

# JMAJ

## Japan Medical Association Journal

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# Basic Policies of the Japan Medical Association

JMAJ 46(1): 1–6, 2003

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*The following is a main part of the address of Dr. Eitaka Tsuboi, President of the Japan Medical Association, which was presented at the 107th Provisional General Assembly of the JMA House of Delegates that was held in Tokyo on October 22, 2002.*

## **Ascertaining the Truth Behind the Social Security Reforms of the Koizumi Cabinet**

Against the background of social confusion and the whirlwind of financial reforms pursued by the Koizumi Cabinet that has put health care in the same category as other industries, the JMA was forced to bitterly accept an unprecedented 2.7 percent cutback of medical fees as part of the government's strategy to revise the medical fee payment system for diagnostic and medical treatment. The proposed 2.7 percent figure did not have any medical basis nor did the Ministry of Health, Labor and Welfare base this cutback on any constructive concept about medical fees. It was simply a financial measure used by the ministry to compile their fiscal budget for the following year within Koizumi's framework to keep the government bond issue to 30 trillion yen.

The reason why we agreed to this figure based on a very unconvincing explanation was due to the extremely exhausted state of our socioeconomy and for the sake of the general public, which was gasping at the risk that the government was taking.

However, to add further insult to injury, the

financial burden of the salaried employee for health costs was raised to 30 percent followed shortly thereafter by an announcement that a segment of the financial burden of elderly outpatients would also be increased. These are reckless moves that we find difficult to tolerate. We must oppose these partial increases that are to be borne by the public and demand that they be revised.

There is a need to advise the government to pursue policymaking that is based on firm social security principles and not simply for the sake of maintaining financial consistency.

Social security in Japan has hitherto been defined according to principles that guarantee a minimum standard of living, i.e., a means of providing poverty relief system. In recent years, the need to rebuild the entire social security system has gradually come to the fore, including the need for reforms of disease prevention measures, guarantees for a safe and sound living standard, long-term care insurance, employment for the elderly and guaranteed pensions, environmental improvements based on normalization principles, and securing financial resources. Thus, social security was finally beginning to be seen as a form of investment that was needed to build a safe and

sound living environment rather than a form of consumption.

However, the anticipation of increased social security costs with the advance of an aging population and low birth rate, compounded by economic stagnation and stringent national finances, has contributed to the growth of a movement to control the impending rise in social security costs. Subsequently, the financial bureaucracy has adopted extreme measures to control the financial resources for social security, which is perceived once again as a costly form of spending.

The trend to pursue financial reforms leaving no sanctuary has grown. This has been particularly true since the inauguration of the Koizumi Cabinet, under which the financial bureaucrats who seem to have neither respect for human dignity nor for the fact that society is comprised of human beings, have single-mindedly pursued financial reform policies. The trend toward policies that control health care, which provides safeguards against public health hazards, is particularly vehement; and the situation has devolved to the point where the intrinsic qualities of health care are not discussed and completely ignored. Furthermore, there are even scholars who advocate putting a price on human life.

The health care costs that are footed by the public in the form of taxes and insurance premiums should be appropriately used to maintain the health of the people and to guarantee a safe and sound society. It would not be an exaggeration to state that measures aimed at reducing health costs in order to cover a deficit produced by failed economic policies, and politics that put a price on human life preclude Japan as a modern welfare state. Moreover, the approval to allow private corporations to participate in the health care sector and the high-handedness of freeloading on the public domain of health care are reflective of a truly abnormal state.

To reduce this national risk and to promote an understanding of health care as defined by

the principles of a modern social security system, the only recourse left to physicians is to dedicate our efforts to providing good quality health care in accordance with the public trust that is vested in us. Promoting specific measures such as public disclosure of medical data, providing high quality health care, and guaranteeing its safety are the only means of achieving this goal and protecting the national populace from the public finance driven mentality of the financial bureaucracy. Although this may appear to be a circuitous and long-term solution, I believe that this is what must be done.

A comprehensive social security system implies a life of stability in the years ahead for the national populace and prevents the tendency for aimless accumulation of personal assets. Expanded general consumption may trigger the resuscitation of an exhausted economy.

