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The Journal of Japan Hospital Association

Special Feature

Healthcare for the Future

Tsuneo Sakai

Japan Hospital Association QI Project 2011:

Results and Future Issues

Chika Horikawa

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Japan Hospital Association is committed to contributing to society by enhancing hospital services in Japan.

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Foreword



Tsuneo Sakai

President, Japan Hospital Association

The Japan Hospital Association (JHA) held its elections in May, and this is sure to be a year of changes. The environment surrounding the medical industry has become increasingly severe with an accumulation of unsolved problems such as consumption tax, TPP, and improvement of the healthcare system. This environment has been brought about in part because previous LDP and Democratic Party of Japan administrations were unable to decide upon measures in a timely manner; however, the healthcare industry must also share responsibility for the present circumstances.

Barack Obama made his grand debut as the U.S. President with the slogan, “Change,” and has entered his second term. He has told us that changing the system is no easy task. Because the current Japanese healthcare system looks OK, the current status quo is preferred over any potential confusion that may arise through change. But, I don’t agree. Let me explain the manpower and labor of physicians hired by hospitals. There is strong opposition to a movement led by some politicians to establish a faculty of medicine in the Tohoku Region. Those opposing this movement insist that we already have enough physicians. In reality, there are 162,000 physicians under 70 years of age working at hospitals, and these doctors are working an average of 63.3 hours per week. In order to meet the conditions stipulated by the Ministry of Health, Labour and Welfare, which is up to 40 hours per week, we need to have 1.6 times as many physicians as are now working. It is impossible to fill that need right now. Although number of seat at medical schools has increased, we are going to suffer under the current situation until these medical students finish their training and start working. The problem was caused by calculating the required number of physicians based on the current working environment. In order to move forward with solutions, it is essential to first change the current situation. The current problems at hospitals are a result of inefficiency in healthcare delivery systems and the poor utilization of human resources. Because healthcare resources are limited, we need to exercise maximum wisdom. We cannot discuss the solution here; however, it is important for us to understand that it is impossible to provide desirable healthcare services as long as the systems remain the same. While the National Council on Social Security System Reform has been discussing the improvement of healthcare delivery systems, the status has not changed from the Council in 2008. Indeed, the situation has become more serious and I simply hope that they will avoid making the same mistakes that they have made in the past. The Council will make some decisions by the end of August. We really hope to have some proposals for major changes, and to move forward to initiate effective measures.

I will continue to promote “visualization.” Hospitals are suffering from the load of surveys governments and organizations have asked for. If the data from such surveys are effectively used to improve the situation for hospitals, their efforts would be well rewarded. However, this is not necessarily what is happening. The surveys are not linked and many of them contain the same questions, something that needs to be improved. I promote the efficient collection of necessary data and reducing the burden of hospital staff. What we want to have is high-quality data, and I ask the government to disclose that data. I would also like to provide user-friendly data processed by the JHA.

I wish all of us a challenging but fruitful year.

The 62th Japan Hospital Association Congress

Healthcare for the Future



Tsuneo Sakai

President, Japan Hospital Association

In today's presentation, "Healthcare for the Future," I will talk about the issues facing Japanese healthcare and the outlook for the future.

(Slide 1) First off, I will talk about how the international community views Japanese healthcare. The international perspective is important part of a balanced evaluation of the system. Then, I will talk about what I consider necessary for the development of a healthcare system capable of effectively meeting the needs of the future. I will also talk about various issues regarding improvement with a focus on the medical payment system and the Medical Care Act. With this background as a foundation, I will then talk about what JHA might do to better contribute to the improvement of Japanese healthcare.

■ International Evaluation of Japanese Healthcare

(Slide 2) In 2011, Japan celebrated the 50th anniversary of its universal health insurance for all. Coincidentally, *The Lancet* published a special issue featuring Japan (Vol. 378, No. 9796). It was the first time for this highly respected

Summary of Today's Speech

- International evaluation of Japanese healthcare
- Requirements for healthcare system improvements
- What we require for medical fees and the Medical Care Act
- Approaches by the JHA
- Conclusion

Slide 1



Tsuneo Sakai speaking as JHA President

International Evaluation of Japanese Healthcare

- THE LANCET
 - Japan: 50 years after the establishment of the universal health insurance system
 - Special Issue on Japan (September 2011)
- Realization of universal healthcare pursued by the nation's Constitution
- Equity of Japanese society
- Actual value of the system was tested by the Great East Japan Earthquake
- A good example of a nation that helps its population live long and well
- Japan successfully provides effective healthcare at a relatively low cost
- Problems
 - Expectation for Japan to exercise strong leadership in healthcare both in Asia and developing countries
 - Japanese youth's firm vision and strong commitment



Slide 2

British medical journal to feature a single country, and it had good things to say about Japanese healthcare.

The Lancet emphasized the equity of Japanese society with the observation that Japan's health insurance system represented the realization of universal healthcare pursued by the nation's Constitution. The journal also cited the Great East Japan Earthquake as a test of the actual value of the system. This should not be taken to mean that the full value of the system was exhibited, but that it was indeed tested, which I believe is correct. The special issue also noted that as one of the most rapidly aging societies in the world, Japan served as a good example of a nation that provided the support required to enable its population to live long and well, and pointed out that with healthcare expenditures representing merely 8.3% of the nation's GDP, Japan was successfully providing effective healthcare at a relatively low cost. This earned Japan special admiration, especially when compared to the U.S. and countries in Europe.

On the other hand, they also mentioned that Japan's healthcare system is not without its share of problems. What they expect is that Japan will exercise strong leadership in healthcare both in Asia and in developing countries. Japan, however, tends to be more active at home than elsewhere. About two weeks ago, for example, I attended an International Hospital Federation (IHF) conference in South Africa, and it was clear that Japan had a lower presence on the international stage than other countries did. Other countries also expect Japan to exercise strong leadership in Asia and in developing countries, which I feel is natural considering Japan's capabilities and economic strength. However, Japan is not yet meeting this expectation.

In the wake of the Great East Japan Earthquake, the number of Japanese youth involved either directly or indirectly in disaster relief or restoration is significant. While we tend to criticize the younger generation for its lack of engagement, the journal was impressed with the Japanese youth's firm vision and strong commitment in acting for the benefit of others, and they did not find Japan's support for these young people lacking. It was extremely gratifying to read this.

■ Requirements for Healthcare System Improvements

What, then, are the problems facing this healthcare system that is so highly regarded by *The Lancet*?

(Slide 3) There are certain fundamental prerequisites to ensuring a healthcare system that satisfies the needs of the population. Most important of these is agreement on the fundamental principle underlying the system. It is meaningless to talk about the kind of healthcare we intend to provide without first agreeing on what the goal is. The fundamental principle should be to provide efficient, safe, high-quality healthcare, and this must be an ongoing pursuit.

The environment surrounding healthcare in Japan has been undergoing significant change; however, certain aspects of the system, such as the Medical Care Act and Medical Practitioners Act, are outdated and prevent prompt responses to change. It is important for us to acknowledge such problems and discuss how best to respond to them.

Finding effective solutions to these problems will require that the system's three primary stakeholders, the public, the government, and healthcare providers, work together.

● The public

The nation's super-aging society means that the patient the system is designed to serve is changing. In acute-care hospitals, for example, the largest patient segment is the old. In addition to their primary medical conditions,

Requirements for Healthcare System Improvements

- Agreement on the fundamental principle: Provision high-quality and safe healthcare
- Appropriate response to significant changes in the environment surrounding healthcare
- Cooperation among stakeholders
- The public
 - Super-aging society: Increase in number of patients with complications
 - Increase of patient needs
 - Changes in regional society
- Government
 - Integration of the social security and tax systems
 - Difficulty in securing necessary medical funding
 - Implementation of policies for the economy and public funding
- Healthcare professionals
 - Sophistication and specialization of healthcare
 - Shortage of healthcare manpower

Slide 3

these patients usually have comorbidities such as high-blood pressure or diabetes, which represents a significant change from the acute care demographic that the system was treating 10 to 15 years ago. It is important for us to recognize the significance of this change.

Another issue is the increase and diversification of patient needs. It is essential that healthcare providers remember their responsibility and obligation to respond to such patient needs.

Another significant issue is the continuing need to realize what we have been pointing out for over 10 years; namely, that the financial crisis facing the healthcare system is not an issue for hospitals and the healthcare industry to solve alone but a problem that society as a whole must address. In other words, it is obvious that the healthcare industry alone cannot correct the problem. When plans for restoration were being discussed after the Great East Japan Earthquake, emphasis on the restoration of medical facilities by the national leadership had a negative impact on regional leadership's ability to pursue its restoration priorities. We need to consider the overall picture and make plans accordingly.

● Government

Meanwhile, integration of the social security and tax systems has been discussed by the government. Within this discussion, the main issue is the kind of healthcare system that should be in place by 2025. Currently, however, the Diet is focused on passing a bill on consumption tax, which means, unfortunately, that our leadership is not giving its full attention to the social security issue. This is not right.

It was during the Nakasone Administration between 1982 and 1987 that the government shifted to the principle of economic supremacy. Since that time, healthcare and education have taken a back seat. Cutting the budget for healthcare and education shows a lack of foresight that will certainly lead to significant problems in the future.

● Healthcare Providers

What, then, are the problems facing healthcare providers? Healthcare has become increasingly sophisticated and specialized. There is a wide range of specializations in, for example, genetics, including gene therapy and diagnosis, and a number of expensive technologies related to these, technologies such as positron emission tomography (PET). Physicians and nurses are also specializing more and more

within each field, which creates walls and gaps among the various fields. In the end, we are left with little or no idea about what the people working right next to us are doing.

Even worse is the shortage of healthcare manpower across the spectrum. Although the uneven distribution of physicians in the regions and specialties has been brought up as a serious issue, the government insists that the situation is fine, and the Japan Medical Association has taken the same stance.

The reason for this disagreement is that we are dealing with differing realities. While the Ministry of Health, Labour and Welfare (MHLW), for example, recommends a 40-hour work week for staff physicians, the average doctor is actually putting in 63.3 hours per week. Looking at the number of physicians from the hospital manager's perspective, then, we are short by about 58% of staffing needs. This fact alone makes it clear that hospitals have a very real physician shortage.

It is important for everyone, the public, government, and healthcare providers, to show flexibility in considering conditions and requirements while focusing on what is needed to provide efficient, safe, high-quality healthcare.

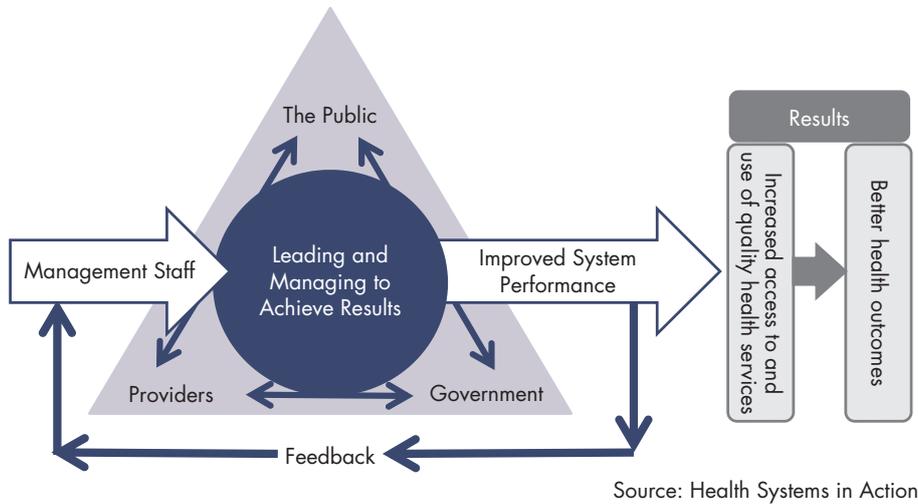
● Framework for the Strengthening of People-Centered Health Systems

Slide 4 shows a systematic pathway to better health outcomes. Providers focus on management and operations to facilitate the provision of quality healthcare and the promotion of national health. In order to optimize conditions for ideal outcomes, cooperation among all stakeholders is essential. It is also necessary to modify the approaches made by hospital managers through appropriate feedback utilizing the PDCA cycle well. If this cycle functions well, health systems will be, in theory, strengthened.

● Government-Planned Medical and Nursing Care System

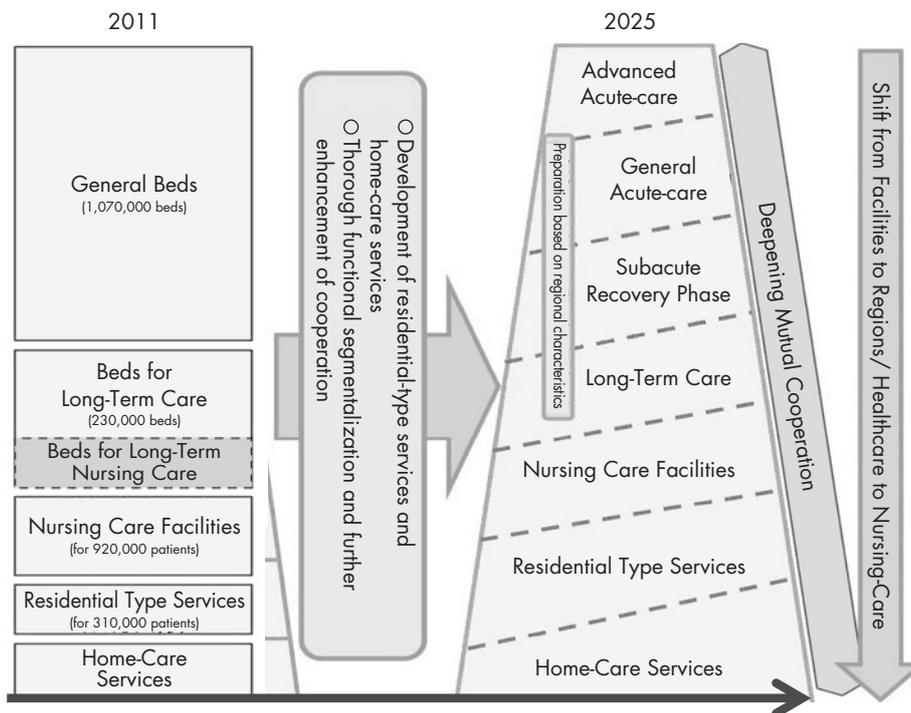
Government-planned medical and nursing care is clearly stated in the above-mentioned integration of the social security and tax systems (Slide 5). It shows types of medical and nursing care facilities, residential type services, and home-care service in 2011, including the number of general beds, beds for long-term care, beds for long-term nursing care, and how they are to be classified in 2025. This is, however, an estimate that does

Framework for the Strengthening of People-Centered Healthcare Systems



Slide 4

Government-Planned Medical and Nursing Care System: Integration of the Social Security and Tax Systems



Slide 5

not, unfortunately, reflect the opinion of those who are actually managing the hospitals. The way to change this is by presenting hard evidence. While the government thinking seems set, we have to continue the discussion on classification of hospitals with general beds.

● Classification of Hospital Beds (FY2025)

(Slide 6) The MHLW has specific plans to classify general beds into “Advanced Acute-care (20%),” “General Acute-care (20%),” and “Subacute Recovery Phase Rehabilitation (30%),” etc. The ministry has also mentioned the need to

Classification of Hospital Beds (FY2025): Integration of the social security and tax systems

- General Beds
 - Advanced Acute-care: 20%
Staff×2, Unit price per day×1.9, Average length of stay -20%
 - General Acute-care: 20%
Staff +60%, Unit price per day×1.5, Average length of stay -33%
 - Subacute Recovery Phase Rehabilitation, etc.: 30%
- Beds for Long-term Care
- Reformation of Hospital Beds: 1,070,000 beds to 1,030,000 beds (1,290,000 beds in 2025)
 - Advanced Acute-care: 180,000 beds
 - General Acute-care: 350,000 beds
 - Subacute Recovery Phase Rehabilitation, etc.: 260,000 beds
 - Regional General Beds: 240,000 beds
- Require data to confirm the feasibility of the system

Slide 6

double the number of staff for patients in the advanced acute phase. I appreciate that they will increase staff to twice the present levels; however, the medical fees are low. So they come back with the suggestion that the unit price per day (e.g. hospitalization costs per day, etc.) be increased to 190% of what it is now. This is also nice; however, it does not change the fact that they are also looking to cut healthcare costs. Seeing the average length of stay as the reason behind the high cost of healthcare, the MHLW wants to reduce the average length of stay by 20%.

The number of general beds, currently totaling 1,070,000, will increase to 1,290,000 in 2025. However, the MHLW thinks it is possible to decrease this number to 1,030,000 with various reforms. The MHLW has proposed the idea of having 180,000 beds for advanced acute-care patients, 350,000 beds for general acute-care patients, 260,000 beds for subacute recovery phase rehabilitation patients, and 240,000 beds for general regional patients. When we heard this, we were simply shocked. We asked how they thought they could accomplish this and wondered what evidence they had based their numbers on. The MHLW then told us to come up with our own evidence. I see this as a challenge posed by the MHLW. We have to give them data that reflects the actual situation. If we cannot, it will be impossible to create a healthcare system that corresponds with reality at hospitals.

● Provision of High-Quality and Safe Medical Care

(Slide 7) Next, I will talk about the provision of high-quality and safe healthcare. According to Avedis Donabedian, it is possible to evaluate the quality of healthcare by looking at three elements; namely, structure, process, and outcome. I think process may include hospital function.

The fact that high-quality and safe medical care is supported by the Medical Care Act and medical fees is extremely important. As I mentioned above, the government tends to respond from a budgetary perspective; therefore, it is hard to provide good medical care with the current system.

What then is the actual healthcare system? This is determined by the healthcare plans in each prefecture. For example, they determine the number of beds required in the secondary medical care region utilizing structure evaluation of the Donabedian model.

The fourth Medical Care Act revision in 2001 classified beds into four categories, general beds, beds for long-term care, psychiatric beds, and infectious diseases beds. What are general beds? This is a large category, which includes beds for advanced acute-care or general acute-care, etc. Is it appropriate?

Another problem that makes it difficult for the Japanese healthcare system to function is hospital classification. The Medical Care Act specifies special functioning

Provision of High-Quality and Safe Medical Care

- Evaluation of Quality of Medical Care: Avedis Donabedian
 - Structure
 - Process (including function)
 - Outcome
- Can we secure high-quality healthcare based on the current Medical Care Act and medical fee system?
- Current state of the healthcare system
 - Promoted by individual local government medical care planning
 - Total number of beds is specified (Structure)
 - Classification of beds (in the 4th amendment of Medical Care Act in 2001)
General Beds, Beds for Long-Term Care, Psychiatric Beds, Infectious Disease Beds
 - What is a general bed?
 - Classification by functions: Special functioning hospitals, Regional medical care support hospitals, etc. (Process)
 - Is it possible to evaluate by outcome?

Slide 7

hospitals, university hospitals, regional medical care support hospitals, etc. utilizing process evaluation of the Donabedian model.

We can see from the above that the current Japanese healthcare structure is established considering the evaluation of structure and process. How about the evaluation of outcome for the healthcare currently delivered at hospitals and clinics? This is a significant issue. If we claim to provide good medical care and believe we are achieving good outcomes, there should be a system to evaluate that care and those outcomes. However, there is no system set up to accomplish this because it is very difficult to do. Should we leave it because it is difficult? I do not think we should.

■ What We Require for Medical Fees and the Medical Care Act – Medical Fees

● Evaluation by means of Medical Fees – What DPC (diagnosis procedure combination) Evaluates?

(Slide 8) The diagnosis procedure combination (DPC) system for the payment of medical fees is used to evaluate the outcome. When DPC was first introduced in 2003, it was used to classify the types of diagnoses. Then, the DPC per-diem payment system (DPC/PDPS) was introduced. DPC includes function evaluation coefficients I and II. This evaluates process and structure, including hospital function, which I will describe later.

What I want to emphasize regarding the amendment of medical fees in 2012 is the introduction of basic

Evaluation by means of Medical Fees – What DPC evaluates?

- Started as DPC (FY2003)
- Integrated as DPC/PDPS (December 2010)
- Evaluation by function evaluation coefficients I & II
 - Evaluation of structure, process, and hospital function
- Introduction of basic coefficients (in the amendment of medical fee system in FY2012)
 - Evaluation of basic hospital function
 - New hospital classification
 - Existing hospital classification
 - University Hospitals vs. General Hospitals
 - Public Hospitals vs. Private Hospitals
 - Large Hospitals vs. Medium and Small Hospitals
 - Acute-care Hospitals vs. Chronic-care Hospitals
 - Hospital in Large Cities vs. Local Hospitals

Slide 8

coefficients. In exchange for the adjustment coefficients, they implemented basic coefficients based on the new principle of evaluating basic clinical functions to introduce a new classification of hospitals.

They have been classifying hospitals into university hospitals vs. general hospitals, public hospitals vs. private hospitals, large hospitals vs. medium and small hospitals, acute-care hospitals vs. chronic-care hospitals, and hospitals in large cities vs. local hospitals. We are currently taking such classifications for granted. However, medical fees have upper limits, and this causes conflict when it comes to dividing up the pie. The current hospital classification results in varying medical fees, which causes conflicts among hospitals.

The current hospital classification is not helpful for the public, either. Where do patients go when they want to see a doctor? They choose a hospital based on convenience and personal experience, without regard to its classification as a university or general hospital, or whether it is public or private. These are the problems in the current hospital classification.

● Hospital Evaluation by means of DPC/PDPS – Function Evaluation Coefficients

(Slide 9) In DPC/PDPS, function evaluation coefficient I indicates hospital structure, allocation of nurses, etc., focusing on the structure itself.

In function evaluation coefficient II, the data submission coefficient indicates how much data was submitted. There are some coefficients whose content cannot be readily understood by their titles. Efficiency coefficient is understandable, but complexity coefficient and cover ratio coefficient are not easily understood. These are used for evaluating processes and functions, not outcome.

