouseCoopers (PwC) (New York). Dr. Wasden said, “Japan’s support for innovation is weaker than other OECD countries.”

The second speaker, Dr. Kosuke Kato, Chairman of the STM Committee at the AMDD, reported details of the “Comparative Survey for the Market Environment of Medical Devices in Japan, China, and South Korea,” an analysis based on interviews with medical device manufacturers. He emphasized that correction of the high entry cost, lag reduction until authorization, and improvement of the system for deciding insurance reimbursement prices are essential for Japan in order to continue providing advanced medical devices for its citizens.

The AMDD also held the 22nd Media Lecture on September 29 on the theme “Protecting Women from Cervical Cancer with the Latest Medical Technologies.” Dr. Yasuo Hirai, Associate Professor in the Department of Obstetrics and Gynecology at the Tokyo Women’s Medical University, and Dr. Tadao Kobayashi, Visiting Professor in the Graduate School of Medicine at Osaka University, delivered the lectures.

Dr. Hirai talked about the theme, “Reality of Three New Technologies for Prevention of Cervical Cancer: Liquid-Based Cytology (LBC), HPV Testing, and HPV Vaccine” (*the lecture is summarized on page one of this newsletter*). Dr. Kobayashi’s lecture, “Problems of Japan’s Cervical Cancer Screening and Necessary Measures,” discussed the cervical cancer screening system in the UK and the importance of cytodiagnosis education as a countermeasure against Japan’s low cancer screening rate. He also said that cotton applicators are still commonly used for sampling and the popularization of high-precision LBC remains an issue for Japan.

Value of Medical Technology (Ophthalmic Materials)

Intraocular Lens: Insertion into the Lens Capsule

An artificial lens was inserted into the eye of a cataract patient in 1949, for the first time in the world (formal record: February 8, 1950).

A cataract is a disease that involves clouding in the lens of the eye due to aging or other factors. Because the clouded lens scatters light, symptoms such as blurred vision, double vision, and glare sensitivity occur. As the disease progresses, visual acuity decreases, and even with the aid of glasses, correction of visual acuity becomes impossible. Cataracts are the leading cause of vision loss in the world. Although there is no magic bullet that removes clouding of the lens, the mainstream treatment method is to remove the content of the lens by aspiration and insert a folded intraocular lens into the remaining thin film (lens capsule) (*see figure*).

Intraocular lenses were authorized in Japan in 1985. Thanks to the latest developments in cataract surgical equipment and the change from hard to soft, foldable implants, the lenses can be inserted from an incision of about 3 mm. Furthermore, various value-added lenses, such as toric lenses that alleviate corneal astigmatism, colored lenses that alleviate glare in the early stages after surgery, and multifocal intraocular lenses with more than one distance of focus, are commercially available.



Only single-focus intraocular lenses (with only one distance of focus) are covered under the Japanese medical insurance system. Multi-focal intraocular lenses are considered as advanced medical technology.

(By Junko Kodama, AMO Japan K.K.)

Overview of 3rd Annual AMDD Conference

The 3rd annual conference of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) was held on September 15, 2011, at the Imperial Hotel in Hibiya, Tokyo. Mr. David W. Powell, Chairman of the AMDD, said in his opening address, "I am proud that AMDD member companies resumed the supply of medical devices, including free offerings, promptly after the disaster in the wake of the earthquake, tsunami, and nuclear accident in the Tohoku region last March."

Mr. Paul Bond, auditor, reported in the business report that the AMDD had donated 10 million yen to relief efforts for the Great East Japan Earthquake. This report, along with the budget draft for fiscal year 2012, was unanimously approved. Following that, six chairpersons from nine AMDD committees reported on activities from the previous fiscal year and explained in detail the business plan for the next fiscal year.

Ms. Helen Peterson, an officer of commerce at the US Embassy in Japan, and Mr. Ralph Ives, Executive Vice President of Global Strategy & Analysis at the Advanced Medical Technology Association (AdvaMed), were invited as guests. Ms. Peterson introduced recent moves in the US-Japan bilateral negotiations for medical devices, drugs, and vaccine policy. This year's special lecture, entitled "The Japanese Economy and Medical Care Policy," was delivered by Dr. Hisao Endo, Professor (Economics) at Gakushuin University. Dr. Endo provided suggestions for the future direction of Japan's medical care administration, based on his experience as the former chairman of the Central Social Insurance Medical Council (Chuikyo).

(The lecture provided by Dr. Endo is summarized on page 2.)

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

*All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.