In his general policy speech, the Prime Minister quoted the words of Mutsu Munemitsu, which implied that this was the best possible solution that could be devised; and I think that these words aptly describe the present state of affairs, but not for health care reforms. Rather, the solutions are premature. I would like the Prime Minister to understand that the JMA has the accumulated know how to successfully execute health care reforms for the Japanese people, if these reforms are implemented solemnly in keeping with the rule of right.

Additionally, our government should rapidly form a consensus to raise Japanese public awareness about sharing the cost of social security. Of the cost that will be shared between public sources, mutual aid, and self-supporting parties, the awareness of the Japanese people, who fall into the latter category, will become extremely important in the mid-21st century. Cutting edge advanced medical care such as genetic treatment and other forms of new medical technology will provide limitless benefits for the national populace, while triggering enormous increases in health care costs. The decreasing population of the younger genera-

tion, who will bear the burden of these costs, impede efforts to secure a stable source of revenue. If the issue of securing a self-supporting source of revenue in the sharing of social security costs is not resolved at an early stage, the social security system may collapse. Although many are aware of this impending crisis, concrete measures have not evolved and this fact has further contributed to the apprehension.

The JMA has proposed a concrete self-help policy to secure an independent financial resource (known as independent investment) several years ago. If an agreement can be successfully reached on this policy, the indecision on the issues that are in contention such as combined public and private treatment, public and private insurance, and advocacies that are comparable individual requests will disappear.

A discussion on modern social security doctrines should be taken up by the general public to protect our social security system.

### **Revision of the Medical Fee Payment System and Reforms of the Health Care System**

Due to the unprecedented deficit revisions produced by the financial structural reforms enacted by the Koizumi Cabinet, which greatly curtailed the growth in medical fees, there was a need to prepare measures to alleviate these drastic changes. One specific means was a confirmation document that was exchanged with the chair of the LDP Policy Research Committee. This document was created with the objective of revising a series of health care related laws and it is comprised of four clauses — medical fee payment system, repayment of high cost health costs of the elderly, a 30 percent co-payment of health costs, and health reforms. We do not know whether each of these four clauses in the confirmation document will be implemented as promised. Many of the memorandums that have been exchanged between the JMA and LDP in the past have tended to remain unimplemented. But this

time, we will confirm without fail that these items are implemented as planned.

The first issue that was pointed out by JMA regarding revisions of the medical fee reforms was about designating basic hospitalization fees for patients hospitalized for more than 180 days as a special health cost. The viewpoint that was advocated by JMA was relevant, and according to the “Notice to Section Managers” issued by the Ministry of Health, Labor and Welfare, respiratory care, treatment for pneumonia, and five other new pathological and treatment conditions were excluded. In future, revisions will be made through supplementary notices for inconsistent case examples as they occur.

Additionally, with regard to the 30 percent reduction in surgical fees based on a standard number of cases, the JMA successfully moderated a segment of the standard for facilities through a memorandum sent to the Ministry of Health, Labor and Welfare. However, this is only an emergency measure, and we have informed the ministry that other revisions that are medically groundless should be abolished.

We are presently debating calculation restrictions that apply for rehabilitation services that greatly affect the field of orthopedic and general surgery, successive decreases in re-diagnosis fees, and other unjustifiable and inconsistent revisions through the Central Social Insurance Medical Council and continue to lobby relevant Diet members.

As part of these efforts, calculations for chronic pain control, antiphlogistic secondary pain and other treatment measures, administrative notices were issued aimed at reducing the restrictions, but we are hurriedly studying the extent to which such measures have produced relief at the actual patient examination sites.

As for abolishing the “fixed remuneration for all outpatient examination costs” that have been strongly demanded by members, the JMA will implement a second survey study on the itemized statements of medical expenses; and

based on the findings obtained and a review of the impact of these revisions, appropriate measures will be pursued.

To convince the Ministry of Health to shift to a perspective that evaluates professional technology with more respect, measures to directly link the professional qualifications of the licensed physician or specialist to the medical fee payment system or administrative methods that deny professional freedom must be abolished. We believe that the next package of revisions should include measures to shift from a method of cutting additional items, which was an especially conspicuous revision, to a method of adding items as needed; and we have communicated our viewpoint to the ministry accordingly.