● Hospital Evaluation by means of DPC/PDPS – Basic Coefficients: New Hospital Classification

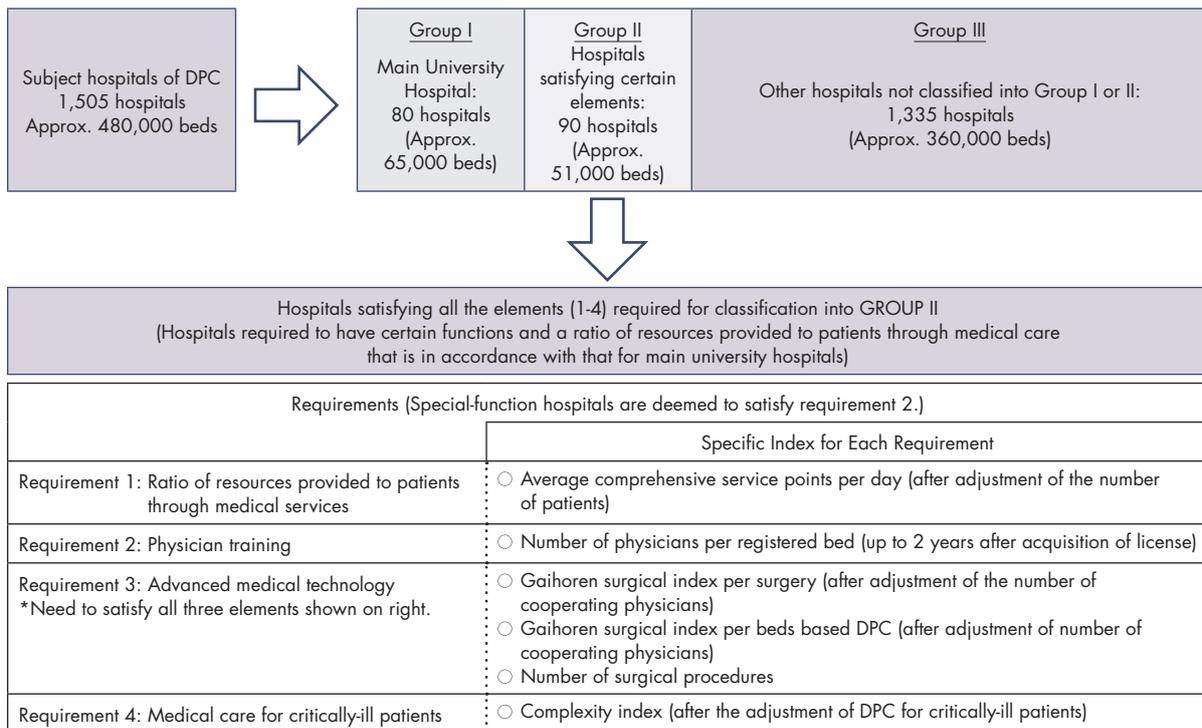
(Slide 10) I will now talk about the above-mentioned implementation of basic coefficients and the new hospital classification. There are 1,505 subject DPC hospitals, totaling approximately 480,000 beds. This new system classifies main university hospitals as bases (Group I) and others as Group II or III. Group II hospitals are required to have certain functions and a ratio of resources provided

Hospital Evaluation by means of DPC/PDPS – Function Evaluation Coefficients

| Coefficient | Coefficients | Subject of Evaluation |
|--------------------------------------|--|-----------------------|
| Functional Evaluation Coefficient I | Hospital structure/ Allocation of nurses | Structure |
| Functional Evaluation Coefficient II | Data Submission Coefficient | Process/ Function |
| | Efficiency Coefficient | |
| | Complexity Coefficient | |
| | Cover Ratio Coefficient | |
| | Emergency Healthcare Coefficient | |
| | Regional Healthcare Coefficient | |

Slide 9

Hospital Evaluation by means of DPC/PDPS – Basic Coefficients: New Hospital Classification



Slide 10

to patients through healthcare that is in accordance with that for main university hospitals. The functions consist of four elements, healthcare service density, physician training, advanced medical technologies, and medical care for critically-ill patients. Hospitals satisfying these elements can be included in Group II.

With the amendment of medical fees, among the 1,505 subject DPC hospitals, 80 main university hospitals (approximately 65,000 beds) are classified into Group I,

90 hospitals (approximately 51,000 beds) are classified into Group II, and 1,335 other hospitals are classified into Group III. Of course, this is a new system whose validity needs to be examined and discussed. However, the Chairman of the DPC section is satisfied with the results of the classification, including the hospitals classified into three groups. I wonder if there are any problems with this classification.

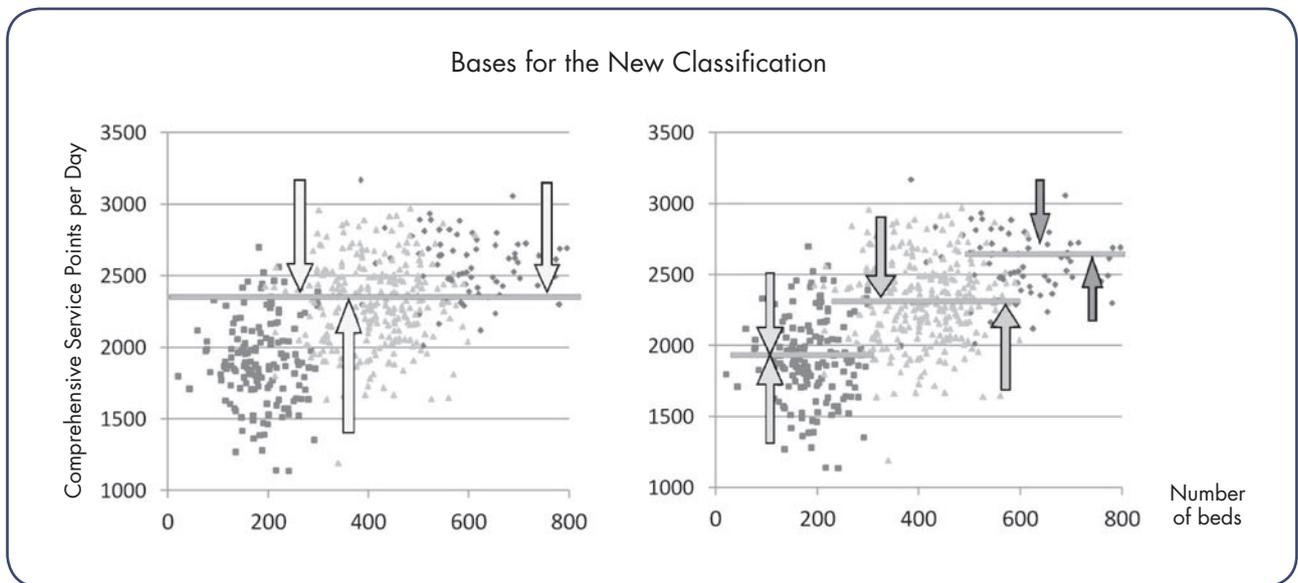
● **Bases for the New Classifications**

How did they arrive at this classification of hospitals? Slide 11 shows a distribution graph with the horizontal axis giving the number of beds and the longitudinal axis giving the comprehensive service points per day. Regardless of the classification of DPC comprehensive healthcare, the baseline is the service points. This includes data from all DPC hospitals.

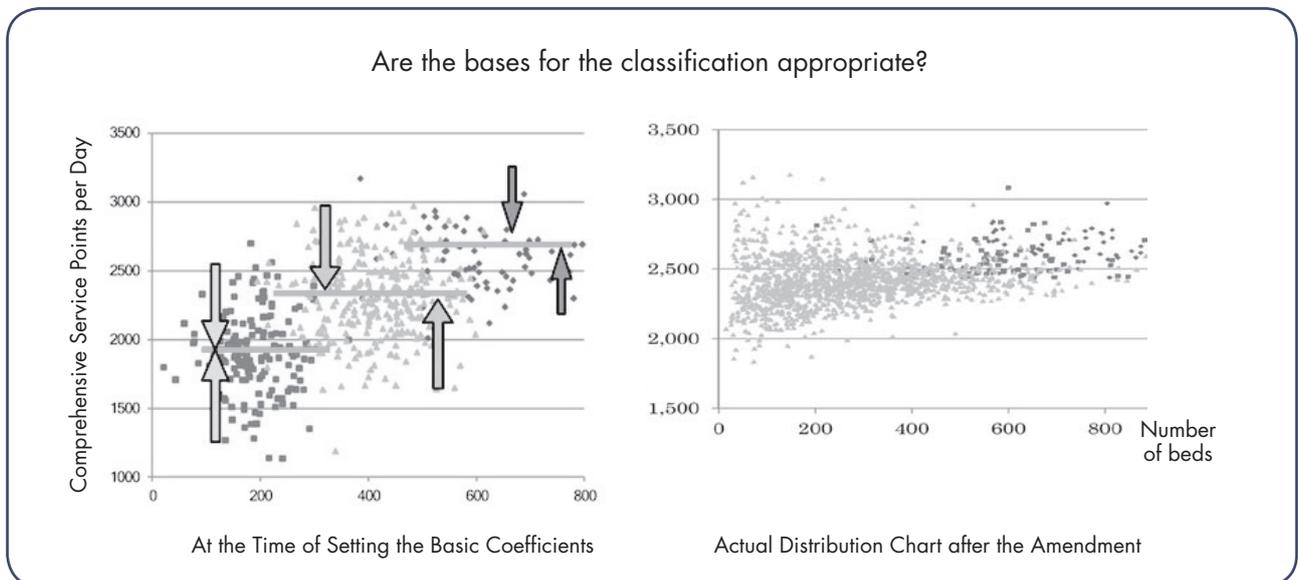
In the previous system, there was only one coefficient (as shown in the graph on the left in Slide 11). Separating them into three distribution charts (as shown in the right graph), they are clearly identifiable. When I first saw

this, I took it to be an accurate representation of the actual state of hospitals, which indeed seemed to support the appropriateness of classifying facilities into three categories. However, it was an imaginary picture created by the MHLW.

The distribution graph shown on the right in Slide 12 indicates the results of classification implemented by the amendment of medical fees in FY2012. It does not show clearly separated graphs as shown in the imaginary picture on the left. However, I feel that dark green and gray parts could represent one group. The problem, as I see it, is that the data has been presented without having been properly



Slide 11



Slide 12

analyzed, which calls into question whether the reasons for the classification are appropriate.

● Current Evaluation utilizing DPC/PDPS

(Slide 13) However, I personally feel that classification focusing on clinical function is highly regarded at this point. This is my opinion, not the JHA's. It is certain that the previous classification was ill-suited to the current situation.

However, it is doubtful that evaluation utilizing DPC/PDPS reflects the proper clinical functions. As I mentioned above, DPC/PDPS is based on comprehensive service points per day, which is not equal to the ratio of resources provided to patients through medical services. Comprehensive service points express only part of the ratio of resources provided to patients through medical services. Main university hospitals conduct complex surgeries and other complicated procedures, which require staff and significant resources. However, I know the comprehensive service points do not always match the ratio of resources provided to patients through medical services.

As I showed in the distribution chart above, it is also questionable whether classification into three groups is appropriate. I feel that classification into two groups may be better.

In the end, the evaluation continues to be limited to structure and process, including function. I hope the future will see the evaluation of outcome as well.

Current Evaluation utilizing DPC/PDPS

- Classification focusing on hospital functions is highly regarded.
- Necessary to examine if the correct hospital functions are reflected.
 - Comprehensive service points per day are the base.
 - Used as medical care density
- Necessary to examine if classification into three groups is appropriate.
 - Are two groups better?
- Evaluation at this point remains at the level of structure and process (function).
- Hope to lead to the evaluation of outcome in near future
 - Give incentives for quality medical care through the medical fee system
 - Need to promote QI projects: JHA QI Projects
 - Attempt to introduce pay-for-value (P4V)
 - Hope Japanese medical system can lead the world

Slide 13

For example, the JHA QI Project promotes QI interest, and I hope to use incentives that encourage evaluation. I want to give points to those who work hard. Eventually, I hope this will turn out to be a test run for a P4V, or pay-for-value model.

As I mentioned before, when I was in South Africa to give a presentation, many countries had implemented diagnosis-related groups (DRG). People from these countries said that while the Japanese structure was very difficult to understand, it seemed reasonable. With this in mind, I hope the MHLW exerts the effort required to allow us to become a better model for the world in this field.

■ What We Require for Medical Fees and Medical Care Act – The Medical Care Act

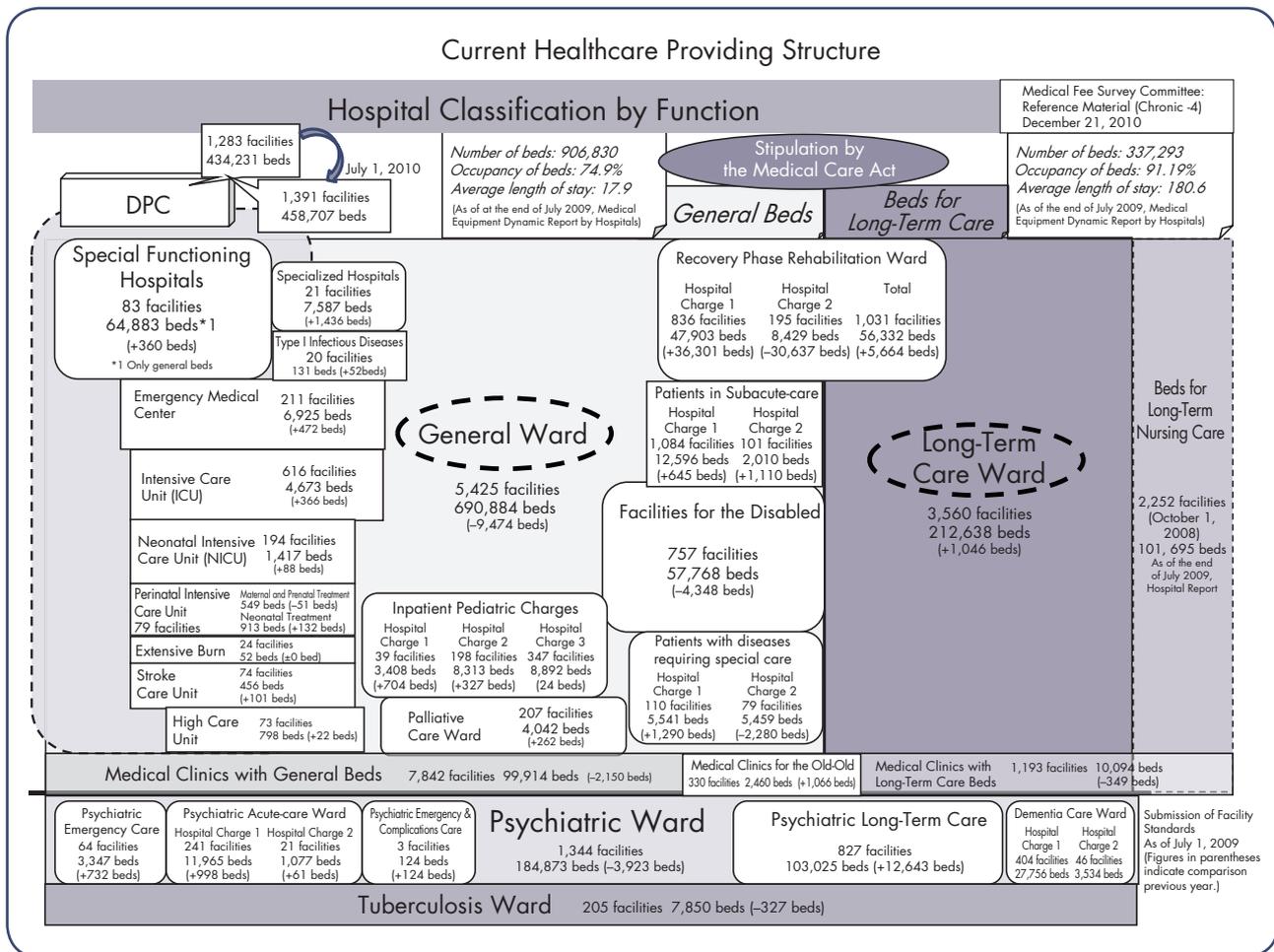
Let me now move on to the Medical Care Act. The chart shown in Slide 14 illustrates the current healthcare structure. Beds are classified into general beds and beds for long-term care. The General bed category includes a wide range of beds, making it hard to understand. There are special-function hospitals and other specialized hospitals, emergency medical service, special intensive care, etc., all with complicated structures for additional points. With a system that is almost impossible for us to understand, our poor patients are really lost.

● What Should We Do Based on the Medical Care Act?

(Slide 15) I have already talked about the evaluation of clinical quality utilizing DPC, so now, I will talk about what we should do based on the Medical Care Act.

I believe it is necessary to establish a stable and secure healthcare system, one that enables us to provide high-quality and safe healthcare. The current system, shown in Slide 14, is too complex to understand, especially the function of general beds. Therefore, I say it is necessary to classify the functions of general beds. However, we need to consider that it will become harder and harder to maintain the quality of healthcare if we operate hospitals based on the strict rules specified by the Medical Care Act. The Medical Care Act allows us to classify hospital functions; however, it is difficult to evaluate outcome. I believe it is necessary to evaluate outcome not based on the Medical Care Act, but based on the medical payment system.

Current Healthcare Providing Structure



Slide 14

What Should We Do Based on the Medical Care Act?

- Establishment of a stable and secure healthcare system
- Establishment of a structure for providing high-quality and secure healthcare
- Current system is too complicated to understand
- Function of general beds not clarified/ Necessary to classify the functions of general beds
- Strict specifications by the Medical Care Act does not fit
- Possible to classify the functions of general beds, but difficult to reflect the outcome
- Evaluate the outcome through the medical fee system
- Necessary to establish a seamless and user-oriented system

Slide 15

What we require for the new healthcare system is a seamless and user-oriented structure.

● Classification of the Functions of General Beds

(Slide 16) Classification of the functions of general beds has been brought up in discussions. First of all, there were discussions on the classification of general beds as acute-care beds and requirements for certification as such.

Let me give you some examples of the topics that have been discussed.

Basically, we all share the idea that classification is necessary. Based on a mutual understanding of the basic concept, we have discussed the need to establish a healthcare system provided by the Medical Care Act by understanding, analyzing, and utilizing information regarding hospital functions.

Classification of the functions of beds should not interfere with a facility's ability to select function and direction; however, hospitals would be obliged to report

Classification of the Functions of General Beds – Working Group for Acute-care

- Basic concepts
 - Need for classification of function
 - Establishment of a healthcare system provided by the Medical Care Act by understanding, analyzing, and utilizing information regarding hospital functions
 - Medical facilities can select function and direction
- A structure for reporting hospital function and type of beds
 - Functions such as acute-care, subacute-care, recovery phase, etc.
 - Functions, characteristics, human resources, medical equipment, hospital structures, etc.
- Measures of promoting cooperation in regions and well-balanced classification of functions
 - Understanding of the current conditions by local government
 - Discussion on the creation of regional healthcare visions in the next 5-year healthcare plan
- Role of the national and local governments, healthcare providers, patients, and the public
 - Necessary to specify by the Medical Care Act

Slide 16

the functions they chose to their local governments. They will be required to report not only the function, but also the hospital characteristics, human resources, medical equipment and hospital structures, including hospital function.

Although this is no easy task, this process will clarify the state of each local government. Based on this, visions of regional medical care will be established in the 5-year healthcare plan created in 2018.

We have been discussing the idea that the role of the national and local governments, healthcare providers, patients, and representatives of the public should be included in the Medical Care Act, which I think may be a significant change.

■ Approaches by the JHA

● JHA Visualization to Secure High-Quality and Safe Healthcare System

(Slide 17) Based on the foregoing, the JHA is working to make data and systems accessible to everyone, which also means making the JHA organization accessible both from inside and out. We collect and analyze raw data and data that have seldom been utilized.

We continue working to make data and systems more accessible with the hope of utilizing the results to

seek better hospital classifications. We also want to use the results to support member hospital management and cultivation of human resources, and to formulate policy recommendations for the government.

We are involved in online surveys, online conferences, support activities for medium and small hospitals, surveys on the impact of healthcare fee revisions, etc. As I mentioned above, QI projects are also carried out as extremely important activities for the JHA.

Slide 18 shows the data possessed and utilized by the JHA, which are basic data from the national census, clinical data, and various estimates, which were all stored in the database.

● Issues in Making Data and Systems Accessible

(Slide 19) Although we have started making data and systems accessible, we also have some problems. What we need to do now is to enhance analysis after data collection. After that, we want to promote user-friendly information disclosure to member hospitals. After disclosing information, we receive feedback and apply the PDCA cycle to improve the quality. At the same time, we promote data and system accessibility for the cultivation of management at member hospitals.

Furthermore, we are considering collaboration with other hospital organizations or external think tanks to promote the execution of governmental policies. We would like to establish a think tank inside the JHA if possible.

JHA Activities for Accessibility to Secure a High-Quality and Safe Healthcare System

- Making JHA organization transparent both from inside and out
- Collection and analysis of available data
- Collection and analysis of data that has not been used
- How to use the data
 - New hospital classification
 - Support for hospital management and cultivation of human resources for member hospitals
 - Policy recommendations
- What we are currently doing
 - Online surveys
 - Online conferences
 - Support for medium and small hospitals
 - Survey on the influence of medical fee revisions
 - Analysis of hospital management (with Public and Private Hospital Federation)
 - QI projects

Slide 17

Data utilized by the JHA

Basic data from the national census

- Total population
- Population by sex
- Population by age (5-year age groups)
- Population by age (other age groups)
- Population by nationality
- Population by labor force status
- Population by industry
- Number of households (by number of family members, family type)
- Indices
- Time-series changes (increase/decrease)

Healthcare Data

- Daytime population
- Comparison of daytime and nighttime population
- Number of households by annual income
- Population per medical institution
- Number of hospitals/ Number of beds
- Number of clinics
- Ratio of patients by classification of disease
- Number of physicians by specialty

Estimates

- Population projections (- 2035)
- Estimated number of patients (- 2035)
- Estimated number of outpatients by clinical department

Slide 18

Issues in Making Data and Systems Accessible

- Shift from data collection to data analysis
- User-friendly information disclosure to member hospitals
- Feedback from member hospitals
- Cultivation of management staff for member hospitals by making data and systems accessible
- Functioning PDCA cycle to improve quality
- Cooperation with other organizations
- Establishment of think-tank functions

- * Appreciation of corporations providing cooperation in making data and systems accessible
- Eneco System Co., Ltd.
 - Giken Shoji International Co., Ltd.
 - New Medicine in Japan
 - Kokusai Kogyo Co., Ltd.