Hearings of the working group to review the LDP's medical fee payment system have continued and JMA's proposed reforms that will enable reproduction by creating a system that incorporates the cost of health services are being strongly advocated. Other JMA proposed reforms will be successively explained mainly to the LDP; and activities to promote an understanding of these reforms will be actively pursued.

Each institutional reform item advocated by the JMA has been clearly defined in the concept on structural health care reforms as can be seen in the addendum of a segment of the revised health laws such as the Health Insurance Act that were recently legislated; and we will solemnly continue to pursue the reforms that JMA has hitherto advocated, namely the creation of a health system for the elderly, the reorganization and integration of health insurance, a review of the medical fee payment system, a review of health care services, and others.

A working group has been created within the LDP as well as the headquarters to pursue structural reforms within the Ministry of Health to review these proposals.

The JMA has repeatedly revised its proposals, while substantiating content and details,

but it will also create a system to review structural health care reforms within the association aimed at promoting reforms that benefit the national populace.

Of the health insurance laws that have been revised, the explanation of the law that will be legislated on April 1, 2003 pertaining to the 30 percent co-payment by the Minister of Health, Labor and Welfare to the Committee on Health, Welfare and Labor of the House of Councillors was studied. Although it is a rather passive countermeasure, JMA is presently aiming to alleviate the future financial burden of the individual by persuading the Ministry of Health to respect the independency of health cooperatives, which has hitherto decided its own insurance finances, and allow the ratio of co-payments to be substantially lowered through the fringe benefits offered by each health cooperative. This approach can also be applied to the National Health Insurance. When a large disparity is seen in the government's outlook with regard to government-managed health insurance, the Diet is consulted.

Based on the series of reforms that have been recently adopted, I have realized that a reexamination of the activities of the Japan Physician's Federation index is needed, and both the Japan Physician's Federation and the JMA should possess a specific means of appealing to the seat of politics with regard to health policies. I also strongly feel that it is especially important that the local medical associations pursue meticulous health politics. Therefore, a health politics committee was created immediately at the JMA headquarters to review the activity index of the Japan Physician's Federation and to achieve three-dimensional reforms of political health activities, including measures to bolster the strength of the local medical associations.

In future, I would like to dedicate my efforts to participating in JMA's policymaking decisions as well as in election support activities and to improve the capacity of the JMA as a policymaking group.

## Public Relations Activities

The JMA will aggressively pursue public relations activities to gain the understanding of the general public by proposing health policies that represent the best interests of the Japanese people.

I am aware that these efforts are as yet inadequate, and we must aim for further progress and development. Presently, public relations activities are being pursued and the joint publications entitled, "The Crossroads in Health Issues" and "Health Junction", have been disseminated to health institutions for use by patients.

Furthermore, we are expediting our efforts to establish the information and public relations center that was promised in the past, while searching for specific measures to develop effective public relations activities.

## Japan Medical Association Research Institute (JMARI)

The scope of JMARI's study and research activities has expanded in tandem with the growing complexity of the health care environment. In order for JMA to be able to cope with the rapid development in the fields of advanced medicine, especially molecular medicine, research to adapt cutting edge medicine to community health care sites, e.g., personalized health care and other forms of community medicine, have been pursued. Subsequently, the scope, quality, and direction of its activities have been substantial.

Furthermore, the task of corroborating the medical grounds of the various bureaucratic oriented health care policies that have been rapidly issued and to make counterproposals continues to increase.

In summary, I am able to report that the activities of the JMARI are adequate in content and development. However, we are gradually confronted with the task of exploring prospective concepts about how we want JMARI

to evolve in the future, and I would like to ask for the cooperation and support of each member in this endeavor.

## World Medical Association (WMA)

The 2002 WMA General Assembly was held in Washington D.C, on October 2 and my three-year term of office as the WMA presidency officially ended. Thanks to the strong support of each member, I was able to accomplish many achievements and to successfully fulfill the responsibilities of the office.