Slide 19

The JHA alone cannot make data and systems accessible. This requires cooperation from various corporations, such as Eneco System Co. Ltd., Giken Shoji International Co., Ltd., Monthly New Medicine in Japan, Kokusai Kogyo Co., Ltd.

■ Conclusion – What is necessary for the healthcare system is a paradigm shift.

(Slide 20) I think what is necessary for the healthcare system is a paradigm shift. We need to be free from conventional concepts.

● The Healthcare We should Strive to Realize – High-Quality and Safe Care

We have not established a unified healthcare goal. I believe we need to focus on providing efficient, safe, high-quality care. The MHLW also has the same goal. When you imagine your family getting sick, what do you want to for them? You hope in the end that your family receives high-quality and safe medical care, don't you? Both hospitals and government need to consider what we can do to realize this goal as efficiently as possible.

● Initiative – Cooperation among the Public, Government, and Healthcare Providers

Who will take initiative? We have relied on the government. The government gave hospitals responsibility and offered subsidies. But the subsidies came from tax revenue, which in turn came from a hard-working public. So, it is not quite right for the government to ask the hospitals to obey its policies simply by handing out subsidies. I think we

Conclusion – What is necessary for the healthcare system is a paradigm shift.

| | Old Paradigm | New Paradigm |
|--|--|---|
| The healthcare we should strive to realize | Not clear | High-quality and safe care |
| Initiative | Government | Cooperation among the public, government, and healthcare providers |
| Major topic of discussion | Speculative discussion – Macro data | Along with the actual state of hospitals – Micro data |
| Classification of hospitals | Hierarchical | Classification of functions |
| Incentives | Healthcare fee system – Structure, process | Medical Care Act, Medical fee system – Outcome value |
| Governance management | Not clear Horizontal relationships | Strong top management leadership Roles for and cooperation among middle-level managers |

Slide 20

need to remember the necessity of changing the existing paradigm to cooperation among the public, government, and healthcare providers.

In our position, we tend to see hospital management from our specific perspective. For example, “Medical fees have changed, so let’s have a 7:1 nurse-patient ratio because it is better for the patients.” However, there is no big difference between 7:1 and 10:1. There are some studies on the comparison of these two ratios from the patient’s perspective, and they did not show any big differences.

How about patient participation in hospital management? This has become a significant issue in the evaluation of hospital functions. Hospitals are now required to have patients or representatives of the public participate in hospital committees to provide hospital information and seminars. It is not easy to do, but we need to do it.

So, who takes the initiative? I say that healthcare needs to be a cooperative effort among the public, government, and healthcare providers.

● Major Topic of Discussion – The Current State of Hospitals (Accessibility of Micro Data)

We have speculative discussions based on macro data.

When we asked the MHLW how data regarding the classification of general hospitals would be managed in the new system, they said that data management would be

included in the healthcare planning of local governments. When we asked if the MHLW had confirmed this, the MHLW said that the local government must be handling it. In fact, local governments actually do manage healthcare data. In order to create 5-year plans, however, these accumulated data is not easy to access. We need to sift through five, six, or even seven layers of information to find what they need. Even if we can find the data, what we find is simply raw data without any explanation. We are asking local governments to provide the results of analyses, which is basic and essential. It is always necessary to analyze data and understand results.

Under the new paradigm, discussions will be centered on the state of hospitals. Healthcare should be planned in accordance to regional conditions. For example, the healthcare required in Nagasaki Prefecture with its many remote islands is significantly different from that required in Tokyo. What we need to do, therefore, is to collect micro data reflecting the conditions of hospitals in the region and make the data available to everyone. This is the key to promoting progress in other areas.

● Classification of Hospitals – Classification of Functions

The existing classification of hospitals is based on an outdated hierarchical system. Hospitals should be classified according to functional segments and reflect outcome.

● Incentives – Evaluation of Outcome should be Included in the Medical Care Act and Medical Payment System

Hospital management is facing serious funding problems. However, we need to have some incentives even under such circumstances. Incentives do come in medical fees. For example, the Nutrition Support Team (NST) is a subject of additional points for the system. However, the medical payment system only reflects the evaluation of structure and process. Therefore, it is essential to create a structure that enables the evaluation of outcome value by the medical payment system and Medical Care Act.

● Governance Management – Strong Leadership, Enhancement of Mid-Level Managers

Hospital managers are working hard to enhance governance management. About 20 years ago, physicians were promoted to management positions and became hospital managers although they were not interested in management at all. There is a rule in Japan that top management at hospitals has to be made up of physicians. For this reason we see physicians who are not interested in management at all and who have no management knowledge filling these important positions. They are often at a loss as to what to do.

Hospitals employ a wide range of nationally certified specialists, which may create horizontal relationships. This leads to a situation in which it is difficult to know what the person next to you is doing. If the top management exercises effective leadership, such problems can be solved.

Actually during the past 10 to 15 years, it has gotten much better. I think we will have more people in the near future expressing the opinion that top management at hospitals does not necessarily need to be physicians. In the United States, many hospitals have managers who are not physicians; however, you can also hear there that when the hospital manager is not a physician, it is hard to manage the system well.

Only 20% of the hospital managers in the U.S. are physicians. Among hospital managers in the U.S., 2 to 3% are nurses. Among 8,700 hospitals in Japan, about 300 have nurses serving as assistant directors.

I want to emphasize the necessity of strong top management leadership at hospitals. It is also important

to have specific roles for and cooperation among middle-level managers, including all professions such as physicians, nurses, other healthcare personnel, and office workers. In order to make the system work well, not only the top management, but also other members of the staff need to play their roles appropriately.

(Slide 21) This photo shows Tokyo Skytree, a new Japanese symbol, and Mt. Fuji, which has been the Japanese symbol for a long time, together. As in this photo, Japanese medical care will grow by implementing new technology and mechanisms while we maintain the aspects of the system that have continued to prove their worth.



Tokyo Skytree and Mt. Fuji

Slide 21

Japan Hospital Association QI Project 2011: Results and Future Issues



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■ Introduction

The Japan Hospital Association (JHA) QI Project was launched in FY 2010 by the Ministry of Health, Labour and Welfare as a project to evaluate and publicize the quality of medical care in FY 2010 (hereinafter Promotion Project). The JHA had been one of the three organizations commissioned to cooperate, and after completing the one year cooperation period, took over the Project from the Ministry of Health, Labour and Welfare and restarted it as a JHA project to improve the quality of member hospitals. 30 hospitals participated in the Promotion Project, but in FY 2011, the first year after JHA took over, the project began with 85 participating hospitals (25 continuing, 60 new).

As for indicators, the eleven used in the Promotion Project were used. No changes were made to the definitions for the seven that could not be calculated by DPC (diagnosis procedure combination) alone. However, the four that could be calculated by DPC were defined to conform to the clinical indicators of the National Hospital Organization, that have more detailed definitions (Table 1).¹

The main goal of the Japan Hospital Association's QI Project is for hospitals to make every effort to improve while releasing its own data over time, improving the quality of medical care as a result. The main purpose of participating hospitals to share their data is not to rank them with cross-sectional comparison, but is regarded as one approach towards the motivation to improve each hospital's data over time. Comparison of facilities is only to understand the position of the individual hospital. The quality of the individual hospital should be improved by knowing what improved hospitals have been doing and

incorporating those activities for its own betterment.

After completing one year of our activities, we conducted a questionnaire about reactions within the hospitals and improvement activities. We examined the results and issues connected to proceeding with the QI Project on an ongoing basis.

■ Questionnaire and Results of Improvement Activities

1) Style of questionnaire

Individual feedback data was drawn up for the 85 hospitals based on data submitted as of April 21, 2012. A line chart was made to show the indicators submitted monthly and DPC calculated indicators (Figure 1-a). The yearly submitted indicators and those with smaller parameters are shown in a bar graph (Figure 1-b). This data was sent as feedback to each hospital, while a questionnaire about the QI Project was conducted on our website.

The questionnaire included overall QI questions such as, "Have you changed the positioning of, or established a new committee to improve the quality of medicine using QI?" "Where do you report QI evaluation results in the hospital?" "What were the reactions and opinions on site?" and for each indicator, "Was it difficult to calculate indicators?" "Did you conduct improvement activities?" "Do you have any improvement activities planned from now on?" In addition, the hospitals were asked to report on reasons their level was higher/lower than other institutions, as well as specific details of their improvement activities. Regarding improvement activities conducted and those planned, they were asked to choose as many of the following that apply.²

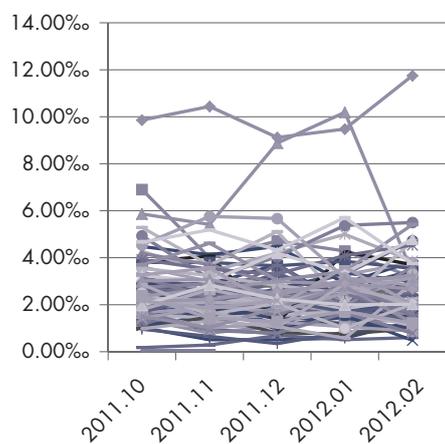
■ Table 1: Changes in indicator definitions between FY 2010 and FY 2011

| No. | | Type | Indicator title in FY2010 | Change in definition | Indicator title in FY2011 |
|-----|-----|---------|---|----------------------|--|
| 1 | | Outcome | Patient satisfaction (outpatients) | No | Patient satisfaction (outpatients) |
| 2 | | Outcome | Patient satisfaction (inpatients) | No | Patient satisfaction (inpatients) |
| 3 | | Outcome | Mortality rate of discharged patients | No | Mortality rate of discharged patients |
| 4-1 | | Outcome | Accidental fall rates of inpatients | No | Accidental fall rates of inpatients |
| 4-2 | | Outcome | Incidence of injury caused by fall | No | Incidence of injury caused by fall |
| 5 | | Process | Prophylactic antibiotic administered within one hour prior to surgical incision | No | Prophylactic antibiotic administered within one hour prior to surgical incision |
| 6 | DPC | Outcome | Rate of emergency readmission within 6 weeks of discharge | Yes | Rate of emergency readmission within 6 weeks of discharge |
| 7 | DPC | Process | Preventive action for pulmonary thromboembolism in surgical patients | Yes | Preventive action for pulmonary thromboembolism in surgical patients (mid- to high risk) |
| 8 | | Outcome | Incidence of pressure ulcer | No | Incidence of pressure ulcer |
| 9 | | Outcome | HbA1c (NGSP) < 7.0% (HbA1c (JDS) < 6.6% | No | Blood glucose control of diabetics: HbA1c (NGSP) < 7.0% (HbA1c (JDS) < 6.6% |
| 10 | DPC | Process | Rate of aspirin administration to patients with acute myocardial infarction | Yes | Rate of clopidogrel bisulfate or aspirin prescription at discharge for patients with acute myocardial infarction |
| 11 | DPC | Outcome | Incidence of potentially preventable venous thromboembolism | Yes | Incidences of pulmonary thromboembolism in surgical patients (mid- to high risk) |

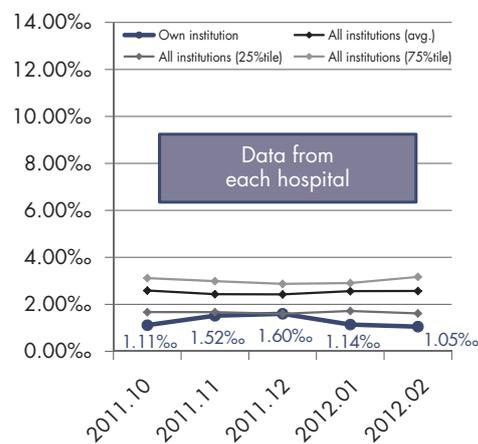
■ Figure 1-a: No. 4 Accidental fall rate of inpatients

| | |
|-------------|--|
| Numerator | Number of accidental falls reported to medical safety office (incident/accident reports) |
| Denominator | Number of inpatients |

Total cooperation institution

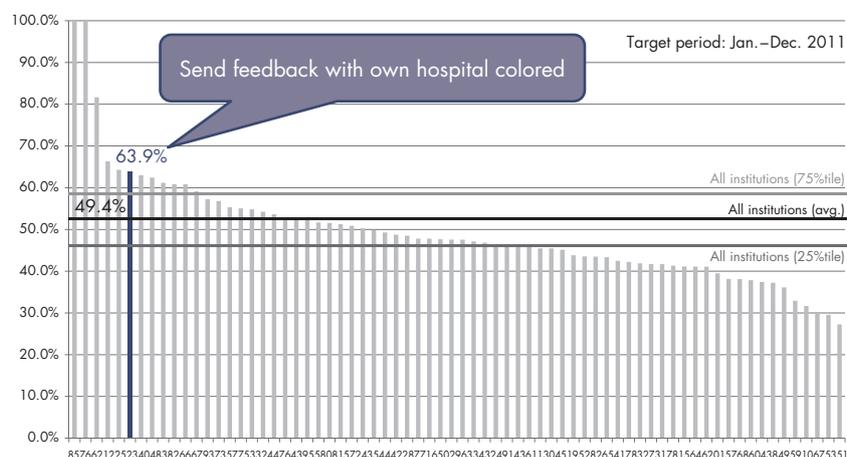


St. Luke's International Hospital



■ Figure 1-b: No. 9 Blood glucose control of diabetics

| | |
|-------------|---|
| Numerator | Number of outpatients with final HbA1c (NGSP) under 7.0% (Number of outpatients with final HbA1c (JDS) under 6.6%) |
| Denominator | Number of patients receiving drug therapy for diabetes |



1. Reviews and purchases regarding establishment, facilities and equipment
2. Reviews and/or changes regarding guidelines and rules
3. Reviews and/or changes regarding management processes
4. Sharing information within the hospital and feedback regarding indicators
5. Holding study groups and lectures
6. Reaching out to patients
7. Securing personnel
8. Other

2) Questionnaire results

Two weeks were allotted to answer the questions, and 76 hospitals responded (89.4% response rate).

To the question, “Where do you report QI evaluation results in the hospital?” more hospitals suggested meetings that are attended by members of hospital management (hospital administration and operation meetings – 53.9%, board meetings – 32.9%) than the hospital as a whole (22.4%). Responses to the question, “What were the reactions and opinions on site?” were generally good, with negative 0.0%, somewhat negative 1.3%, neutral 52.6%, somewhat positive 40.8%, and positive 5.3%.

When asked about the difficulty to calculate the indicator of patient satisfaction (outpatients and inpatients), most were neutral. This is likely not a matter of whether the calculation was difficult, but an indication

of how difficult it was manually, as every hospital distributes a satisfaction questionnaire printed on paper. Many improvement activities were seen, including the review of reservation slots, a workshop on reception, and expansion of the parking lot.

48.7% answered that the calculation of the mortality rate of discharged patients was extremely easy. However, because this is an outcome indicator and that the medical institution’s features (number of staff, number of beds, existence of an emergency center/intensive care unit or palliative care ward, average length of stay, regional characteristics) and patient profile (age, gender, type of illness and severity) come into effect, involvement is thought to be difficult, thus most hospitals did not conduct improvement activities.

Many hospitals replied that the accidental fall rate of inpatients was generally easy to calculate (easy + extremely easy, 62.7%). The most common improvement activity was number 4 – sharing information within the hospital and feedback regarding indicators – at 71.1%. When observed in more detail, efforts included feedback of results from each ward after occurrences and times were analyzed, and sharing information by marking the bed name of high-risk patients.

Compared to other indicators, many hospitals said it was difficult to calculate the rate of prophylactic antibiotics administered within one hour prior to surgical incision (difficult + extremely difficult, 65.8%). Causes

of this are thought to be that the exclusion criteria of the definition is complex, the denominator is the number of discharged patients who underwent surgery, and it is necessary to trace back if the length of stay is long-term. Because of the difficulty to calculate, many hospitals said that they did not conduct improvement activities. Of those that did, nearly 40% responded by choosing 4 – sharing information within the hospital and feedback regarding indicators – as with the accidental fall rate of inpatients. More specifically, implementations included changes to procedures to administer antibiotics after entering the operating room, adding administration of preoperative antibiotics to the pre-op timeout checklist, and sharing data within the hospital before conducting a survey on the awareness of preoperative antibiotics.

Not many hospitals responded that calculating incidences of pressure ulcer was extremely difficult or extremely easy. 41.3% were neutral. The popular improvement activities were again number 4 – sharing information within the hospital and feedback regarding indicators – at 63.2%. Next to that was number 5 – holding study groups and lectures – at 51.3%. Looking at them more closely, efforts included revision of the pressure ulcer manual, made pressure ulcer rounds, and purchased body pressure dispersion bedding.

For blood glucose control of diabetics, the response was that it was the most difficult of the seven indicators each hospital was asked to calculate themselves (most difficult + difficult, 69.7%). The cause for this is thought to be that the number of days prescribed needed to be

calculated into each prescription and that there are many patients with diabetes. The improvement activities here too, were mostly number 4 – sharing information within the hospital and feedback regarding indicators – (39.5%) and some hospitals were not only providing feedback to the hospital as a whole, but to the individual doctors as well.

Regarding the other four indicators that were calculated by DPC, because it was the first time to provide feedback using a chart, the hospitals could not see if they had gotten better or worse. For this reason, the majority of hospitals did not conduct improvement activities.

3) Results of improvement activities

As stated above, each hospital has conducted activities for improvement and some showed tremendous achievements in just a few months. For the accidental fall rate of inpatients, Aizawa Hospital made an improvement from 1.94‰ in October 2011 to 0.92‰ in February 2012 (Figure 2-a). For their improvement activities, they have reviewed processes and made flowcharts to proceed with information sharing within the hospital. Likewise, Kikuna Memorial Hospital, although varying from month to month, improved from 2.23‰ in November 2011, its highest in the five months, to 0.48‰ in February 2012 (Figure 2-b).

Two hospitals showed great improvements in the rate of prophylactic antibiotics administered within one hour prior to surgical incision. One was the Rissho Koseikai Hospital, which went from 60.0% in October 2011 to 87.7% in February 2012 (Figure 3-a). They say that their

■ Figure 2: Improvements in accident fall rates in patients

Figure 2-a: Aizawa Hospital

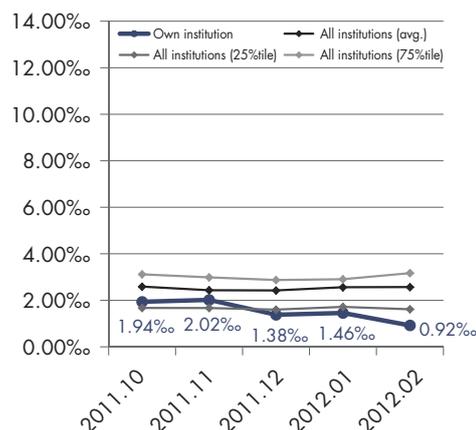
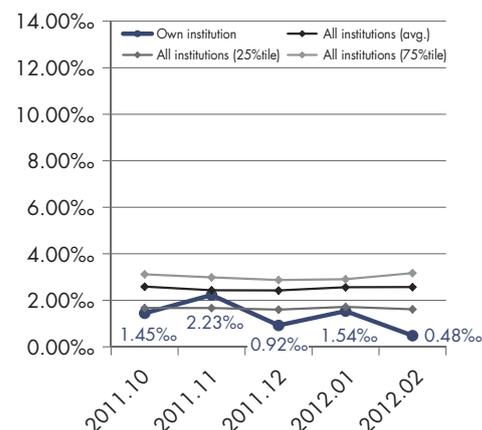


Figure 2-b: Kikuna Memorial Hospital



■ Figure 3: Improvements in rates of prophylactic antibiotics administered within one hour prior to surgical incision

Figure 3-a: Rissho Koseikai Hospital

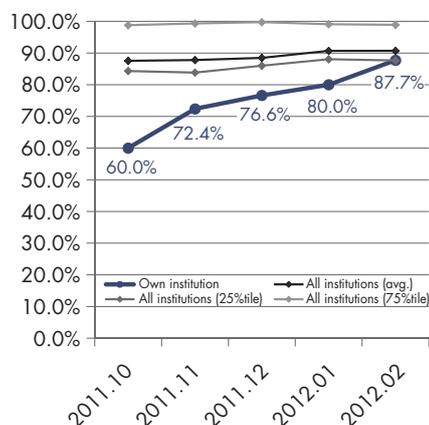
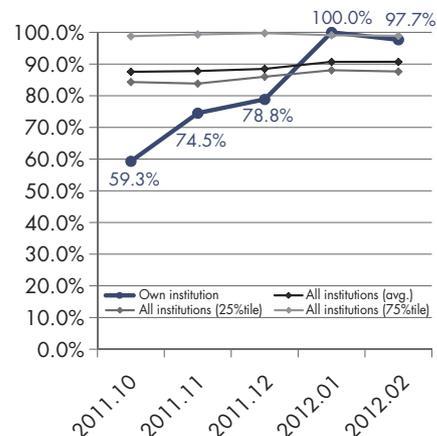


Figure 3-b: Hashima City Hospital



improvement is only due to information sharing, however they also say that a committee has set a goal by displaying the feedback data. Further improvements can be expected. The other hospital is Hashima City Hospital, which showed an improvement from 59.3% in October 2011 to 100% by January 2012 (Figure 3-b).

As can be seen from the questionnaire results, most of the indicator improvement activities were “sharing information within the hospital and feedback regarding indicators.” Sharing information and visualizing the indexes became a strong motivation factor for activities of improvement, thus leading to positive results. It can be concluded that 1) the Hawthorne effect, and 2) improvement in performance by comparison (comparison with evidence, comparison with other doctors and other medical institutions) are working to improve QI through QI evaluation and publication.

■ Issues

1) Choosing and reviewing indicators

Through the year, we have been calculating and analyzing the 11 indicators. It is probably more appropriate to show numerical values of how in practice the clinical process has been carried out through clinical research demonstrating that improvement activities raise the possibility of achieving the best health outcome for the patient.³ From now on, it is likely necessary to select process indicators as well as outcome indicators that are connected to those process indicators.

Also, regarding the indicators that were found difficult to calculate as per the questionnaire results, it is necessary

to review calculation methods. Simplification might make calculations easier, however then there becomes a need to examine the validity of the indicators thoroughly. Moreover, what we know as common knowledge now will not necessarily continue to be common knowledge, depending on results from new clinical research. In order to continue the QI Project, it will be essential to review indicators after each interval.

2) Proceeding with the QI Project on an ongoing basis

There is no end to quality improvement activities. The Japan Hospital Association established a QI Committee in FY 2011 and has since been selecting indicators, preparing defining material, preparing and supplying feedback material, in addition to conducting surveys, collecting and summarizing the questionnaires and preparing reports. Not only that, it has recruited participants for questionnaires on the QI Project as a whole and the calculation of indicators, then analyzed data collected from each hospital. The number of participating hospitals grew from 30 for the Promotion Project in FY 2010, to 85 when the Project was re-launched as the QI Project in FY 2011. The number is expected to reach over 140 for FY 2012. In the future, it will become important to strengthen and upgrade the system for these efforts to proceed in a continuous and efficient manner.

For details, please visit *The QI Project* on the Japan Hospital Association website at: <https://www.hospital.or.jp/qip/>

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Ongoing Physician Practice Evaluation (OPPE): Challenges in Implementation in Japan – An Opinion



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As of the time of this writing, there are six hospitals in Japan that are accredited by Joint Commission International (JCI), and one long-term care facility. One of the JCI standards for hospitals pertains to a requirement for ongoing monitoring and evaluation of medical staff members. The concept is simple enough and it is reasonable to assume that hospital leadership would have developed an ongoing professional practice evaluation (OPPE) process for physicians permitted to practice medicine in their organization. The question is often not whether there is a structure in place to evaluate physician performance, but is one of process and ultimately, outcome. Such a review or evaluation of performance allows leadership to identify trends or issues that could have a negative impact on the quality of care delivered as well as on the safety of the medical care. To date, since all of the accredited hospitals here talk to each other, I know how hard it is to meet this requirement. Although my hospital does fairly comprehensive physician evaluations annually, we were unable to meet this requirement when we were reaccredited in October 2012. We appealed this finding, indicating that a myriad of data was used in evaluating physicians, but our appeal was denied. We felt that we were collecting more than adequate data on our physician's practice patterns and that we had adequate monitoring for outliers and incidents. Furthermore, we used it for physician performance evaluations. JCI did not agree with us, indicating that indeed we were collecting practice data, but that a review of the physician's personnel files did not show a formal linkage, did not use the data comparatively in a proactive manner, nor was there any benchmarking to literature-based medicine or existing

data bases. We are now embarked on a plan to have a more effective OPPE plan in place.

Internationally, not all healthcare systems are the same, and some have a degree of uniqueness in the way they operate. I believe Japan has two aspects of uniqueness that impact the ability to effectively implement an OPPE program within its hospitals. First, physicians are licensed for life without a renewal requirement. Japan is not the only country that licenses its physicians for life, but in my opinion it hampers a periodic review of the appropriateness of continuing licensure based on a review of qualifications or perhaps requirements such as mandatory continuing medical education, for example. If OPPE could be linked to an existing requirement, such as license renewal, or re-credentialing, it could have a better structure. OPPE in the United States is more frequent, but JCI only requires "...at least annually." If the JCI requirement changes to reflect more frequent OPPE, hospitals in Japan will be hard pressed to have adequate resources to support this. I consider this a weakness that potentially could negatively impact patient care. I find it odd that the law requires the periodic renewal of driver's licenses as a public safety concern, but not physician licenses. Commercial pilots have similar requirements to ensure that their qualifications are up to date, again out of public safety concerns. This may have prompted JCI to add a requirement that the hospital review the qualifications and credentials of medical staff members at least once every three years and to make an official and documented decision to renew or deny permission to continue to provide patient care services. Second, with very few exceptions, all hospital physicians in Japan are hospital employees and constitute

a closed medical staff. This is considered to be a strength since physician leaders regularly observe colleagues, peers and juniors on the medical staff closely. It therefore should make evaluation of physician performance easier. Unfortunately, it does not make it as easy as it might seem since observation is not standardized, lacks objectivity and is not evidence based. It makes comparisons difficult and virtually impossible to match against literature-based medicine. Therein lies the dilemma. The OPPE program needs to be objective and evidence based. It isn't good enough for a department head to evaluate a medical staff member based on day-to-day observations alone or working in close contact with them as part of a team - or to simply have access to relevant data.

If working closely with a colleague is not enough to evaluate his or her professional practice, what constitutes objectivity and evidence? The answer is simple – reviewing relevant data. The JCI suggests that the OPPE criteria include the review of operative and other clinical procedures performed by the medical staff members being evaluated and their outcomes. It is not mandatory to do so. This can be an overwhelming requirement when there are hundreds of physicians on staff. It gets even more challenging because an evaluation of the pattern of blood and pharmaceutical use is also provided as an example/suggestion as well as a review for the appropriateness of tests and procedures, length of hospital stay patterns, morbidity and mortality data, the appropriateness of the physician's use of consultation and specialists, and whatever other criteria the organization deems important to consider in its OPPE program. By providing specific criteria to be considered, it is clear to me that the requirement for specific and detailed comparative data analysis is huge. Moreover, adding to the burden is that the OPPE requirement is annual and must be done for every medical staff member permitted to provide medical care to patients within the hospital, which can apply to outpatient care as well.

As can be seen, this is a significant amount of relevant data to be reviewed and judged. The accredited hospitals in Japan as well as those seeking accreditation here have good electronic medical records, which would appear to make data retrieval easy. But this is misleading and although adequate data often exists, there is usually no simple way to easily extract it in a meaningful way. Electronic Medical Records were not designed to extract much of

the comparative data suggested by JCI and it is difficult to rewire them to perform this function. With the possible exception of length-of-stay patterns, profiling individual practitioners electronically is simply not possible without very complex changes as to how records are structured electronically. Periodic chart review is helpful but very, very labor intensive and time consuming. However, the intent of this JCI standard indicates that OPPE data can also be acquired by direct observation as well as through discussions with peers and other staff. However, there is a requirement to consider and use comparative data such as benchmarking to literature-based medicine. This was the issue during our JCI accreditation survey. We were unable to convince JCI that in spite of the lack of documented comparative data in the performance evaluation files of the medical staff, that we really used the data suggested by the standard to compare the individual practitioner's performance. In all honesty, it is highly probable that in some departments, the criteria suggested by the JCI standard was not considered. It would seem that direct observation has severe limitations if comparative data needs to be considered and used because periodic or ongoing direct observations are rarely documented in a standardized process to allow for comparisons to be made. Self assessment is similarly not effective, as there is a natural tendency overestimate the degree of compliance with established requirements. Clinical quality monitoring is helpful as is periodic monitoring of diagnostic and treatment techniques. However, when periodic monitoring of diagnostic or treatment is done, performance may be better than when it is not subject to this monitoring. This is referred to as the Hawthorne effect. This is not to say that these methods are without value, but they are not a substitute to reliable and validated data.

Benchmarking to literature-based medicine is also problematic. In many countries where English is not in widespread use, particularly in healthcare, physician exposure to international literature-based medicine may or may not be common. In smaller and non-academic medical centers with rudimentary medical libraries, books, journals and other periodicals tend to be in the local language, in this case Japanese. Not all literature-based medicine publishing is translated into Japanese and when it is, there is often a delay. This is not to say there is a paucity of Japanese literature-based medicine, but in non-teaching hospitals, access can be difficult. It may be

difficult to suggest to department heads that literature-based medicine be a factor in completing a physician's professional performance evaluation, when this has never been formally done in the past. Not impossible, but getting interdepartmental consensus, searching the literature and then applying it to each individual physician's performance annually will face a degree of resistance. Medical staff cooperation and consensus will be an ongoing obstacle.

Although a generalization that might have some exceptions, Japanese hospitals do not normally share comparative data and even the activities of the Voluntary Hospitals of Japan (VHJ) share very limited data, usually focusing on case mix reimbursement under the DRG hybrid called DPC here. This has a quality assessment component to it, but is far too general to even begin providing comparative data, other than length of stay, in supporting a hospital's OPPE program. There is hope on the horizon and although data sharing is limited to resources mainly from DPC participant hospitals (total 1,505 facilities in 2012), data comparison is available at several websites and is getting proactive. Hospital Intelligence Agency: <http://hospia.jp/>, Annual Report of Clinical indicators, National Hospital Organization http://www.hosp.go.jp/resources/content/11983/ci_h23iryuu.pdf It remains to be seen whether this data can be useful and incorporated into an effective OPPE program in a hospital. Most hospitals here are organizationally stand-alone and consider quality data proprietary and protected.

Another challenge, a large one, is getting consensus from the individual specialty physician departments on how to conduct the reviews and what constitutes appropriateness to ensure it is objective and not subjective. Not easy. If we look just at a review of the physician's use of consultation and specialists, it is not difficult (only labor and time intensive) to determine if a consultation was required by a clinical guideline/pathway/protocol used to guide care, and whether that consultation took place. Unfortunately, this must be extracted manually from the chart and not all care being rendered uses clinical pathways. Once we have total cookbook medicine, we can easily see if following the recipe was documented, but the complexity and variables involved in providing medical care make this most unlikely to occur anytime soon, if at all. It is therefore doubtful that this suggested criteria would be chosen, due to subjectivity when not matching it against protocols. As an example, we have seventeen

OBGYN specialists on staff. Extracting data on antibiotic use from medical records is not easy, determining appropriateness of use is more difficult, and comparing the data among the department staff using literature-based medicine, or national/international databases even more difficult. Then, using that information to formally appraise a physician's performance is significantly challenging.

Most hospitals in Japan are understaffed for this requirement. If we just look at periodic chart review defined annually at the very minimum with a minimum of just ten closed medical records for the 450 full time medical staff at my hospital, it will require a review of at least six aspects of care delivery for each practicing physician. This is a total of at least 27,000 reviews and judgments on the quality and safety of the medical staff, based on the JCI suggested criteria. When we add direct observation, monitoring of diagnostic treatment techniques, clinical quality and safety monitoring, and discussions with peers and other staff, the review and judgment requirements almost double. Determining the number of chart reviews, frequency, and target frequency adds more complexity.

Let us look at just one of those aspects that looks not difficult. In our chart review of ten closed medical records for a surgeon, we want to determine if the pattern of blood usage was appropriate. We can look to see if blood was ordered for the surgery, we can look at the estimated blood loss in the operative note, and we can tell if the blood that was ordered was used. Alternatively, we could look at whether blood was not ordered but was required and urgently sent to the operating theater and used. We have three patterns to judge. Ordered and used, ordered and not used, and not ordered and used. Obviously, ordered and used seems to be an appropriate pattern. Ordered and not used requires a different kind of judgment. Did the surgeon adequately describe/document a reasonable risk precaution to have a unit ready just in case, for this particular surgical procedure? What if on further review, it was found that the surgeon always ordered a unit but never used it, and the financial loss to the hospital from having to discard the unused blood was significant. There is no negative impact on the quality or safety of the medical care, but when comparing his blood usage pattern with that of his peers for this procedure, should this be reflected in the surgeon's OPPE if no one else is taking this precaution for this type of surgery? I don't know the answer. Is there adequate literature-based medicine, in Japanese, that

addresses the appropriateness of blood usage that can be applied to this cohort of physicians at my hospital for this particular surgical procedure? I don't know. In the last case of an unanticipated use of blood when none was ordered, a sample of just ten records may not reveal the true percentage of time that it had occurred in order to compare with peers. The unanticipated use of blood is best to be considered as a reportable event, each and every time it occurs, so a root cause analysis can determine what happened so that corrective actions can be put in place, if needed, to prevent reoccurrence. In this case periodic chart reviews may not pick up a pattern, whereas quality-monitoring systems could more readily identify this. Or, we may want to review only closed medical records in which blood was used by the surgeon. We would need a way to identify those cases. Perhaps the involvement of the laboratory rather than the electronic medical record would be a better source of data. Although both reviews would be time consuming, it shows the benefit of using more than one source of relevant data to evaluate blood usage patterns. Unfortunately, looking at appropriate pharmaceutical usage per individual physician is much more complicated. Added to this is a perception by many physicians that chart review is looking for bad apples and will be used punitively rather than as a tool to improve performance. This is often hard to overcome, especially if the process is perceived to be overly subjective. Perception by physicians can be that OPPE initiatives are judgmental, and not to be used as an action tool, and for this group, perception is reality.

Getting started can be a daunting task in hospitals that have not implemented even the most basic physician performance evaluations. Typically these hospitals rely heavily on department heads to be aware of the performance of the physicians in their departments, to have access to relevant data in the medical records and consider it in completing a performance appraisal document that may rate the physician as superior, excellent, good, or poor. The document contains no text nor any objective data and certainly no comparative data. The expansion of quality monitoring systems and creation of databases linked to the electronic medical records is a staff, money and time problem. The resources that need to be brought to bear, to develop an effective and JCI compliant OPPE program, are not small. Many hospitals CEOs, all of whom are physicians by law in Japan, feel that current oversight of

physician performance by department heads and other clinical leaders is sufficient enough to identify trends or issues that may potentially impact negatively on the quality and safety of the medical care delivered in their hospitals. If and when physician performance is suspect, given the broad oversight, only then would there be a more detailed analysis needed. All hospitals have some type of incident reporting system in place. The return on investment by an expansion of OPPE to meet JCI accreditation requirements can be seen as having little merit. Accreditation by the Japan Council on Quality Health Care, Japan's domestic hospital accreditation organization, does not impose such a requirement. In other words, the perception sometimes is that it needs to be done for the sole purpose of satisfying a JCI requirement, but it is not, under the circumstances, necessarily the right thing to do or the desirable thing to do to improve quality. I think those who so opine are wrong.

The reliability of fair and objective physician performance appraisals is jeopardized whenever reliable data is absent or not considered. Because department heads may have been promoted based on seniority rather than leadership and competency, subjective appraisals may not reflect reality. Often they can reflect a bias that ignores what relevant data might reveal. Some department heads may not have an interest in the time and effort it takes to accomplish fair and unbiased performance evaluations. They may be uncomfortable in identifying and confronting substandard performance. Leadership needs to address this and take appropriate action to make sure this is not the case. I hear arguments that comparative evaluations erode team efforts and that outcomes are not solely the result of physician treatment decisions. Patient outcomes are said to be the result of care decisions made by many persons and often involve decisions made by the patient or a family member. While this is true, the relevant data reviewed should reflect decisions made by members of the medical staff in accomplishing an OPPE program. The JCI requirements do indeed focus on these aspects. There remains the issue of data validity, which is an added concern.

It is unfortunate, but understandable that data is often subject to criticism. Sample sizes that do not reflect the population (too small) is a common concern. "I do the most difficult cases" syndrome is another concern. The experience and qualifications of the reviewer(s) can get called into question. In spite of every attempt to remove subjectivity into the analysis, it seems impossible to

remove it completely. Such is the nature of performance appraisals in general.

The intent of this article is to encourage more use of relevant data in addition to direct observation in developing a good OPPE program. It is to encourage the use of comparative data – comparative data at the local, national or international level as well as benchmarking to literature-based medicine when deemed appropriate and available. The reason is not to ensure compliance with JCI standards, although this can be a desired side effect of a good OPPE program. Rather, I believe that we can all agree that providing medical care is a complex process and that direct observation alone or combined with poorly developed clinical quality monitoring systems may not be enough to reveal inadequacies or patterns/trends that may have a negative impact on our patients. But caution is advised. If you look for OPPE on Google search, you will see examples that are incredibly complex and took years or longer to develop, with all kinds of displays and analytical data. The expression that “it is not rocket science” comes to mind and I think if we are not careful, this could easily turn into way more than what is required to measure/evaluate professional performance. From the international standpoint, one must remember that many countries are struggling with the basics, which often take priority over significant investments in time and resources. Austere budgets, a lack of trained staff, a poor information technology infrastructure, and physician or leadership apathy and/or opposition to measurement can derail the best of intentions.

Working with the medical staff and clinical leaders in a hospital is essential to the success of an effective OPPE program. Their involvement in its development will go a long way towards overcoming the inherent opposition that new programs seem to inspire. The era of information technology in healthcare has been explosive. The proliferation of electronic medical records is now widespread and becoming more robust in Japan but it varies internationally. Quality monitoring systems are advancing rapidly. Evidence based medicine has augmented experience based medicine and this marriage is of great consequence to the analysis of quality in healthcare. We now have the means to provide timely feedback to medical practitioners on how well they perform compared to their peers, literature-based medicine, and widely accepted clinical guidelines. It has the added benefit of reassuring

physicians that their practice patterns and outcomes are acceptable when compared to their peers and best practice norms. This feedback should be valuable in improving and sustaining performance, and all dedicated professionals should welcome it.

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Evidence-based Policy Making for Sustainable Healthcare in Japan: 2025 and beyond



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■ Introduction

In 2025, the baby-boomer generation (people born between 1947 and 1949) will be 75 or older, bringing the nation's population of people aged 65 years or older to 35 million. The current population aging rate, the percentage of the population aged 65 or older is 24.1%,¹ and is expected to be 30.5% in 2025. While the population is expected to reach its peak at 38.78 million in 2042 and begin declining thereafter, it is estimated that the population aging rate will continue increasing. It is also predicted that the number of people aged 75 years or older (the old-old) will exceed the number of people aged between 65 and 74 (the young-old) in 2017, and continue increasing until one in four people will be an old-old after 2050.² Japan's population aging rate became the highest in the world in 2005, and the country has grown into a super-aging society at an unprecedented speed. There are three factors that lead to such a society; 1) long life expectancy, 2) low birth rate, and 3) the limited number of immigrants. Japan's average life expectancy has steadily risen for both men and women to 79.64 and 86.39, respectively (2010), putting them well over the global average. Meanwhile, the birth-rate in the same year was 1.4.

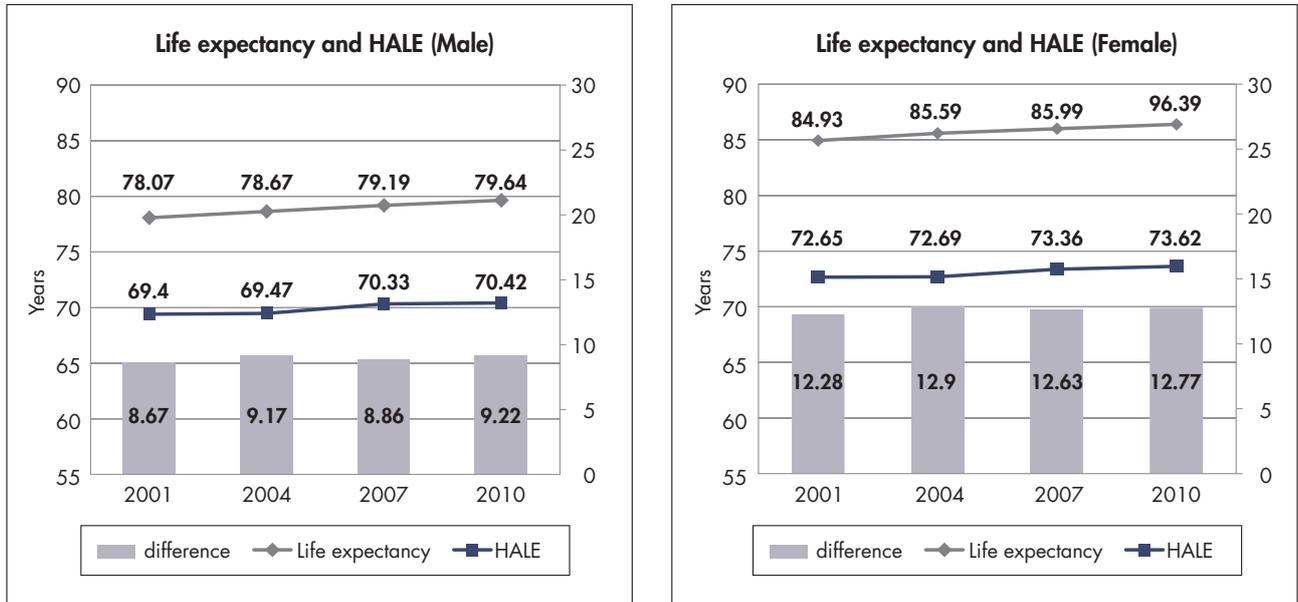
Long life expectancy is something we should be happy and proud of; however, there is a gap between life expectancy and healthy life expectancy (HALE) of about 10 years, years during which the elderly experience difficulties in independent living and require outside assistance in maintaining their daily lives (Figure 1). The problem is that the necessary resources are limited and already insufficient as they are now, and the low birth

rate and limit on immigrants will make the situation even worse. The need for resources is reflected in healthcare costs, and the absolute value of per-capita healthcare costs reminds us of the indisputable fact that the elderly require more healthcare resources. According to the basic data regarding health insurance (December 2012), per-capita healthcare costs for the old-old (891,060 yen) were 4.6 times that of the rest (192,945 yen) in 2010.³ As stated above, the elderly population is expected to grow, with more old-old than the young-old after 2017. Therefore, further increase in the healthcare cost is inevitable. This paper explains the rise in the healthcare costs, countermeasures and their consequences, and examines what the consequences suggest in terms of how policy making should approach the issue.