An especially memorable event during my term of office was WMA's first invitation to the World Economic Forum and my participation in that forum which was held in Davos, Switzerland, where I was able to present my views from a medical standpoint on the issue of medical genetics and industry. Another significant event was the adoption of JMA's proposals on the "WMA Declaration on Patient Safety" and the "WMA Declaration on Advanced Medical Technology and Medical Ethics" by the WMA General Assembly, enabling JMA to leave an indelible footprint in the annals of the WMA. This is due to the support of our far-sighted physician members to whom I would like to extend my deepest gratitude.

To enable the JMA to maintain its position as an opinion leader within the ranks of the WMA, I would like to continue to actively pursue WMA activities.

## Conclusion

I have presented my policy speech on the administration of the upcoming affairs of the JMA with high aspirations. In view of the fact that the debates on reforms that will determine the conditions of our society have been enacted in a whirlwind of confusion by the Koizumi Cabinet, is all the more reason why these reforms must not simply be finance driven bureaucratic policies, but should respect legislation that governs the existence of human

beings. To create a social security system that will provide an anxiety-free future where citizens are able to raise their children with a sense of security, we must recognize anew the

exceedingly large role of the JMA, unite with diverse perspectives, and strive to foster a sense of service to the country.

# Pathohistologic Background and Treatment of Idiopathic Pulmonary Fibrosis —A need to understand as a respiratory disease in the elderly—

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**Abstract:** Idiopathic pulmonary fibrosis (IPF) is a distinct clinical entity with a characteristic patho-histology of usual interstitial pneumonia (UIP). Although pulmonary fibrosis caused by other etiologies with a similar UIP pattern needs to be excluded in the diagnosis, most patients with IPF are in their 60s and 70s, indicating that IPF should be recognized as a respiratory disease of the elderly. Long-term clinical follow-up of patients with IPF reveals that, in addition to a slow and steady decline in pulmonary function, a high incidence of complication with lung cancer and acute exacerbation after common cold in winter lead to a poor prognosis. Thus, prudent care and periodic referral to a specialist are necessary in the clinical management of elderly patients with IPF. In addition to the intractable fibrotic change seen in the lung, it should be kept in mind that patients with IPF are also vulnerable to changes in the lung that occur with aging.

**Key words:** Idiopathic pulmonary fibrosis; Development of lung cancer;  
Acute exacerbation

## Introduction

Idiopathic pulmonary fibrosis (IPF), or chronic idiopathic interstitial pneumonia, has an unclear etiology, and its treatment has not yet been established. IPF is an intractable disease, comparable to lung cancer, with an average life expectancy after diagnosis of 3 to 5

years. A recent etiologic survey in the U.S. revealed that the prevalence of this disease is high among individuals in their 60s and 70s. Clinicians in Japan, who have found themselves treating increased numbers of patients in advanced age, also have the impression that this disease is increasing. In this regard, it is of importance to recognize IPF as a respiratory

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disease in the elderly.

### **What is Idiopathic Pulmonary Fibrosis?**

Inflammatory lung diseases of known etiology include those that are occupational (asbestos inhalation), drug-induced, and radiation-induced as well as those associated with collagen diseases. IPF, however, is an interstitial pneumonia of unknown etiology that is most commonly encountered in clinical practice. In spite of many years of investigation, the terminology, definition, and pathology of this disease have not fully been clarified in the U.S., Europe, or Japan.

To improve this situation, an international consensus statement concerning IPF was published in a U.S. medical journal in February 2000.<sup>1)</sup> According to the statement, IPF is defined as chronic pulmonary inflammation with histopathologic features of usual interstitial pneumonia (UIP), occurring in latent form mostly in persons above 50 years of age and excluding collagen diseases and inhalation- or drug-induced pulmonary inflammation.

Because UIP is not a familiar pathologic term, it may be necessary to explain the histology of the lung in patients with UIP. The pathology of UIP is characterized by a patchy pattern of virtually intact alveoli coexisting with inflammatory changes in the alveolar region formed at different times. Fibrosis is conspicuous in the pleura and in areas around the interacinous interstitium (particularly in the lower lung field). Fibroblastic foci, fibrosis accompanied by alveolar collapse due to loss of the alveolar epithelium, and honeycomb lung structure due to bronchiolectasis are also seen.