● The fundamental driving cause of increase in healthcare cost

Due to this sizable share, many tend to have the impression that the elderly are the main cause of the rise in healthcare costs. It is true that the per-capita healthcare costs for the old-old are 4.6 times that of the rest. However, when the rate of increase in NME (National Medical Expenditure) by age group is compared, the rate of increase for the old-old has been lower, almost always, than that for the under-65 group (Table 1). Similarly, while the estimated number of new admissions (per capita) has stayed the same for the population aged 70 or older, that for the population aged younger than 70 has been on the increase.⁴ It seems that many elderly are doing what they can to stay healthy, and many providers are doing what they can, while not

■ Figure 1: Difference between life expectancy and HALE



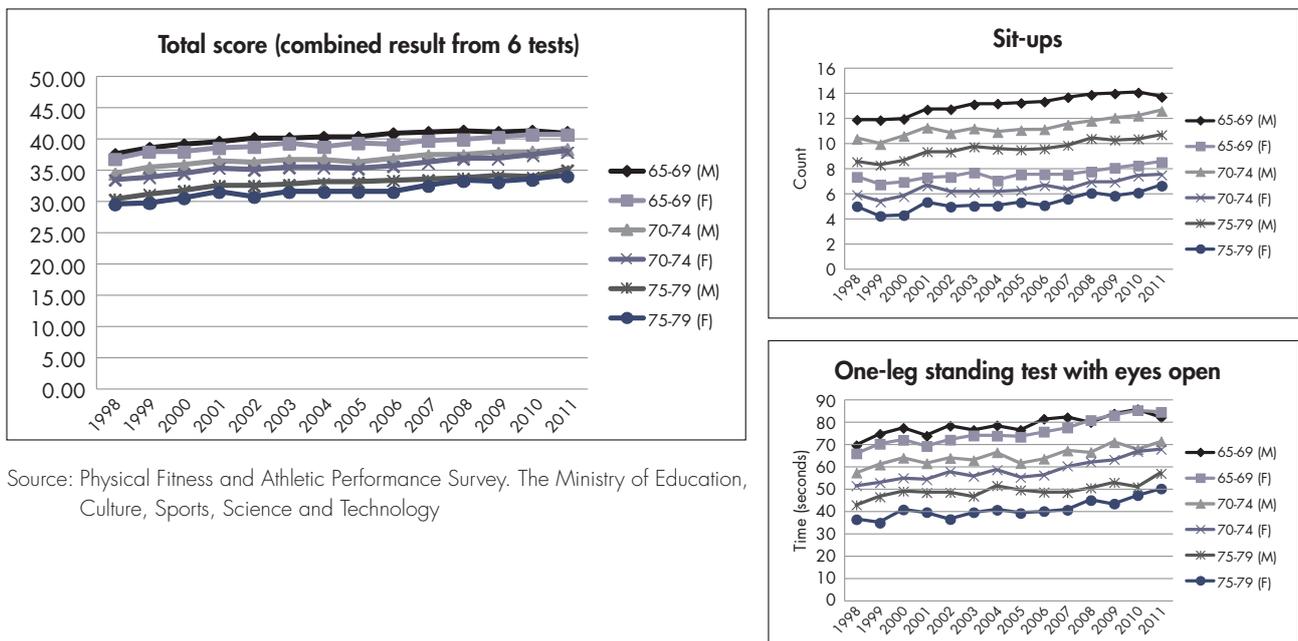
Source: Healthy Life Expectancy (HALE) is from "Study on Future Prediction of Healthy Life Expectancy and Cost Effectiveness of Lifestyle Disease Control" funded by MHLW Grants. Life expectancy is from "Simplified Life Table" created by MHLW.

Note: Healthy life expectancy is the period that has no limitations in daily activities. Average life expectancy is based on that at the age of 0.

overdoing it (such as providing unnecessary services). This argument is also supported by the fact that the elderly are scoring higher on physical tests than before (Figure 2). Though we cannot relate this directly to a lower need for healthcare resources, it suggests that today's elderly are in better condition overall. No wonder a concept like prospective age emerges. It was first proposed by the

researchers Warren Sanderson and Sergei Scherbov in 2005. They explain it as "a new age concept, a forward-looking concept based on the person's remaining life expectancy," and claim that "If the life expectancy for a 30-year-old in 2005 is the same as for a 40-year-old in 2055, then the future 40-year-old can expect to stay alive for as many more years as a 30-year-old today can expect

■ Figure 2: Trend in scores of physical tests for the elderly



Source: Physical Fitness and Athletic Performance Survey. The Ministry of Education, Culture, Sports, Science and Technology

■ Table 1: Trend in National Medical Expenditure and rate of increase by age groups

| Age group | 2010 | | 2009 | | 2008 | | 2007 | | 2006 |
|------------|----------------------------|------------------|----------------------------|------------------|----------------------------|------------------|----------------------------|------------------|----------------------------|
| | Per capita NME (1,000 yen) | Rate of increase | Per capita NME (1,000 yen) | Rate of increase | Per capita NME (1,000 yen) | Rate of increase | Per capita NME (1,000 yen) | Rate of increase | Per capita NME (1,000 yen) |
| Total | 292.2 | 3.5% | 282.4 | 3.6% | 272.6 | 2.0% | 267.2 | 3.0% | 259.3 |
| Under 65 | 169.4 | 3.9% | 163.0 | 2.6% | 158.9 | 0.6% | 157.9 | 2.5% | 154.0 |
| 0–14 | 143.6 | 8.1% | 132.8 | 2.2% | 130.0 | 2.3% | 127.1 | 5.1% | 120.9 |
| 15–44 | 106.1 | 2.7% | 103.3 | 2.3% | 101.0 | 1.2% | 99.8 | 4.8% | 95.2 |
| 45–64 | 268.2 | 2.8% | 261.0 | 2.7% | 254.1 | 0.0% | 254.2 | 0.9% | 251.9 |
| 65 & above | 702.7 | 2.2% | 687.7 | 2.1% | 673.4 | 1.1% | 666.3 | 1.0% | 659.8 |
| 70+ | 794.9 | 2.1% | 778.3 | 2.4% | 760.0 | 0.7% | 754.5 | 1.5% | 743.4 |
| 75+ | 878.5 | 2.7% | 855.8 | 3.1% | 830.0 | 0.0% | 830.3 | 1.0% | 822.0 |

Source: 2012 Report on National Medical Expenditure by MHLW

■ Table 2: Prospective age

| Age in 1955 | Prospective age (equivalent age in certain year) | | | | | | | | | |
|-------------|--|------|------|------|-------|--------|------|------|-------|-------|
| | Male | | | | | Female | | | | |
| | 1980 | 2005 | 2010 | 2030 | 2055 | 1980 | 2005 | 2010 | 2030 | 2055 |
| 40 | 45.1 | 49.8 | — | 53.0 | 54.8 | 46.2 | 52.7 | — | 55.7 | 57.3 |
| 50 | 54.9 | 59.6 | — | 62.8 | 64.6 | 55.7 | 62.2 | — | 65.2 | 66.8 |
| 65 | 69.0 | 73.8 | 74.4 | 77.1 | 78.9 | 69.5 | 75.9 | 76.4 | 78.8 | 80.3 |
| 75 | 77.9 | 82.5 | — | 85.8 | 87.5 | 78.2 | 84.5 | — | 87.2 | 88.7 |
| 80 | 82.3 | 86.7 | — | 90.0 | 91.6 | 82.5 | 88.7 | — | 91.3 | 92.7 |
| 90 | 91.6 | 95.3 | — | 98.9 | 100.4 | 91.8 | 97.4 | — | 100.1 | 101.3 |

Source: "Society in revolution of long-life," Ryuichi Kaneko, J. of Population Problems, 66–3 (2010.9); article from the Nikkei, September 19, 2012

to live." Table 2 shows that a man of about 75 years old today is equivalent to a 65 year old in 1955. It is a concept and not a fact to base policies on, but it helps us to perceive the elderly in a broader perspective.

Thus, contrary to the natural first impression that the elderly are the main cause of the rise in healthcare costs, the trend of healthcare resource usage by the population appears not much different from that of the rest of the population. In addition, what used to be a possible difference has already been addressed, for example, by the establishment of the Long-Term Care Insurance System. Of course, there is still much to be achieved; however, it is now more important to work on issues common to both the elderly and the young in order to reduce healthcare costs. In fact, the recent rates of increase in healthcare costs compared with the previous year are said to be more related to advancements in healthcare than to aging. For example, the 3.9% increase in 2010 is broken down

into the following factors 1) Advancements in medical care (2.1%),⁵ 2) Impact of population aging (1.6%), 3) Revision of medical service fees (0.19%), and 4) Impact of population increase (0.0%). This means that the major cause of the increase in healthcare costs is recent technological innovation in pharmaceutical products and healthcare device.

● Measures for the control of healthcare costs and their effect

There is a measure that directly approaches the driving cause previously presented. It focuses on raising the share of generic drugs, which tend to be more inexpensive than non-generics. The share of generics both in volume and cost has historically been low in Japan compared to other countries. For instance, the current share of 23.1% (as of September, 2011) is far from that of other countries such as the U.S. (72%), the U.K. (65%), and Germany (63%).⁶

Though the figures cannot be compared on the same grounds because the definition of generic drugs differs by country, there seems to be room for improvement. The government's way of trying to encourage the use of generic drugs is through economic incentives, bonus reimbursement rates for using more generic drugs. The goal set in 2007 (when the share was 18.7%), was to reach more than 30% in 2012. The share has increased, but not enough to even clear this target, which is significantly lower than the international norm. Therefore, the approach continues. For instance, an additional 6, 13, or 17 points per prescription used to be offered as a bonus reimbursement rate if a healthcare institution's overall shares of generic drugs (by volume, for the 3 previous months) were more than 20%, 25%, or 30%, respectively. Now with the latest fee schedule from April 2012, it has been changed to 5, 15, or 19 points for shares of more than 22, 30, or 35%, respectively.

Since the share of generic drugs is rising, but at a slower speed than planned, not much reduction in healthcare costs can be expected in the near future through this measure. What becomes important, in turn, is to conduct a strict analysis of the cost effectiveness of pharmaceutical products and healthcare technology in the determination of healthcare insurance coverage. One example would be the experiment planned by The Central Social Insurance Medical Council (CSIMC) and the Expert Subcommittee on Cost-Effective Assessments of particle radiotherapy. Particle radiotherapy is definitely valuable in saving the eyesight of patients with neck and head cancer, and should be actively promoted. However, we have not reached a consensus of opinion on the application of particle radiotherapy in other types of cancers that are treated equally well by and provide the same QOL as surgery and other radiotherapies. Therefore, we carried out an ex-ante survey, a questionnaire on QOL and mortality for various prostate cancer treatments in FY 2009.⁷ This is to compensate for disadvantages related to the study, such as the low number of cases, which undermine accuracy and result in a failure to reach definite conclusions.

As a result, the following three points were clarified: First, five-year mortality was high in watchful waiting followed by, in declining order, endocrine therapy, other radiotherapy, particle radiotherapy, and surgery. For example, T3 cases that cannot be treated by surgery and are also difficult to treat by brachytherapy are usually treated by particle radiotherapy combined with hormone

therapy. The mortality rate of particle radiotherapy is lower than other radiotherapies by approximately 1 percentage point, but higher than surgery by approximately 1.1 to 1.4 percentage points. Second, we utilized EQ-5D and investigated the average QOL of patients six months after the start of treatment. T1 and T2 cases showed almost no changes; however, in the T3 stage, there was a slight difference in the most critical level, level 3. It is very interesting that watchful waiting revealed the highest values and particle radiotherapy revealed the lowest in all of the following indices: (1) Range of movement; (2) Personal care; (3) Routine activities (work, study, housekeeping, family, and leisure); (4) Pain/ discomfort; and (5) Anxiety/ moping. This suggested that physicians generally feel that the QOL of patients who have undergone particle radiotherapy is high. Third, we investigated the distribution of patient conditions, between levels 0 and 100, in the sixth months after the start of treatment. As a result, while T1 and T2 cases revealed the highest weighted average with particle radiotherapy, T3 cases revealed a higher weighted average with other radiotherapies and surgeries than particle radiotherapy. The CSIMC and Expert Subcommittee on Cost-Effective Assessment have not decided future plans yet; however, it is more necessary than ever to carry out such analyses to determine whether individual therapies are worth investing limited financial resources into in order to rigorously choose medical technologies and pharmaceutical products whose cost utility has been shown.

Though its primary purpose is to facilitate the standardization and visualization of health care systems, the diagnosis procedure combination (DPC) system has also been expected to be effective in reducing healthcare costs. It has been 10 years since the system was initially introduced in 2003. Since then, the number of institutions utilizing the DPC has increased to 1,496 hospitals (approximately 20% of the total number of hospitals), and a total of 474,981 beds (approx. 53%) implementing the system in April 2013. DPC is, as defined, a patient classification and not a payment method. Yet, the name is often used to address the payment system itself since the classification is used in the bundled payments for acute care services, DPC/PDPS (diagnosis procedure combination/per-diem payment system). Each DPC classification has its own three levels of rates per day, and rates used in payment calculation depend on how long a

patient is hospitalized.⁸ The amount of the payment for services under the bundled payment system is calculated by multiplying the rate per day by the number of days, and then multiplying the sum of these products by the hospital-specific conversion coefficient. This amount and the amount of payment for services outside the range of the comprehensive evaluation,⁹ as well as other fees,¹⁰ constitute the total payment for a patient. In 2012, there were 2,927 DPC classifications, and 2,241 of these were included in the comprehensive evaluation. The number has increased from its initial implementation, when 1,860 out of 2,552 classifications were included. Many changes have been made to the DPC/PDPS, mostly at the time of fee schedule revision every two years. One of the major changes in the 2012 revision was the hospital-specific conversion coefficient.

Some parts of the hospital-specific conversion coefficient are now dependent on the newly created hospital grouping, which groups hospitals into three types according to their overall capacity and past record as healthcare providers. Type I are teaching hospitals (80), type II are semi-teaching hospitals with functions resembling to that of type I (90), and type III hospitals include the rest (1,326). Though there was explanation as to how type II hospitals were determined, the change brought much controversy that left unresolved resentment and shaken self-respect, since being a type III rather than a type II meant a smaller coefficient, which made it more likely to yield a lower reimbursement for the same hospital. In addition, the part dependent on the hospital grouping is expected to be enlarged. The government has announced its intention to change the remaining parts that are now independent of the grouping into those that are dependent on it. The change is scheduled to take place over the next six years with three fee-schedule revisions. It may work to strengthen the government's control over the healthcare costs, at least over the part paid under the DPC/PDPS. So far, DPC/PDPS has not been successful in bringing the expected cuts. One reason is that DPC is based on a per-day rate. Further decrease in the average length of stay, therefore, is hard to expect. In fact, according to a study using DPC-related data collected through our Hospital Visualization Network, the number of days of hospitalization for 2,533 patients who had undergone cataract surgery was shortened at facilities with longer admission periods before implementation of the DPC

system; however, this was not the case at hospitals whose number of days of hospitalization were shorter prior to the implementation of the DPC system.¹¹ Nevertheless, the government continues to try by utilizing its power over price setting.

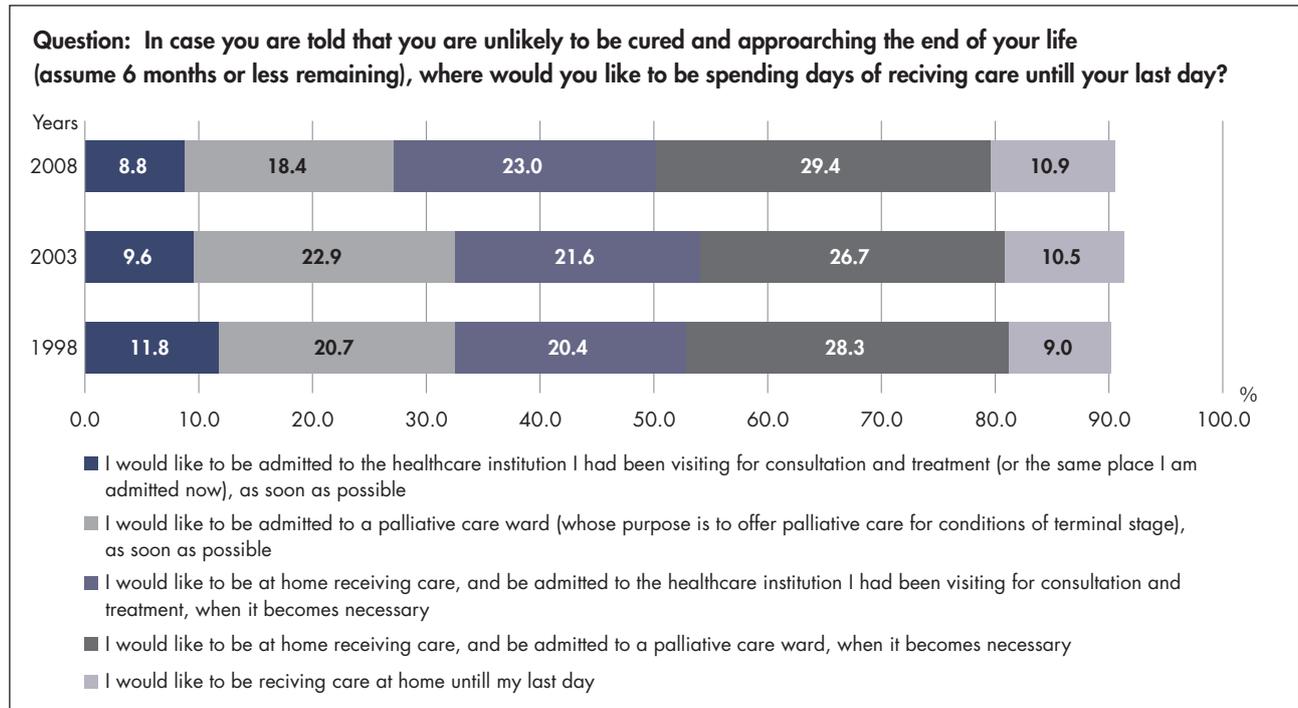
In fact, much of the government's effort to contain healthcare costs has been centered on exerting control over the fee schedule. The shift to home care is another example. Registered healthcare institutions that satisfy certain criteria are offered the privilege of claiming various reimbursement points permitted only to or set higher for such institutions. It all began with the report on the "National Survey of End-of-Life Care" submitted in 2004 by the Committee on the End-of-Life Care. Based on the report, the Ministry of Health, Labour and Welfare summarized the result of the survey that approximately 60% of the nation desired to spend end of life at home, and set out to develop the medical home care system on this ground, aiming to increase the share of death taking place at home or other similar places to 40%.^{12, 13} At first, measures such as the one previously described were introduced in 2006 and applied to clinics registered as home care support facilities. From then on, the extent to which points were distributed expanded in various ways with each fee-schedule revision. In the meantime, the number of such clinics grew from 9,434 in 2006 to 12,487 in 2010, and the number of hospitals grew from 7 in 2008 to 331 in 2010.¹⁴ The trend continued and the last fee-schedule revision in 2012 created a two-tier system for home care support clinics and hospitals. Those satisfying additional criteria¹⁵ were registered at the higher level and gained the ability to claim a greater number of reimbursement points.

Yet, despite all this effort, the percentage of deaths occurring at home has barely changed since 2005, as can be seen in [Table 3](#). It may take more time for the effect to become visible. However, a closer look at the results of a questionnaire in the aforementioned survey casts doubt whether there will actually be a substantial change in the share of deaths at home. In a 2008 survey, as much as 27.2% still sought admission to healthcare facilities as early as possible ([Figure 3](#)). The majority (23.0% plus 29.4%) expressed the intention of leaving home at some point in time, and those who wished to stay at home "until the end" accounted for only 10.9%. Thus, most of the aforementioned 60% would like to do so only for a certain

period of time, and not from the beginning to the end. As the figure shows, in fact, the share of the population indicating this preference has stayed basically the same for the past three surveys. Home care has been sought by

many to a certain extent; however, home care that extends to the very last, it seems, is not. That is why, therefore, a future increase in the share of deaths at home is hard to expect for now.

■ Figure 3: Result of National Survey on End-of-Life Care



Source: The report on the Survey on End-of-life Care (latest conducted in March, 2008), presented as reference at the first meeting of End-of-Life Discussion Board of MHLW in Oct. 27, 2008.

Notes: Omitted 4 answers (ex. preference over admission to nursing homes as well as NA) were all less than 5% each. Translations by the author

■ Table 3: Trend in the share of place of death

| Year | Place of death (%) | | | | | |
|------|--------------------|---------|-----------------------------------|--------------|------|--------|
| | Hospitals | Clinics | Long-term Nursing Care Facilities | Nursing Home | Home | Others |
| 1960 | 18.2 | 3.7 | — | — | 70.7 | 7.5 |
| 1970 | 32.9 | 4.5 | — | — | 56.6 | 6.0 |
| 1980 | 52.1 | 4.9 | — | — | 38.0 | 5.0 |
| 1990 | 71.6 | 3.4 | 0.0 | — | 21.7 | 3.3 |
| 1995 | 74.1 | 3.0 | 0.2 | 1.5 | 18.3 | 2.9 |
| 2000 | 78.2 | 2.8 | 0.5 | 1.9 | 13.9 | 2.8 |
| 2005 | 79.8 | 2.6 | 0.7 | 2.1 | 12.2 | 2.5 |
| 2006 | 79.7 | 2.6 | 0.8 | 2.3 | 12.2 | 2.4 |
| 2007 | 79.4 | 2.6 | 0.8 | 2.5 | 12.3 | 2.4 |
| 2008 | 78.6 | 2.5 | 1.0 | 2.9 | 12.7 | 2.3 |
| 2009 | 78.4 | 2.4 | 1.1 | 3.2 | 12.4 | 2.4 |
| 2010 | 77.9 | 2.4 | 1.3 | 3.5 | 12.6 | 2.3 |
| 2011 | 76.2 | 2.3 | 1.5 | 4.0 | 12.5 | 3.5 |

Source: Vital Statistics by MHLW, 2011

In fact, there are results from other surveys that suggest likewise. One such gives an important insight. In a two-period (2007 and 2010) survey conducted in a depopulating area with a population aging rate of 40.9%, researchers found that the percentage of people who would prefer home for terminal healthcare decreased significantly over the 3 years, while the percentage of those who would prefer hospitals or institutions significantly increased. They note that in a depopulating area, there is a decrease in the number of people who would prefer home for terminal care.¹⁶ In fact, the finding seems to coincide with the percentage of deaths at home by prefecture. The 3 most populated of Japan's 47 prefectures, Tokyo, Osaka, and Kanagawa, also ranked high at 2nd (16.1%), 4th (15.0%), and 6th (14.8%) with respect to the percentage of deaths taking place at home.¹⁷ Population density is considered to have a significant influence on the percentage of deaths that take place at home. Therefore, with the decreasing population in Japan, not much demand can be expected to arise for the kind of comprehensive home care that extends to the final day. In such case, pursuing this type of care to a greater extent throughout the country may not be a good idea. Trying to force this through could waste scarce resources, and even bring excessive stress on those put into the position of providing those resources.