The clinical signs and symptoms of IPF include dry cough, exertional dyspnea, fine crackles called Velcro rale in the end-inspiratory phase as noted upon auscultation, and clubbed fingers found in about half of the patients. Decreases in vital capacity and pulmonary diffusing capacity as well as hypoxemia are also typical.

High-resolution CT scanning (1- to 2-mm sections) reveals ground-glass, linear, or honeycomb features in the vicinity of the pleura in the bilateral dorsal lower lung fields. If the CT findings are well characteristic, surgical lung biopsy to establish diagnosis is not always required.

The above-mentioned international consensus statement also provided descriptions of other pathological conditions to differentiate their histopathological features in addition to UIP; i.e., acute interstitial pneumonia (AIP), diffuse alveolar damage (DAD), bronchiolitis obliterans organizing pneumonia (BOOP), non-specific interstitial pneumonia (NSIP), respiratory bronchiolitis-associated interstitial lung disease (RBILD), and desquamative interstitial pneumonia (DIP). In response to this statement on IPF (as of 2002), the Japanese Respiratory Society is setting forth their guidelines and the Study Group of the Ministry of Health, Labor and Welfare is preparing a fourth edition of its clinical diagnostic criteria.

### **Idiopathic Pulmonary Fibrosis as a Respiratory Disease in the Elderly**

Although idiopathic pulmonary fibrosis (IPF) is a generic term for inflammatory lung injury of unknown etiology, it actually shows a characteristic distribution of patients, especially in smokers of advanced age. The prevalence of IPF has long been considered to be about 3 per 100,000 population. However, a detailed epidemiological study carried out in the state of New Mexico in the U.S. revealed that the prevalence was 33.5 per 100,000 persons (20.3 per 100,000 men and 13.2 per 100,000 women).<sup>2)</sup> In addition, analysis of the distribution of the patients' age showed that the prevalence was 2.7 per 100,000 among those aged 35–44 years, whereas it was 127 per 100,000 among those aged 75 years or older, consistent with our daily clinical experience in Japan. Unfortunately, no epidemiological survey on IPF has not recently been performed in Japan (Fig. 1). IPF can thus be

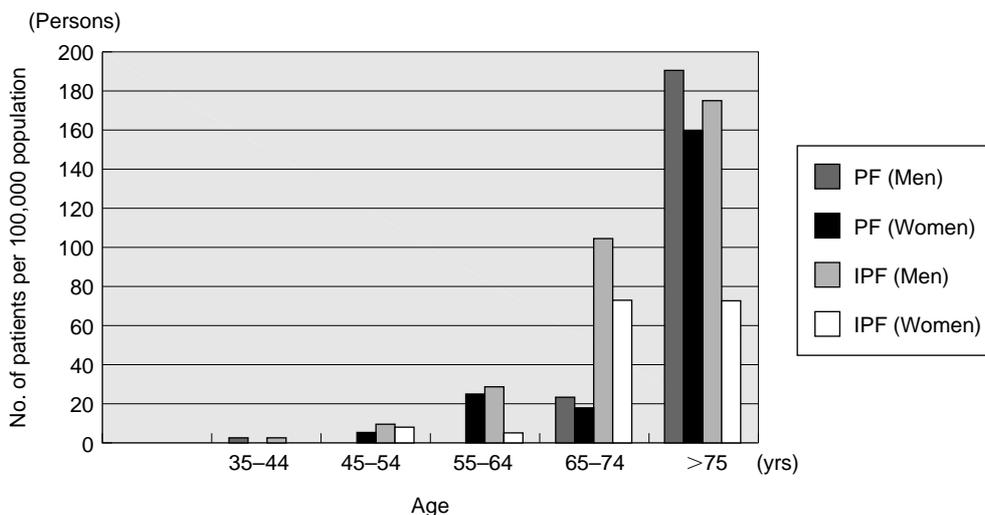


Fig. 1 Prevalence of pulmonary fibrosis (PF) and idiopathic pulmonary fibrosis (IPF) by age in Bernalillo, New Mexico, U.S.A.<sup>2)</sup> (Number of patients per 100,000 population between October 1, 1988, and September 30, 1993)

regarded as a respiratory disease that manifests late in life. Its severity is reflected in the poor average life expectancy of 3 to 5 years after diagnosis (or 28.2 months after the manifestation of clinical symptoms).<sup>1)</sup>