● Strains behind the figure

Among those in this position is the working generation. According to the 2007 basic industrial structure survey, the number of people who quit a job because of the need to provide nursing care for a family member is increasing (Table 4). In fact, it hovered around 100,000 per year, with a gradual increase from 2002 to 2006, but jumped to over 140,000 per year between 2006 and 2007, which matches exactly the time when the shift to home care began.¹⁸ In

■ Table 4: The number of people leaving job due to care giving for family member

| | Total | Male | Female |
|---------------------|---------|--------|---------|
| 2006. 10 to 2007. 9 | 144,800 | 25,600 | 119,200 |
| 2005. 10 to 2006. 9 | 104,300 | 19,100 | 85,100 |
| 2004. 10 to 2005. 9 | 103,500 | 20,400 | 83,200 |
| 2003. 10 to 2004. 9 | 98,900 | 16,000 | 82,900 |
| 2002. 10 to 2003. 9 | 92,500 | 14,700 | 77,800 |

Source: The Basic Industry Survey, 2007, Ministry of Internal Affairs and Communications

another survey, of the people who had the experience of providing nursing care for a family member, one in four had to change the way they worked, more than 20% had reduced income, and a little over 10% had income losses of more than 50%.¹⁹

People of this generation are already under substantial stress providing their own resources to support the current healthcare system. In FY 2012, of the 12.7 trillion yen required by the Medical Insurance System for the Old-Old to cover healthcare for individuals aged 75 and older, as much as 40% was borne by other insurance schemes that cover individuals mostly aged under 75.^{20, 21} Therefore, a considerable part of the premiums paid by under-75 goes to healthcare provided to the old-old, and these rates have been increasing steadily. In particular, the average (income based) insurance premium rate charged by the Japan Health Insurance Association rose significantly from 8.2% to 9.34% in 2010, continued rising to 9.5% in 2011, and to 10.0% in 2012. This rise in the premium rate is the result of the Association suffering under the designated contribution to the Medical Insurance System for the Old-Old.²² The influence of this rise in premium

■ Table 5: Rate of increase in premium rates by age groups

| Age brackets | Premium rate (2010) | Premium rate (2009) | Rate of increase |
|--------------|---------------------|---------------------|------------------|
| 20-24 | 9.8 | 9.3 | (5.4%) |
| 25-29 | 18.7 | 17.2 | (8.7%) |
| 30-34 | 21.1 | 19.5 | (8.2%) |
| 35-39 | 23.4 | 21.8 | (7.3%) |
| 40-44 | 25.6 | 24.4 | (4.9%) |
| 45-49 | 27.9 | 26.1 | (6.9%) |
| 50-54 | 27.7 | 26.0 | (6.5%) |
| 55-59 | 24.4 | 22.7 | (7.5%) |
| 60-64 | 15.8 | 15.5 | (1.9%) |
| 65-69 | 12.2 | 11.9 | (2.5%) |
| 70-74 | 9.9 | 9.7 | (2.1%) |
| 75-79 | 6.9 | 7.0 | -(1.4%) |
| 80-84 | 6.7 | 6.7 | (0.0%) |
| 85-89 | 5.5 | 5.3 | (3.8%) |
| 90-94 | 4.5 | 4.4 | (2.3%) |
| 95-99 | 3.8 | 3.7 | (2.7%) |
| 100- | 3.2 | 3.2 | (0.0%) |

Source: Basic reference material regarding health insurance (by age bracket)

rates are all coming down on the working generation. While the insurance premium rates for individuals aged 70 or older increased from -1.4% to 3.8%, the rate of increase for individuals between 25 and 60 was 5.0% or more, with the exception of individuals between 40 and 44 (Table 5). These financial stresses are not the only effects, and accumulated stress even reaches extremes. According to the National Police Agency, the number of cases of homicide and bodily injury motivated by exhaustion from long- and short-term nursing care has increased.²³

● Final notes

All things considered, it is inevitable that home care is expected to and will need to play a bigger role in the coming years. However, appealing to the same traditional values of the old days and pursuing the ideals is unrealistic and would be disastrous in much changed society of today. Those days, when the society was young and enduring and had a much lower population aging rate, should not be brought in for use as a comparison. People are aware of this, and their message is evident in the results of the survey. The shift to home care is expected to come hand in hand with institutional care. It can only stand in coexistence with an assurance for enough institutional care. Yet, when people's messages are not accepted as they are, unfavorable effect such as the excessive pressure on the working generation occur. If this generation is worn out, their health (and that of their dependents quite likely as well) will decline, leading to an even greater increase in total healthcare costs, and thus putting society at added risk. Contrary to the importance of what they suggest, evidence of such effects tend to be neglected because they do not necessarily influence current figures such as the National Medical Expenditure. What should be considered is not the "healthcare cost" addressed with these statistical figures, but the "cost of healthcare for society" that includes such factors not currently accounted for in these figures. Being more attentive to and making policies that are in agreement with the evidence and messages coming from the public would be the slow but steady approach to sustaining healthcare in Japan. In this sense, incorporating institutional care at end of life would be the model now for the enhancement of medical home care.

Reference

- 1 September 1, 2012
- 2 FY 2012 Annual Report on the Aging Society by Cabinet Office, Government of Japan
- 3 Figures include cost of inpatient care, other costs related to hospitalization, cost of outpatient care and pharmaceutical costs, as well as dental costs. Source: Basic materials regarding health insurance (FY 2010)
- 4 Explanation made on statistics from the two year period from approximately 2010 to 2012. The average length of stay (ALOS) during the period is on the decrease for the both population. Source: Current Trend of Annual Average length of hospitalization, estimated number of new hospitalizations, and estimated average number of days hospitalized by Ministry of Health, Labour and Welfare Health Insurance Bureau Actuarial Research Division, January 2013.
- 5 FY 2010 Annual Report of Changes in Medical Care Expenditures, MHLW Health Insurance Bureau, Actuarial Research Division
- 6 Report by MHLW on enhancement of the use of generic drugs, March 2012
- 7 Koichi Kawabuchi, Shigeru Sugihara, Tomoyuki Takura: FY 2009 Subsidy for Cancer Research by Ministry of Health, Labour and Welfare (Research Project) "Comprehensive study on the effectiveness, application, and cost-effectiveness of particle radiotherapy" (Principal Investigator: Tadashi Kamada)
- 8 Each rate is used only for the days that fall between the two consecutive borderline days (which differ by DPC). Thus, three different rates are used if LOS falls between the second and the third. When LOS is longer than the longest (third), fee-for-service payment applies for the days exceeding the third borderline days.
- 9 Services such as surgical operations and endoscopic examinations are paid outside of the DPC system.
- 10 For instance, meals and private room charge
- 11 Kazumitsu Nawata, Koichi Kawabuchi: An Analysis of the New Japanese Payment System for Cataract Operations. Public Health Frontier, 1(1), 1-6, 2012
- 12 Including special nursing homes, group homes, etc.
- 13 Reference material 1 delivered at the 17th Social Security Council Health Insurance Panel held on July 29, 2005
- 14 Reference material presented at DPC subcommittee

meeting under the Central Social Insurance Medical Council on April 3, 2013

- 15 For instance, having 3 or more physicians on staff and 2 or more records of attending a death in the previous year
- 16 Hiroshi Asami et al., Reduced willingness to receive home terminal care in the depopulating areas based on an investigation in the Oknoto area, *Ishikawa Journal of Nursing*, Vol. 9, 2012
- 17 Reference 22
- 18 This survey is carried out every five years, and the results from the latest survey in 2012 have yet to be released (scheduled for release in the summer of 2013). The number, however, is predicted to have increased.
- 19 Summary of Survey on the Actual State and Awareness of Individuals Providing Nursing Care, Meiji Yasuda Institute of Life and Wellness, Inc., August 23, 2012.
- 20 There are over 3,000 insurers for people under 75. Most insurers fall under three schemes. The occupation-based type Society-managed Health Insurance scheme covers employees and their dependents at firms of a certain size. Japan Health Insurance Association-administered health insurance, is another occupation-based type scheme, which collectively covers employees and their dependents at smaller firms (Though it is grouped as an occupation-based type, it also has characteristics of a region-based type since premium rates differ by prefecture after organizational restructuring in 2008). The National Health Insurance scheme is a region-based type, designed to cover people who are self-employed, part-time workers, etc.
- 21 Approximately 15% was borne by the insured old-old themselves through insurance premiums and copayments, and another 45% was financed by the public fund.
- 22 The contribution to the Medical Insurance System for the Old-old is dependent on the number of enrollees. The Japan Health Insurance Association, which has more members than other systems, bears a significant burden that accounts for 40% of its total costs. Other health insurance providers are no better off. 584 societies of the Society-managed health insurance scheme (which accounts for 40% of the total member societies in the scheme), had to raise premium rates in FY 2012. Also referred in other names including

“Late-stage medical care system for the elderly.”

23 Crime in 2008 and 2011, the National Police Agency

The challenge of estimating the prevalence of dementia in the elderly



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■ Abstract

Aim: To examine the validity of the estimation of the prevalence of dementia in the elderly based on long-term care insurance (LTCI) data.

Methods: Japanese LTCI data among frail elders over 65 years of age (193 men, 360 women) from a central area of Osaka prefecture in 2005 was analyzed using the dementia discrimination criteria of a dementia autonomy level higher than level 2. Of those, no cases with a prior diagnosis of dementia were reexamined to ascertain dementia-equivalent status.

Results: Of the 70 reexamined cases (25 men, 45 women), 6 men and 16 women scored as dementia-equivalent. In addition, 7 men and 7 women experienced severe sequelae of cerebrovascular disease (CVD). Two men and 8 women showed symptoms equivalent to mild cognitive impairment (MCI). Ten men and 14 women showed no dementia/MCI. Based on the sum of subjects previously diagnosed with dementia and those with symptoms equivalent to dementia upon reexamination, the estimated prevalence of dementia in subjects over 65 years in the study region was 5%.

Conclusions: Assuming a 50% capture rate of dementia based on the LTCI data ($N = 553$) from a review of previous research, the estimated prevalence of dementia was increased to 10% after incorporating the results of this study. The prevalence of elderly dementia according to LTCI data should be estimated based on a determination of dementia-equivalence in terms of the level of care required: dementia, equivalent to dementia (i.e., requiring daily care similar to that for dementia), and severe sequelae of CVD. Furthermore, the capture rate should be carefully considered.

Keywords: cerebrovascular disease (CVD), dementia-

equivalent for care, long-term care insurance (LTCI), the prevalence of dementia, vascular dementia (VaD)

■ Introduction

As of 2010, an estimated 35.6 million people worldwide suffer from dementia; related costs were estimated at \$604 billion (USD).¹ This rate is predicted to double every 20 years, so the number of people with dementia is projected to be 115.4 million by 2050.² In Japan, data from the Long Term Care Insurance (LTCI) system is used to estimate the prevalence of dementia in the elderly. The most frequently used criterion is the number of LTCI participants rated as “dementia autonomy higher than level 2” according to the LTCI system (Table 1).³ A family physician and LTCI-certified researcher evaluate an elderly applicant’s mental state from a medical and social services point of view, respectively.⁴ The latter estimation of the number of elderly with dementia was reviewed in 2012: 2.8 million people in 2010 (9.5%), and a projected 4.7 million people by 2025 (12.8%). As of 2010, 1 in 10 people over 65 years of age had dementia; half of these were living at home.⁵ However, according to recent epidemiological research, the prevalence of dementia is rising quickly. In 2009, epidemiological surveys were conducted on approximately 5,000 residents over the age of 65 in seven municipalities of rural Japan. The prevalence of dementia shown in these surveys was 12.4–19.4% (14.4% on average).⁶ This gap calls into question the accuracy of this prevalence estimate and suggests that some problems may be lurking in the LTCI data-based estimation method.

The other measures used by the Japanese LTCI system to identify elderly dementia are the Cognitive Performance Scale (CPS)⁷ and diagnosis by a family

■ Table 1: Levels of dementia autonomy in the Japanese Long-Term Care Insurance system

| Level | Judgment criteria | Concrete example |
|-------------|---|--|
| Independent | | |
| 1 | Although some dementia is present, the person is almost independent in everyday domestic and social life. | |
| 2 | Although some communication difficulty and behavioral symptoms are evident in daily life, the person can function independently with supervision. | |
| 2a | Definition applies to activity outside the home | Often gets lost and makes noticeable mistakes in reading, writing, and calculation |
| 2b | Definition applies to activity in the home | Unable to manage medication, talk on the telephone, perform self-care |
| 3 | Need for care, communication difficulties and behavioral symptoms interfere with daily life | |
| 3a | Definition applies mainly to daytime activities | Needs help with eating, dressing, defecation, and urination. |
| 3b | Definition applies mainly to nighttime activities | |
| 4 | Frequent difficulties in communication, behavioral symptoms interfere with daily life; need for continuous nursing care. | |
| M | Severe symptoms, physical disease, or peripheral significant psychiatric symptoms; need for specialty care. | Behavioral problems caused by delirium, delusions, agitation; psychiatric symptoms and behavior such as harming self or others |

physician. The author has previously reported physician diagnosis in earlier articles: 22% men and 20% women of LTCI samples were dementia patients. The present study examines the validity of the estimation of the prevalence of dementia based on LTCI data.

■ Material and methods

This study was conducted in a central area of Osaka prefecture, the third largest metropolitan district in Japan. The study zone spanned 15 km² with a total population of 95,866 men and 104,812 women at the end of March 2006.⁸ Of these, 17,104 men and 23,290 women were over 65 years of age. The proportion of elderly individuals above 65 years old certified as frail by LTCI was estimated to be approximately 19%.⁹ The author randomly chose 605 samples of LTCI certifications; all of which were issued between October 2005 and March 2006 and included visit descriptions and family physicians' summaries and comments. The sample size comprised 9% of all LTCI applicants in the study zone in the fiscal year 2005. Personally identifiable information other than gender and age had previously been deleted from these documents. The author observed the privacy regulations of the district and did variable treatment in order to render the data doubly anonymous. Of the 605 persons, 21 did not meet the inclusion criteria and 31 individuals were younger than 65 years. For each of the remaining 553 patients, the author

examined results of the investigation for certification and the family doctor's summaries and comments.

First, the distribution of dementia autonomy on the LTCI system with or without a diagnosis of dementia from a family physician was aggregated. Second, the author evaluated cases with no physician's diagnosis of dementia but in which the patient's dementia autonomy level as rated by the LTCI system was higher than 2. Then, the patient records were examined to determine whether the cognitive decline could be the product of certain diseases other than dementia. Next, communication scores, observations of behavioral and psychological symptoms of dementia (BPSD)¹⁰ and other notes from the family physician's summaries, the long-term care researchers' notes, and CPS scores were used to group subjects into one of 3 categories: no dementia, mild cognitive impairment (MCI),¹¹ or dementia-equivalent.

The classification of *no dementia* was applied to subjects meeting more than four of the following criteria of autonomy: an evaluation as independent by the long-term care researcher, a CPS score of 0, a high communication score congruent with independence, no BPSDs, and no physician notes concerning suspected dementia.

Persons of which an evaluation as independent or level 1 by a long-term care researcher and a CPS score of 0–2, meeting more than three of the following criteria were categorized into the *MCI* group: short-term

memory disturbances as noted by a physician, LTCI researcher-observed forgetfulness, communication scores incongruent with independence, no BPSDs, and no notes of suspected dementia.

Dementia-equivalent status was determined if more than three of the following criteria were met: an LTCI dementia autonomy level higher than 3, more than two BPSDs, a CPS score of 3–6, short-term memory disturbances as noted by a family physician, personal care scores indicating that specific assistance is required, and low communication scores. Some additional findings and notes also substantiated a determination of dementia, such as repeated mild cerebral infarctions or hemiplegia requiring medication management.

Subsequently, the prevalence of dementia in the district was estimated by totaling the number of dementia-diagnosed and dementia-equivalent cases. The diagnostic criteria for dementia were CPS scores of 3–6 and an LTCI dementia autonomy rating higher than level 2.

■ Results

The distribution of dementia autonomy on the LTCI system with or without dementia diagnosis is shown in **Table 2**. Cases with no physician's diagnosis of dementia but in which the patient's dementia autonomy according to the LTCI system was higher than 2 are shown in **Table 3**. In total, 6 men and 16 women ($n = 70$, 25 men and 45 women) were classified as dementia-equivalent:

4 men and 8 women scored 2 on the CPS and 2 men and 8 women 3–6 on the same. Three out of the 8 women with unspecified dementia-equivalence and whose CPS scores were higher than 3 were bedridden due to femoral fractures. In addition, 7 men and 7 women experienced severe sequelae of cerebrovascular disease (CVD). Ten men and 10 women showed decreased cognitive function as a result of CVD, vascular dementia (VaD), or severe

■ **Table 2:** The distribution of dementia autonomy on the LTCI system with or without dementia diagnosis evaluated by family physician

| Level | No dementia diagnosed | | Dementia diagnosed | |
|-------------|-----------------------|-----------|--------------------|-------|
| | Men | Women | Men | Women |
| Independent | 90 | 193 | 0 | 2 |
| 1 | 35 | 51 | 2 | 6 |
| 2a | 7 | 14 | 4 | 7 |
| 2b | 7 | 16 | 4 | 22 |
| 3a | 7 | 8 | 14 | 18 |
| 3b | 0 | 3 | 5 | 6 |
| 4a | 4 | 4 | 12 | 8 |
| 4b | 0 | 0 | 2 | 2 |
| M | 0 | 0 | 0 | 0 |
| Total | 150 | 289 | 43 | 71 |

Bold indicates cases with no physician's diagnosis of dementia but in which the patient's dementia autonomy on the LTCI system was higher than 2.

■ **Table 3:** Causes of cognitive decline and CPS scores in cases without a physician's diagnosis of dementia but in which the patient's dementia autonomy on the LTCI system was higher than 2

| Over 65 years of age Cause of cognitive decline/CPS scores | Men | | Women | |
|---|-----|-----|-------|-----|
| | 0–2 | 3–6 | 0–2 | 3–6 |
| Equivalent to vascular dementia (VaD) | 1 | 2 | 3 | 0 |
| Equivalent to unspecified dementia | 2 | 0 | 4 | 0 |
| Equivalent to unspecified dementia (bedbound) | 1 | 0 | 1 | 8 |
| Sequelae of cerebrovascular disease (CVD bedbound) | 2 | 5 | 3 | 4 |
| (recount) Dementia-equivalent for care | 6 | 7 | 11 | 12 |
| Mild Cognitive Impairment (MCI) | 2 | 0 | 8 | 0 |
| No dementia | 3 | 0 | 1 | 0 |
| Hepatic encephalopathy, alcoholic encephalopathy | 2 | 0 | 0 | 0 |
| Psychiatric and neurological disorders | 1 | 3 | 7 | 3 |
| Cancer, depression associated with cancer | 0 | 1 | 1 | 1 |
| Fracture | 0 | 0 | 1 | 0 |
| Total | 14 | 11 | 29 | 16 |

■ Table 4: Distribution of the study sample by dementia discrimination criteria, age, and gender

| Age (years) | Study sample | | | Dementia diagnosed | | | Dementia diagnosed & dementia-equivalent for care | | | CPS 3-6 | | | Levels of dementia autonomy in the Japanese LTCI level ≥ 2 | | |
|--|--------------|-------|-------|--------------------|-------|-------|---|-------|-------|---------|-------|-------|--|-------|-------|
| | Men | Women | Total | Men | Women | Total | Men | Women | Total | Men | Women | Total | Men | Women | Total |
| 65-69 | 25 | 39 | 64 | 3 | 0 | 3 | 5 | 4 | 9 | 6 | 5 | 11 | 6 | 8 | 14 |
| 70-74 | 30 | 82 | 112 | 7 | 7 | 14 | 7 | 7 | 14 | 7 | 9 | 16 | 10 | 12 | 22 |
| 75-79 | 64 | 90 | 154 | 14 | 21 | 35 | 16 | 27 | 43 | 11 | 17 | 28 | 18 | 28 | 46 |
| 80-84 | 39 | 78 | 117 | 11 | 20 | 31 | 14 | 23 | 37 | 9 | 12 | 21 | 16 | 23 | 39 |
| 85-89 | 27 | 47 | 74 | 5 | 15 | 20 | 9 | 18 | 27 | 7 | 15 | 22 | 9 | 23 | 32 |
| ≥90 | 8 | 24 | 32 | 3 | 8 | 11 | 5 | 15 | 20 | 4 | 10 | 14 | 7 | 14 | 21 |
| Total | 193 | 360 | 553 | 43 | 71 | 114 | 56 | 94 | 150 | 44 | 68 | 112 | 66 | 108 | 174 |
| Prevalence in the study sample | | | | 22% | 20% | 21% | 29% | 26% | 27% | 23% | 19% | 20% | 34% | 30% | 31% |
| Estimated prevalence in the study area | | | | | | 3.8% | | | 5.0% | | | 3.8% | | | 5.8% |

sequelae of CVD. Two men and 8 women showed symptoms equivalent to MCI. Ten men and 14 women were classified as no dementia /MCI.

Distribution of the study sample among the four dementia discrimination criteria is shown in Table 4: family physician’s diagnosis of dementia, the dementia-diagnosed and dementia-equivalent for care, those with a CPS score of 3-6, and those with an LTCI rating higher than level 2. The estimated prevalence of dementia in people over age 65 in the study zone in each of these groups was 3.8%, 5.0%, 3.8%, and 5.8%, respectively.