In addition, the possibility that IPF may be associated with familial aggregation has been pointed out. After familial aggregation of IPF was noticed in a chest X-ray survey of siblings among several IPF patients, a small-scale prospective study was performed at the Institute of Development, Aging and Cancer, Tohoku University. The study examined family members (usually siblings) of indexed patients, after having obtained their informed consent, and defined pulmonary fibrosis by CT evidence of fibrotic changes and relatively sensitive indices of pulmonary function [ $PaO_2$  (arterial oxygen partial pressure) < 80 Torr or %DL<sub>CO</sub> (diffusing lung capacity for carbon monoxide) < 75%]. The results showed aggregation of cases within second-degree relatives in 20 (37%) of the 54 families examined.<sup>3)</sup> Many of the affected members in these 20 families were in their 60s or 70s, and most male patients were heavy smokers. These results indicate that the lungs

of most IPF patients are not simply chronically inflamed, but are aged and injured by heavy smoking. Thus, prudent care and referral to a specialist are necessary in the clinical management of those patients.

### Clinical Characteristics and Treatment of Patients with IPF Who are Smokers of Advanced Age

#### 1. Dyspnea

IPF tends to show latent development. It is common for a periodic chest X-ray examination or CT to disclose pulmonary fibrosis before any difficulty in breathing is perceived. As expected from the predominance of smokers in IPF, we frequently see patients who show a mixture of destructive and fibrotic changes caused by smoking-induced chronic inflammation (usually emphysema in the upper lung field and fibrosis in the lower lung field) despite the absence of typical fibrosis and lung volume reduction on chest X-ray films.

Patients with IPF usually begin to complain of dry cough after a course of 2 to 3 years devoid of subjective symptoms. They then may

become aware of difficulty in breathing while climbing stairs, i.e., exertional dyspnea. Although those patients usually have a resting PaO<sub>2</sub> value above 70 Torr, SpO<sub>2</sub> (oxygen saturation) on pulse oximetry is often below 90% in those who have exertional tachypnea.

The severity of IPF is classified as grade III when PaO<sub>2</sub> under room air inhalation at rest is less than 70 Torr, and such cases are registered as intractable disease cases as specified by the Ministry of Health, Labor and Welfare.<sup>4)</sup> However, since exertional dyspnea is a problem in everyday life, revision of the conditions sufficient for registration is now under consideration to include SpO<sub>2</sub><90%. Although home oxygen therapy (HOT) is indicated for the patients in whom PaO<sub>2</sub> is less than 60 Torr, this therapy needs to be initiated when there is prominent hypoxemia on exertion.

Formerly, the clinical course of patients with IPF in the stable or chronic phase was observed without any treatment. However, it has become apparent that the glutathione (GSH) level in alveolar lavage fluid is decreased in IPF patients, and inhalation therapy with N-acetyl cysteine (NAC) (Mucofilin<sup>®</sup>) has recently been employed to compensate for this. Clinical studies of oral therapy with this agent have been carried out in Germany. The drug was originally indicated for chronic bronchitis, and it improves subjective symptoms in some IPF patients who are smokers. However, oral administration of Predonine<sup>®</sup> (equivalent to 0.5 mg/kg) is necessary for relief of symptoms in the patients who have increasing cough in the slowly progressive phase.

## 2. Complication of lung cancer in patients with IPF

Most IPF patients, particularly male patients, are smokers, and the incidence of concomitant lung cancer among these patients is high (15–30%) due to the promoting effect of the chronic inflammatory milieu.<sup>5)</sup> In fact, CT scans of patients who have been referred to specialists because of suspected lung cancer often disclose concomitant initial fibrous changes in

the lung. Thus, it is also necessary to examine smoker-patients for changes in tumor markers and sputum cytology while observing the clinical course of IPF. Recently, respiratory epithelial cell-derived serum makers such as the surfactant apoproteins (SP-D, SP-A) and mucin (KL-6) have become available for clinical use, facilitating observation of the clinical course of IPF. Serum carcinoembryonic antigen (CEA), a representative tumor marker, often reaches the upper limits of normal in IPF patients because of inflammation-induced destruction of the respiratory epithelium. If the serum CEA level increases further, careful evaluation of CT scans and a survey of gastrointestinal tumors are necessary.