■ Discussion

● The difficulty of diagnosing dementia

Delineation between normal aging and dementia cannot but be affected to some extent by the physician’s value judgments and clinical experience, and the boundary between MCI and mild dementia is unclear.¹² In particular, distinguishing the precursor state of dementia in the early stages of slow progressive types of dementia is very difficult¹³ because as many as 25% of patients with MCI may recover.¹⁴

Public consensus is widespread that dementia is a common disease of aging. Given the diagnostic guidelines, even a non-psychiatric physician can precisely diagnose dementia. Nevertheless, 70% of family physicians treating dementia find drafting their opinions somewhat difficult.¹⁵ Moreover, they cannot help but be cautious because patients and their families can be very confused by a diagnosis of dementia. In diagnosing dementia, the physician must take

into account the relevant environmental factors. One of the diagnostic criteria for dementia is the degree to which reduced intellectual functions disrupt family and social life. However, the type and extent of necessary social function varies widely by individual and support structure. With many family members available to support the patient in a large family home environment, there may be little need of LTCI benefits and therefore no need for a formal diagnosis of dementia. On the other hand, an elderly person living alone faces several challenges related to mobility, nutrition, safety, and disease management for which they would require LTCI assistance. Thus, as households grow smaller with urbanization, the prevalence of dementia (as measured by the number of formal diagnoses) increases. The definition of dementia should therefore be changed to “personal living functions impaired by brain dysfunction, especially in memory and judgment, that interferes with an individuals’ ability to sustain independent living.”¹⁶

● The need to establish a “dementia-equivalent” category of care

The dementia autonomy level of higher than 2 by LTCI can apply to a person with no dementia, MCI, and/or psychiatric and neurological disorders other than dementia. Although the CPS is a reliable evaluation method used worldwide,¹⁷ the specific cause of the impairment should be assumed. Another weakness of the CPS is that BPSDs are not sufficiently reflected in estimating the amount of time to care. The biggest drawback is that because the dementia autonomy level in LTCI does not

account for the cause of the decline in cognitive function, preventive measures cannot be established. If the main medical condition presented is musculoskeletal disease, the orthopedic physician who writes the summary and opinion for LTCI might not mention the diagnosis of dementia. Then, a committee of medical doctors, co-medical workers, and social welfare representatives judge that the patient requires care equivalent to a dementia patient in care-required certification. Sixty percent of such committees always focus on the symptoms of dementia by certification.¹⁵

To facilitate the planning of preventive measures for evidence-based long-term care, it is essential to specify the main causes and typologies of dementia. When vascular dementia (VaD) patients are bedridden with disorders such as aphasia, or they exhibit severely impaired activity of daily living (ADL) functioning, the case should not be considered VaD, but rather severe sequelae of CVD.¹⁸ Furthermore, since preventive measures are the same, severe sequelae of CVD should be considered equivalent to dementia. In this study, persons with a dementia-equivalent need for care (the sum total of dementia, dementia-equivalent, and severe sequelae of CVD) accounted for 27% of the elderly requiring long-term care. From the perspective of practical and concrete disease prevention, a preventive measure for VaD—a protocol composed of strict blood pressure management and glycemic control—is easier to implement than one for Alzheimer’s disease (AD).

VaD and AD share the same risk factors as diabetes and hypertension.¹⁹ Although reduced insulin signaling is a sign of longevity, it also triggers brain aging, which is exacerbated by the accumulation of β -amyloid resulting in the hyperphosphorylation of tau protein and destabilization of microtubules. This also decreases nerve cell function

via the formation of neurofibrillary tangles, and causes neuronal cell death and synaptic loss.²⁰ Therefore, Type II diabetes is considered a risk factor for AD. Many studies suggest that CVD risk factors are deeply involved in AD.²¹ In studies focusing on regional units in which CT imaging has not been routinely performed, CVD is often overlooked; therefore, mixed (VaD + AD) dementia might be diagnosed as AD. Although VaD cases frequently follow a clinical course similar to that of AD, many of them cannot be clearly explained due to the variety of infarction mechanisms. Vascular lesions might gradually lead to the likelihood of dementia.²² When the relative risk was reported by dementia types in an evidence-based review, the strength of association diminished in the following order: VaD > mixed (VaD + AD) > AD.²³

● Aging factors and pharmaceutical technology for dementia prevention

Mean age of No/dementia diagnosed by family physician and dementia-equivalent for care were shown in Table 5. Dementia diagnosed women by family physician was significantly higher age than non-demented women ($P < .0001$). In general, the contribution of the aging factor increases with time. The population as a whole is aging; the increasing number of people over 75 and even 85 years of age or older is the biggest factor for the rise in dementia prevalence. Although aging is always a risk factor for dementia, it is very difficult to evaluate the extent of its contribution. If patients with asymptomatic cerebral infarction but no dementia present with dementia after 10 years, its cause would be both aging-associated compensatory attenuation and vascular lesions. Then, can dementia only be increased in our global super-aging society? Pharmaceutical technology has the potential to

■ Table 5: Mean age and Standard deviation of patients’ age of no-dementia and dementia diagnosed, and dementia-equivalent for care (years)

| Cause of cognitive decline | Men (SD) | Women (SD) |
|--|-------------|------------|
| No/Dementia diagnosed by family physician | 77.3 (7.1) | 77.5 (6.8) |
| Dementia diagnosed by family physician | 78.7 (6.4) | 81.7 (5.9) |
| Equivalent to vascular dementia (VaD) | 85 (7.2) | 85.3 (6.1) |
| Equivalent to unspecified dementia | 84.5 (6.4) | 86 (9.7) |
| Equivalent to unspecified dementia (bedbound) | 84 | 86.8 (6.9) |
| Sequelae of cerebrovascular disease (CVD bedbound) | 79.4 (10.3) | 72.6 (6.1) |
| (recount) Dementia-equivalent for care | 81.8 (8.5) | 82.0 (9.7) |

halt the increasing prevalence of dementia.

Currently, the main anti-Alzheimer's drug strategies focus on the removal of amyloids, inhibition of amyloid formation, and prevention of abnormal accumulation of tau protein.²⁴ Specifically, some medications target the pharmacological activation of neprilysin and immunotherapy for the removal of amyloids,²⁵ the use of amyloid β and amyloid γ secretase inhibitors, and the use of γ secretase modulators for inhibiting amyloid formation. According to the latest research, γ -secretase itself has the ability to decompose and detoxify amyloid β_{42} .²⁶ There is currently a 20-year time lag between the appearance of early symptoms of dementia and the accumulation of amyloid proteins in the brain.^{27, 28} At present, research to elucidate the difference between MCI and AD on the one hand and normal aging on the other is progressing.²⁹ In the future, once an inexpensive, low-invasive biomarker has been developed, diagnostic screening before the onset of AD will be available.^{30, 31}

● Accurate estimation of the prevalence of dementia

In the present study, the prevalence rate is 5.8% when calculated using only those rated as dementia autonomy level 2 or higher as per the LTCI system. A study conducted in 2002 based on an analysis of data from 2.3 million people produced a similar estimate of 5.7%.³² Their index of dementia patients included diseases other than dementia and excluded the elderly with dementia who were not participating in the LTCI system.⁴ Of 70 patients with a dementia autonomy rating of LTCI level 2 or higher in this study, 10 men and 14 women would not be categorized as dementia-equivalent according to their method of analysis. When the criteria for estimating dementia in the elderly population (over 65 years of age) is expanded to include the dementia-diagnosed and the dementia-equivalent, the estimated prevalence is 5.0%. Epidemiological studies of the elderly between the late 1990s and 2000s estimated the prevalence of dementia in Japanese over age 65 to be 8–11%.³³ In the present study, as of 2005, I estimate that at least 3% of older adults with dementia have not been captured in the LTCI system. Studies in Tokyo showed that 28.7% of older adults whose Mini Mental State Exam (MMSE) score was 20–23, indicating moderate dementia, had no long-term care certificate. In addition, only 46% of older adults whose

MMSE score was less than 20, indicating moderate to severe dementia, had received LTCI services at home.³⁴ Studies in Obu, a city in Aichi prefecture, showed that 28.7 % of older adults with dementia had no long-term care certificate; another 5.1% and 15.4% were classified as independent and level 1 dementia autonomy levels in the LTCI system, respectively.³⁵ Therefore, assuming that this group of approximately 50% of the total number of elderly people with dementia would be classified as level 2 or higher in the LTCI system, after incorporating these results from previous research, the estimated prevalence of dementia according to this study would be increased to 10% from 5%. Due to the prolonged global economic recession, the number of older adults living in poverty has increased.³⁶ If the number of older adults who cannot afford the copayments and LTCI premiums increases, the validity of the estimate itself based on the LTCI data will further decrease. When estimating the prevalence of dementia from LTCI data, the capture rate should be carefully considered.

The new inequality in healthcare access will be a concern. The number of dementia patients is expected to increase rapidly in low- and middle-income countries,² therefore we need global dementia prevention and treatment measures that will be unaffected by economic disparities.

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Clinical manifestation and outcome of oldest old patients with cancer



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■ Introduction

A national survey revealed a total of 1526 thousand patients with “malignant neoplasm” in 2011.¹ Half of these patients were 70 years of age or older. With an increase in the incidence of cancer among the elderly, an increase in cancer among the oldest old patients is also expected.

There have been reports of patients with cancer from the medical provider side, but not from the standpoint of long term care facilities. This report will address the oldest old cancer patients from the point of view of patients within long term care facilities.

Out of 89 people, there were 54 residents over the age of 85, accounting for 60.7 % in S Facility for the elderly. There were at least 10 cancer patients (18%) of over 85 years. An analysis of the cancer patients in this facility was performed and revealed four residents with diagnosed cancer, three residents with suspicion of cancer, and an additional three guests who had been treated for cancer below the age of 84. Out of the four patients with diagnosed cancer, three had received treatment. The remaining patients suspected of cancer or already having been diagnosed with it did not receive any treatment.

Keywords: oldest old, latent cancer, laughter therapy, cancer survival

■ Case reports

Three types of people in the long term care facility were reported: residents with cancer, residents suspected of having cancer, and residents with a past history of cancer.

- A. Residents with cancer (colon, liver, MALT, and lung) diagnosed by histopathology (average age 92.3)
- B. Residents diagnosed with cancer (stomach, lung) with radiological and or endoscopic results with slightly elevated tumor marker without histopathology (average age 93).
- C. Residents with a past history of cancer surgery (stomach, uterus, and breast) (average age 87.7). Two cases were operated 28 and 30 years ago and one case had a hysterectomy at the age of 83 years.

Average age of the onset of the cancer in these patients was 83.7 and the average present age was 91.5 year old (Table 1). These residents were living happily. There were no physical symptoms related with cancer that

■ Table 1

| | | Onset Age | Present Age |
|-------------|--------|-----------|-------------|
| A | Case 1 | 94 | 96 |
| | Case 2 | 91 | 93 |
| | Case 3 | 90 | 91 |
| | Case 4 | 85 | 88 |
| B | Case 1 | 91 | 95 |
| | Case 2 | 89 | 93 |
| | Case 3 | 93 | 95 |
| C | Case 1 | 61 | 91 |
| | Case 2 | 60 | 88 |
| | Case 3 | 83 | 85 |
| Average Age | | 83.7 | 91.5 |

took away from the quality of life despite some patients suffering from dementia. These residents had not reached the terminal stage of cancer. Residents with or without dementia did not show any depressive tendencies. When residents show symptoms of cancer, they were admitted to the hospital and were not present in this facility.

● **A-1 Case 1: M.C., 96y/o, F, with hepatocellular carcinoma (Figure 1)**

She had jaundice, with an upper right colicky pain and was diagnosed as having cholecystolithiasis and a hepatocellular carcinoma at 94 which was evidenced by a CT scan. Her liver function test revealed T-Bil 6.0 mg/dl, AST 140IU/L, ALT 160IU/L, and ALP 1596IU/L. Antibiotics were given for two weeks and no invasive intervention was done for the liver carcinoma. The liver function showed better results after one month on April 13, 2009: T-Bil 0.9 mg/dl, AST 33IU/L, ALT 26IU/L, and ALP 734IU/L. She had an optimistic disposition and lived happily without any symptoms related to liver cancer.

In two years, she suddenly showed polarized vision and was thick-tongued. A brain CT scan showed she had a vascular stroke. Her liver function the next day was as follows: T-Bil 0.6 mg/dl, AST 127 IU/L, ALT 77 IU/L, ALP 706 IU/L, and γ -GTP 124 IU/L. Tumor marker PIVKA-II was 4870 mAU/mL (normal: <40). Abdominal CT showed a huge tumor occupied more than 90% of right

lobe of the liver. She expired by stroke with asymptomatic liver cancer.

● **A-2 Case 2: T.K., 93y/o, F, with sigmoid cancer (Figure 2)**

At 91, this patient had a sudden illeus on May, 2011. Ba enema showed severe obstruction. A simple resection of the sigmoid colon was done and found Borr2, a well differentiated adeno-carcinoma. After the operation, she gained weight from 36 kg to 44 kg in 8 months. She is a positive-minded person and continues to live happily.

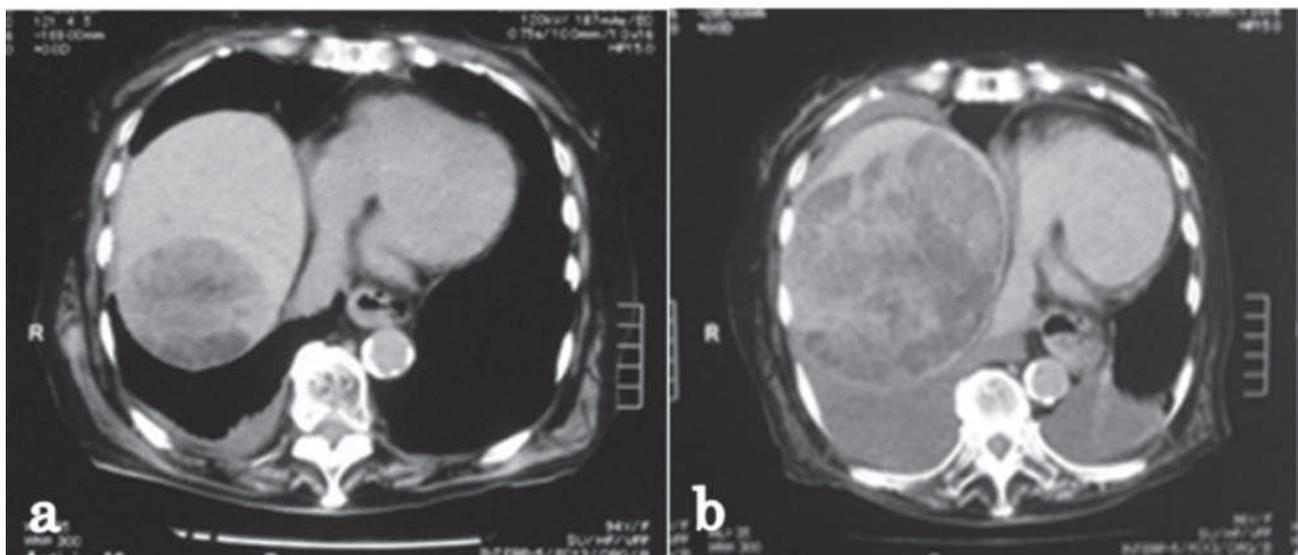
● **A-3 Case 3: T.S., 91 y/o, F, with lung cancer and squamous cell carcinoma of the left thigh (Figure 3)**

She was diagnosed with a lung cancer in the upper right lobe at the age of 90. Radiation therapy was performed for three months. At the age of 86, she had a mass on the left thigh removed, which proved to be a squamous cell carcinoma. She was a Public health nurse and a cheerful person.

● **A-4 Case 4: T.K., 88 y/o, F, with MALT lymphoma (stomach)**

At 85, this patient had melena and anemia. MALT lymphoma was diagnosed by endoscopic biopsy. No Helicobacter Pylori was found. A blood transfusion was

■ Figure 1: A-1 Case 1: M.C., 96y/o, F with hepatocellular carcinoma



a: Cholecystolithiasis and hepatocellular carcinoma were diagnosed by CT on Mar.16, 2009. (Hepato-cellular carcinoma, 94 y/o)
 b: In Oct.16, 2011 (two and half years later), a huge cancer occupied almost the entire right liver at CT. (Chemotherapy for gallstone, Hepato-cellular carcinoma, 96 y/o)

■ Figure 2: A-2 Case 2: T.K., 93y/o, F with sigmoid colon cancer



Ba enema showed severe obstruction. A simple resection for the cancer was performed.

■ Figure 3: A-3 Case 3: T.S., 91 y/o, F, with right lung cancer



Radiation therapy was performed for three months.

done. She had hypothyroidism in 2005. She had bladder cancer at 81 (2007) and five endoscopic resections were done until 2010. No chemotherapy or radiation was given. She has no symptoms for MALT lymphoma in April 2013. She has a happy disposition and continues to live happily.

● B-1 Case 1: K.S., 95 y/o, F, with lung tumor (Figure 4)

A tumor shadow was found during a routine annual chest X-ray and a CT scan revealed a tumor in her right lower lobe at the age of 91. Tumor markers were slightly increased CEA 2.8 ng/mL (<5.0), CA19-9 42.1 μ/ml (<37.0), SCC 2.4 ng/ml (<1.5). She is content and continues to live happily.

● B-2 Case2: K.O., 93 y/o, F, with bilateral lung cancer (Figure 5)

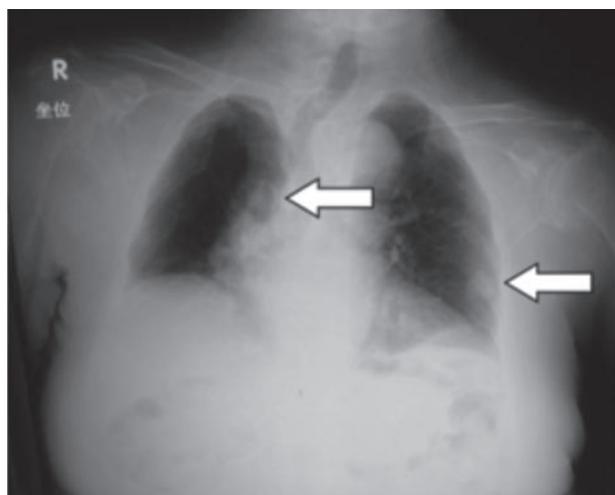
She had adenocarcinoma (bronchioloalveolar type) in her r-lung and an upper right lobectomy was done 23 years

■ Figure 4: B-1 Case 1: K.S., 95 y/o, F with right lung tumor



A tumor shadow was found r in her right lower lobe at 91 years of age.

■ Figure 5: B-2 Case 2: K.O., 93y/o, F, with bilateral lung cancer



An X-ray showed the stapling of bronchial stump of r-lung lobectomy for adenocarcinoma done in 70 y/o (upper arrow) and a new mass in the left-lung in 89 (lower arrow). Elevated tumor marker (CSA and SCC) suggested primary cancer of the left lung.

before. She had a stroke which resulted in l-hemiplegia at the age of 87. She had upper right colic pain which proved to be a gallstone by ERCP at the age of 89. L-lung cancer (primary) was found by accident. No intervention for the left lung cancer was done. Her tumor markers were elevated as CEA 16.6 ng/ml (<5.0), SCC1.4 ng/ml (<1.5). She is asymptomatic and has a happy personality.

● B-3 Case 3: M.S., 95 y/o, M, with suspected gastric cancer

He sometimes has slight gastric pain. Endoscopy revealed a gastric polyp at the age of 93, but no further examinations were conducted because of his age. He has bilateral gynecomastia and has interest in sex.

C has three people currently 85 years of age or older, with a history of cancer before age 85. One of them had surgery at the age of 83.

● C-1 Case 1: T.K., 91y/o, with history of surgeries for gastric cancer and uterine cancer

She was operated on for these two cancers 30 years ago. She has dementia but has warm and helpful character.

● C-2 Case 2: K.S., 88 y/o, with history of left breast cancer

She had a right mastectomy about 28 years ago. She is suffering from deformity of the hands due to rheumatoid arthritis but does not complain much about it.

● C-3 Case 3: M.O., 85 y/o, with history of uterus cancer

She had a hysterectomy at the age of 83. She is positive minded about all things.

■ Discussion

Presently none of the studied residents show symptoms associated with cancer. Some residents had gained weight. One expired by stroke. In her case, despite 90% of her liver's right lobe being cancerous, she was asymptomatic. We may call this type of cancer a "harmless" cancer.

It is believed that the elderly have a higher frequency of cancer. As humans age, cancer cells are able to grow easily due to the body's weakened immunological state being unable to eradicate them.

Kitagawa defined this as "natural life cancer" which

allows the elderly to die in peace without pain or aggressive treatment, as if this is a natural end to one's life.²

Within the Oldest Old, the reason for cancers not showing adverse symptoms can be thought of as follows:

In the present case, several patients with an average age of 91 with asymptomatic cancer were reported. The cause of this "harmless" cancer may be listed as below according to the literature.

1. Telomere shortening and alterations³
Tumor suppressor gene activity with biologic aging contributes to cancer risk for individuals. Telomere shortening and alterations may occur in individuals that live longer.
2. Lower biological malignancy (activity)
Slow progress cancers such as MALT lymphoma, and macromolecular tubular type adenocarcinoma are less malignant. Our cases were all well-differentiated cancers, as opposed to small cell cancers of the lung.⁴
3. Older patients tend to have a less aggressive tumor biologies making them more likely to be lower in grade, hormone receptor-positive, HER2-negative, and node-negative than tumors in younger women.⁵

Historically, older patients with cancer were excluded from or under-represented in clinical trials.⁴ Oncologists are less likely to offer trial participation to older patients—yet when offered, older patients are as likely to participate as younger patients (50% v 56%).³

● Psychosomatic factor

According to Seligman, people with a positive outlook, good life engagement and living meaningful lives can live happily for a long time. A new idea of epigenetics is that the environment can change the expression of the gene. Having a positive mind allows people to live with fun.⁶ All of our case studies had or have positive minds or are undergoing laughter therapy.

The incidence of cancer and mortality trends in the oldest old differ from the general population. Few physicians recognize that mental health must be very crucial factor for the life of the patient who has cancer or a malignant tumor in his body. However, WHO stated that "Health" should be defined as not only the absence of disease but also having a healthy mind. The oldest old are likely to have multiple co-morbid conditions, and

there is a need to find better ways to diagnose and treat cancers in this unique segment of the population.⁷ There is a possibility that a positive attitude is responsible for the absence of cancer symptoms.

Greater risk of aggressive cancer treatment for the elderly are expected. The methods of cancer treatment in the elderly must have special consideration. With respect to the elderly, cancer treatment that respects the QOL of limited life expectancy is a problem.

■ Conclusion

Ten cases of oldest old who have cancer, the possibility of cancer, and past history of cancer were reported. Although these residents were informed of their own cancers and were not shielded from heartbreaking ordinary life events, they all have bright personalities and are living happily without any trouble at the facility. It is thought that positive thinking contributed towards the residents' ability to keep themselves from being adversely affected by cancer symptoms.

Further research for epidemiology and scientific research including genetic view point should be performed to increase cancer survival.



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A Trial of Improvement of Immunity in Cancer Patients by Laughter Therapy



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■ Abstract

Purpose: The study was on the impact of laughter therapy on immunological improvement of patients with gastrointestinal cancer undergoing surgery and chemotherapy.

Materials & Method: Immunological measurements were performed in 41 cases with patients aged 68.9 years suffering from gastric or colorectal cancer. Intervention using Laughter Therapy was applied to 12 out of the 25 patients subjected to laproscopic surgery and 12 out of 19 patients subjected to chemotherapy.

Results: Immunity of patients within the control group who had surgery decreased. Immunity of patients within the control group who had chemotherapy decreased.

With intervention of Laughter Therapy, the immunity of patients with surgery had either decreased or was the same. However, with intervention of Laughter Therapy using the Smile-Sun Method, the immunity of chemotherapy patients increased, notably in patients with colorectal cancer. The improvement of immunity within the control group was 0 out of 7.

Conclusion: Patients with advanced cancer have lower immunity which is further decreased with surgery or chemotherapy. Chemotherapy patients who undertook the Laughter Therapy using the Smile-Sun Methodology during treatment in the hospital showed significantly higher immunity levels.

The results of this study indicate that patients with gastrointestinal cancer, who undergo laparoscopic surgery or chemotherapy for stomach or colorectal cancer,

benefit from a formal program of psychotherapeutic support during the in-patient hospital stay in terms of immunological improvement.

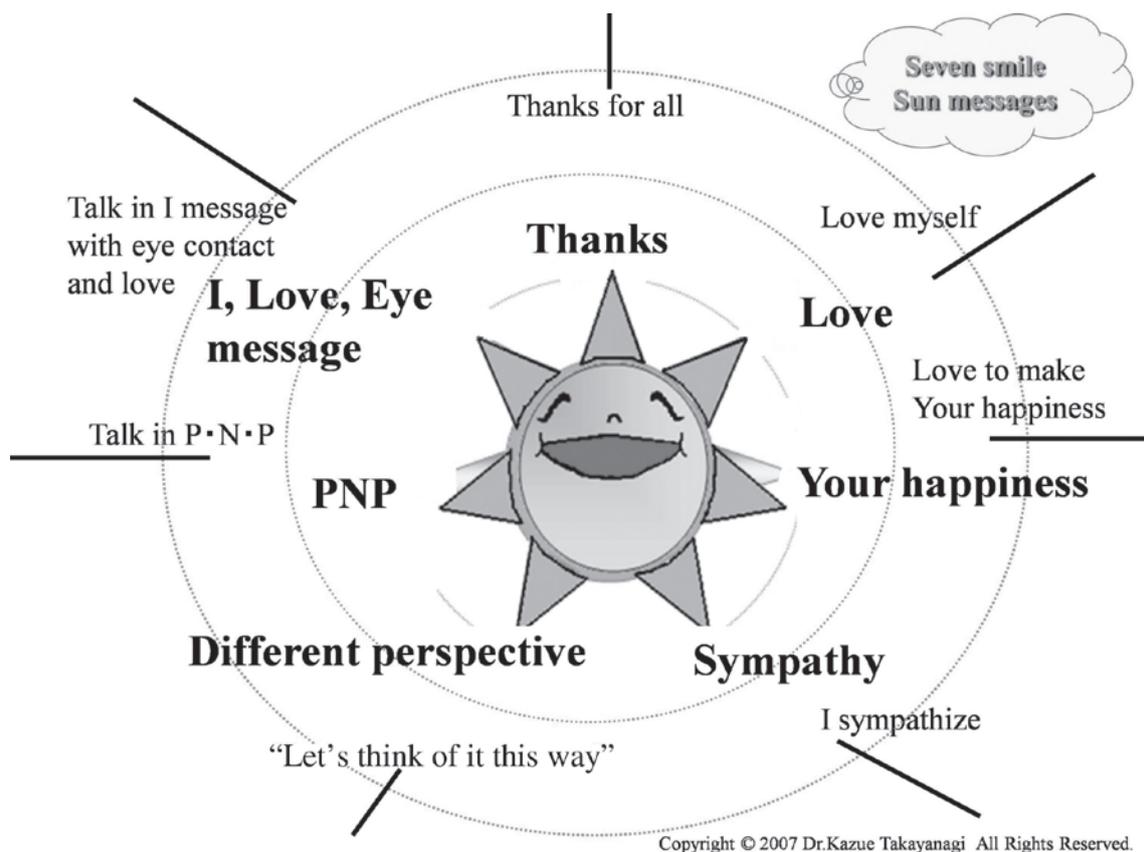
■ Introduction

The impact of laughter therapy on immunological improvement for patients with gastrointestinal cancer undergoing surgery and chemotherapy was studied. This laughter therapy using the Smile-Sun Method is one of the psychotherapeutic support for stability of the patient's state of mind.

The Smile-Sun Method was developed by Kazue Takayanagi as a method of eliciting natural laughter, which unlike superficial laughter, does not stimulate the amygdala, and producing a sense of security and mutual acceptance that contribute to the lightening of mood and the alleviation of depression.¹

Laughter has five principles: safety, relaxation, effectiveness, vividness, and happiness. Laughter education is done using the Smile-Sun Method. There are four strategies:

- a. Promoting self-efficacy (i. I love myself, ii. I make you happy)
- b. Dealing with stressful situations (iii. Admitting negative feelings, iv. Changing view-points)
- c. Dealing with people: ideas for further mutual benefit (v. "I" messages: I, "AI" ("Love" in Japanese), Eye message, vi. P-N-P; positive-negative-positive talk)
- d. Appreciation (g. Expressing appreciation)



■ Method

a) Smile-Sun Method training

Smile-Sun Method Training Program was implemented at Tsuchiura Kyodo Hospital for the purpose of increasing self-cure ability, promoting natural healing, increasing the motivation and promoting a positive attitude among the hospital staff and patients, and increasing the comprehensive quality of treatment.²

Laughter Therapists receive the following training. Four sessions of Smile-Sun training (1 session = 16 hours) were carried out for a total of 64 hours over a period of 8 days to train Laughter Therapists capable of implementing the method throughout the hospital. The training curriculum consisted of (1) the theory of laughter, (2) the practice of drawing natural laughter using role play, and (3) practical training in both individual and group therapy. All staff including physicians, nurses, pharmacists and administration participated in the Smile-Sun Method lecture for at least four hours.

Intervention for patients using Laughter Therapy by staff was performed during hospitalization.

b) Making the Kokotomo System

These 64 hours trained staff were called KOKOTOMO and each was assigned to an individual patient as a friend during hospitalization in this study. KOKOTOMO is literally translated as a 'friend from the bottom of the heart'. They wear a special scrub suit and are introduced as a friend without mentioning their profession.

KOKOTOMO visited the appointed patients and introduced themselves as an authorized part of the system at Tsuchiura Kyodo Hospital. They stayed with the patient for at least 15 min. each day and offered consumer oriented talk about in a positive mood. They were not allowed to talk about the details of the treatment and did not introduce themselves as health professionals. These sessions were called Laughter Therapy.

c) Choice of subjects

54 Patients with colorectal cancer and gastric cancer who underwent laparoscopic surgery or chemotherapy were enrolled in this study. Eligibility criteria were as follows:

- 1) Presence of pathologically proven gastric cancer or colorectal cancer;
- 2) Life expectancy of more than three months;

- 3) Ability to answer questionnaires;
- 4) An informed consent provided by the patient.

Surgical patients were not fragile or in the advanced stages of cancer. On the other hand, chemotherapy patients were in a more serious condition, such as stage IV advanced cancer, stage of postoperative adjuvant therapy, or recurrent cancer as follows:

Control group in chemotherapy

- 2 x patients with post-gastrectomy
- 1 x patient with advanced gastric cancer without surgery
- 3 x patients with advanced colorectal cancer without operations
- 3 x patients with advanced colorectal cancer with operations

Intervention group in chemotherapy

- 2 x patients with post gastrectomy
- 4 x patients with advanced gastric cancer
- 4 x patients with post-operative colorectal cancer
- 2 x patients with colorectal cancer without operations

Out of the 54 patients who volunteered to participate in the study, 10 were omitted for technical reasons, leaving a total of 44 patients in this study: 20 patients with gastric cancer, 24 patients with colorectal cancer. 25 patients had laparoscopic surgery and 19 patients had chemotherapy.

Immunological measurement was performed in 44 cases of 54 cases enrolled at first. The characteristics of the 44 subject are listed in Table 1. The average age was 68.7 years old. Thirteen patients undergoing surgical treatment in the control group were as follows; six cases of gastric cancer and seven cases of colorectal cancer, with an average age of 68.9 (between 35 and 84). Seven patients undergoing chemotherapy in the control group, one case of gastric cancer and seven cases of colorectal cancer, with an average age of 70.0 years old (between 46 and 84). Patients undergoing surgical treatment in laughter

therapy; seven cases of gastric cancer and five cases of colorectal cancer, with an average age of 67.8 (between 38 and 84). Twelve patients undergoing chemotherapy in laughter therapy group consisted of six cases of gastric cancer and six cases of colorectal cancer, with an average age of 68.8 (between 62 and 83).

d) Intervention

In both the control and intervention (laughter therapy during admission) groups, the immune status was measured before and after treatment. Two Laughter Therapists were appointed as KOKOTOMO to one matched patient and conducted Laughter Therapy.

A controlled trial was conducted in cooperation with the Departments of General Surgery and Oncology, Tsuchiura Kyodo Hospital, Ibaragi, Japan.

e) Measurement of immunity

The scoring system of immune status of the patients that was developed by Hirokawa and others are applied.³ The seven following immunological parameters from patient's blood were measured. 1) number of T cells (CD3+ cells), 2) the ratio of CD4/CD8, 3) number of naive T cells (CD4+CD45RA+cells), 4) the ratio of naive T cells to memory T cells (CD4+CD45RO+cells), 5) number of CD28+ T cells within CD 8 T cells, 6) number of B cells, and 7) number of NK cells. From these parameters an immunological score was developed.

Furthermore, immunological age (IA) was calculated as a new parameter which reflected both the number and proliferative capacity of T-cells.⁴ Immunological measurements were carried out by the Institute for Health and Life sciences. Statistical analysis was done using SAS ver. 9.2. Differences were examined using a X² test.

The ethical issue of this research was approved by the Medical Ethics Committee of the Tsuchiura Kyodo Hospital.

■ Table 1: Subject details

| | Total | | Control Group | | | | | | Intervention Group | | | | | | |
|----------------------|-------|----|---------------|---|----------------|------------|-------------|--------------|--------------------|-----|---|----------------|------------|-------------|--------------|
| | n | n | Sex | | Primary Region | | Average Age | Range of Age | n | Sex | | Primary Region | | Average Age | Range of Age |
| | | | M | F | Gastric | Colorectal | | | | M | F | Gastric | Colorectal | | |
| Laparoscopic Surgery | 25 | 13 | 6 | 7 | 6 | 7 | 68.9 | 35-84 | 12 | 10 | 2 | 7 | 5 | 67.8 | 38-84 |
| Chemotherapy | 19 | 7 | 5 | 2 | 1 | 6 | 70 | 46-84 | 12 | 5 | 7 | 6 | 6 | 68.8 | 58-83 |

Table 1 showed the details of subjects. 25 subjects for laparoscopic surgery and 19 subjects for chemotherapy were divided into two groups; control and laughter therapy intervention.

■ Figure 1: Rader chart of Immunological score

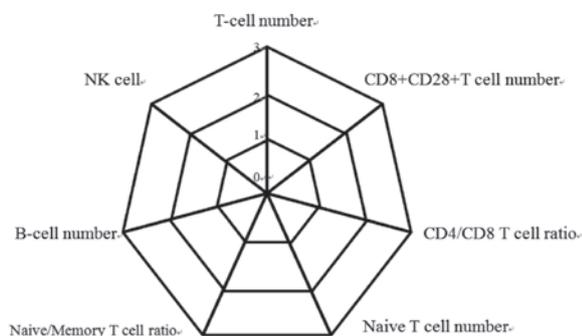


Figure 1 showed immunological score. The value of each immunological parameter falls within a range specified in a database and each parameter was scored into 3 grades based on its value. The measurements of each immunological parameter was scored in three from high (three points), average (two points), and low (one point). The total points was the estimated immunity score. A full score was 21 points.

■ Results

a) Intervention interview session

Immunological checks were performed pre and post treatment (surgery or chemotherapy) with or without intervention. The number of interviews averaged 6.3 times in 8.0 days for surgical cases, and 10.7 times in 15.8 days for chemotherapy cases.

Interview length averaged 109 minutes per admission in surgical cases and 275 minutes in chemotherapy cases. Chemotherapy cases had almost triple the amount of time as compared with laparoscopic surgery.

b) Immunological score

The immunological score demonstrated better immunological status for the intervention group than the control group in chemotherapy ($p=0.0160$) (Table 3). When this immunological score were plotted as Figure 2, the immunologic score of the surgical cases was lower in both control group and intervention group. These results

■ Table 2: Details of intervention interview session

| | Number of Times | Mean | Interview Minutes | Mean Minutes |
|--------------|-----------------|------|-------------------|--------------|
| Laparoscopy | 6.3 | 2-10 | 109 | 20-200 |
| Chemotherapy | 10.7 | 6-21 | 275 | 55-565 |
| Total | 8.5 | 2-21 | 192 | 20-565 |

Table 2 showed the number of interviewing interventions and interview minutes. The chemotherapy group had more frequent and longer interventions.

found more favor of the intervention group, especially in the chemotherapy group. The immunological score of patients who underwent chemotherapy before any treatment was lower than surgical cases (n.s). In surgical treatment, the immunity of the control group decreased (n.s), but in some cases where intervention was applied, the patients were able to maintain their immunity levels.

c) Immunological age (T-cell related immune functions)

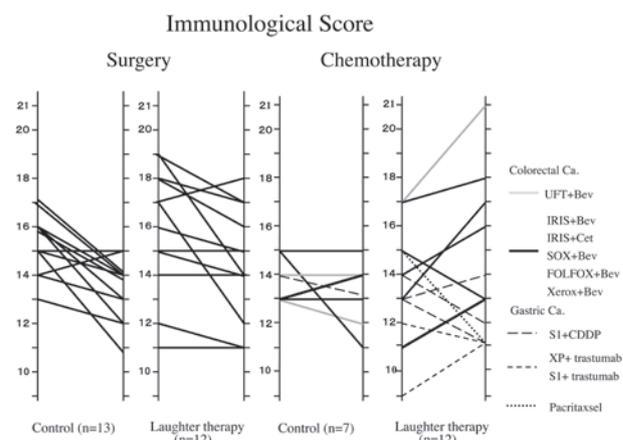
In surgical treatment, the immunity of the control group decreased. On the contrary, 41.7% (5/12) of patients in the chemotherapy group who had Laughter Therapy improved their immunity (Table 3). The number of surgery patients who improved their immunity after Laughter Therapy was 8.3% (1/12). The immunity was improved within the surgery control group by 7.7% (1/13). There were some tendencies of T-cell related

■ Table 3: Change of Immunological score in the chemotherapy group

| Category Analysis | | | |
|-------------------|----------|----------|---------|
| Change | Control | Laughter | P-value |
| Increase | 1 (12.5) | 7 (58.3) | 0.0160 |
| No Change | 4 (50.0) | 0 (0.0) | |
| Decrease | 3 (37.5) | 5 (41.7) | |

Category analysis in the chemotherapy group showed significant changes in the immunological score ($p=0.016$) compared with the control.

■ Figure 2: Change of Immunological score by Laughter Therapy



The immunological score before and after intervention using Smile-Sun Method were plotted with the control. The chemotherapy group showed lower immunity before treatment compared with the surgical group. The regimen of the Chemotherapy is shown on the right.

immune functions being increased by laughter therapy in the chemotherapy group.

■ Discussion

A comparison was made between 13 patients who had surgery (group 1) and 7 patients who had chemotherapy (group 2) within the control group. Before intervention, a decreased immunity within both groups was detected. The surgical patients in group 1 were in their early stages of cancer. The cancer was expected to be removed by laparoscopy. The patients in group 2 already had advanced cancer and a lower immunity score on admission compared with group 1. Immunity of patients within group 1 decreased after 5.8 days due to the invasive nature of the recent surgery. The patients in group 2 were already resigned to their fate as they had been living with cancer for some time. Immunity of patients without intervention within group 2 decreased significantly after 8.4 days.

With intervention of Laughter Therapy, the immunity of patients within group 1 had either decreased or was the same in 8.0 days. Gastrectomy or resection of the colon was invasive enough to reduce immunity.

However, with intervention of Laughter Therapy using the Smile-Sun Method, the immunity of patients within group 2 increased substantially after 15.8 days. Within group 2 patients undergoing laughter therapy, 5 out of 12 patients (41%) improved their immunity, in particular patients with colorectal cancer. In stark contrast, the improvement of immunity within the control group was 0 out of 7.

Among those patients who undertook Laughter Therapy, there were two sets. Set 1 patients underwent surgery and set 2 patients underwent chemotherapy. Patients in set 1 were interviewed 6.3 times for a total of 109 minutes (17.3 minutes per interview) within 8.0 days

of admission to hospital. Patients in set 2 (chemotherapy group) were interviewed 10.7 times for a total of 275 minutes within 15.8 days of admission to the hospital. A patient within set 1 declined the offer of intervention after the first introductory visit citing they were busy with family matters. On the other hand, all patients in set 2 chose to participate in the intervention. While the time offered per interview was fixed at 15 minutes, set 2 patients sought more interview time and each interview lasted for 25.7 minutes.

Kuchler reported on the impact of psychotherapeutic support on survival for patients with gastrointestinal cancer undergoing surgery.⁵ Other papers have been published on the effects of psychosocial treatment on survival of patients.⁶ The survival benefits associated with the provision of psychotherapeutic support was seen in two to ten years in Kuchler's cases but we have been able to determine the effectiveness of Laughter Therapy in a much shorter period.

Laughter could increase the production of endorphins and the activation of natural killer (NK) cells known to induce apoptosis in cancer cells.⁷ Noji et al. reported the case of an 88-years-old patient with advanced gastric cancer.⁸ With the help of soothing laughter, the cancer was morphologically reduced and she survived for five years. There are several other papers which claim that laughter elevates the immune system.^{9, 10} These papers measure results by solely using NK cell activity, IL6, growth hormone, IGF-1 and substance P. In the case of this trial however, the elevation of immune system results were measured using a much more detailed charting system, the Immunological score.³

Hirokawa et al. assessed T cell-related immune function of healthy people and patients with colorectal cancer by scoring system that we adopted for this paper,

■ Table 4: Change of Immunological Age (T-cell mediated Immune functions) by laughter Therapy

| | Control Group | | Laughter Therapy Group | | P-value |
|--------------------|---------------|----|------------------------|---|---------|
| Surgical Group | Improvement | 1 | Improvement | 1 | 0.7868 |
| | Unchanging | 1 | Unchanging | 2 | |
| | Decline | 11 | Decline | 9 | |
| Chemotherapy Group | Improvement | 0 | Improvement | 5 | 0.1588 |
| | Unchanging | 4 | Unchanging | 3 | |
| | Decline | 3 | Decline | 4 | |

Table 4 showed that T-cell related immune function improved in 41.7% (5/12) of the chemotherapy group. A study showing the analyses of gene expression will be available in the near future.

and confirmed a statistically significant change in immune functions of cancer patients.

The number of T-cell is essential for the maintenance of immune function, and T-cell proliferation is the most essential function of T-cell immunity, including the process of antigen recognition and sequential division of T-cells. So, Immunological age (IA) calculated by T-cell number and proliferative capacity of T-cells is thought to be a good parameter of T cell-related immune functions.

The immunological parameter demonstrated better immunological status for the intervention group than the control group.

In our cases, laughter therapy had value. The effects of laughter on post-prandial glucose levels and gene expression in type 2 diabetic patients has already been proven by Dr. Murakami.¹¹ It is anticipated therefore that Laughter Therapy will alter gene expression, but the results of this will not be known for several months. Laughter Education for medical students and healthcare professionals at postgraduate level is currently being delivered.¹²

■ Conclusion

Patients with advanced cancer have lower immunity levels which is further decreased with surgery or chemotherapy. Chemotherapy patients who undertook the Laughter Therapy using the Smile-Sun Methodology during treatment in hospital showed significantly higher levels of immunity.

The results of this study indicate that patients with gastrointestinal cancer, who undergo laparoscopic surgery or chemotherapy for stomach or colorectal cancer, benefit from a formal program of psychotherapeutic support during the in-patient hospital stay in terms of immunological improvement.

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「Japan Hospitals No. 33」(July 2014)の原稿募集!

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- | | |
|---------|--|
| 1. 募集内容 | 本誌は日本の医療や病院の実情を海外に紹介、PR するもので、看護の実態や医療制度の問題なども含み、関連する論文や研究報告など他誌に発表されていないものとする。(国内既発表のもの翻訳で国外未発表のものは可) |
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| 3. 原稿様式 | ① A4 用紙に英文でワープロ使用、メディア媒体での提出を原則とする。 プリントアウト原稿と日本語の要約も添付する。 ② 図、表、写真 (モノクロのみ) は鮮明な原画を添付する。 ③ 執筆者の顔写真1葉も添付。 |
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| 5. 原稿締切 | 2014 年 3 月 31 日 |

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