If lung cancer is diagnosed, treatment is the next issue to be addressed. Even if the disease is in the early stage, results of lung function test and blood gas analysis may lead to the avoidance of radical pulmonary resection, and only enucleation of the tumor may be needed. Frequently, a second primary lung cancer (pulmonary double cancer) is also found. Radiation therapy is contraindicated in IPF patients. When choosing chemotherapeutic agents, those affecting fibrosis of the lung, i.e., CPT-11 (irinotecan), are avoided, and the patients are often observed during the course of illness on monotherapy with such as taxane.

## 3. Acute exacerbation

When the disease is in the slowly progressive phase, particularly in winter, the patients often exhibit increasingly extensive ground-glass opacities or severe consolidation in the lung field following viral infection, including usual common cold. Dyspnea becomes severer, inflammatory reaction is enhanced, and serum levels of respiratory epithelial cell-derived LDH, SP-D, SP-A, and KL-6 show steep increases. This condition is called acute exacerbation. It is speculated that the generation of NO in the lung under viral infection promotes further lung injury.

It is desirable for IPF patients to avoid over-

seas travel or use a face mask inside airplanes because it is well known that the air circulated inside planes is not clean, particularly on long flights. The author has experienced two cases of acute exacerbation of IPF after the patients had returned from a trip to the U.S. or Europe. Both patients died of acute exacerbations.

For the treatment of acute exacerbation, antibiotic medication by drip infusion should be initiated as soon as possible. Because steroid use would be prolonged and cause undesirable infection, it should be held in reserve until a lack of response to the antibiotic therapy is observed for two days. Steroid therapy usually begins with pulse methylprednisolone followed by additional Predonine<sup>®</sup> (basically 1 mg/kg). Since the condition of lung injury is underlying in acute exacerbation, prevention of pulmonary edema by diuretic therapy is of course required in the critical care stage.

In patients undergoing acute exacerbation, it is difficult to differentiate by chest X-ray examination between infectious disease, pulmonary edema, and acute interstitial pneumonia. Therefore, reduction of the steroidal dose should be attempted, with consideration given to good timing in terms of changes in the above-mentioned respiratory epithelial cell-derived serum markers while repeating CT scans at relatively short intervals. The steroidal dose should be reduced over several months. When the dose of Predonine<sup>®</sup> is reduced to less than 20–25 mg, particular caution is necessary because of possible recurrence of lung inflammation.

Even after the critical stage of acute exacerbation is controlled, the patient's pulmonary function and gas exchange deteriorate even more, and activities of daily living are further restricted. Progression of illness is also acceler-

ated. Although the decrease in pulmonary function is relatively slow in IPF patients, it is clear from analysis of long-term outcome that acute exacerbation and development of lung cancer determine the patient's prognosis.

## Conclusion

Idiopathic pulmonary fibrosis (IPF) is a chronic inflammation of the lung that is particularly common in smokers of advanced age. The clinical aspects of IPF described in the present communication, namely, the management of slowly progressive dyspnea; treatment of complicating lung cancer, which occurs at high frequency; and treatment of acute exacerbation, which directly affects prognosis, may provide a useful guide in the setting of general clinical practice.

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# Aspiration and Aspiration Pneumonia

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**Abstract:** It is not rare for aspiration to occur in association with a severe paroxysm of coughing in elderly people. In such cases, a depressed cough reflex may result in severe aspiration pneumonia. Aspiration becomes clinically evident when the patient chokes or has a fit of coughing during a meal. In contrast, a less obvious form of aspiration, which is almost asymptomatic, is called micro-aspiration. When food or drink, saliva containing oral microbial flora, or regurgitated gastric acid is aspirated into the airway, severe inflammation of the lower respiratory tract and lung parenchyma occurs. Since aspiration can cause pneumonia and serious airway damage, the prevention of aspiration is important, particularly in elderly people. Pathogenic microorganisms are more likely to colonize the oral cavity in patients with swallowing disorders. Thus, when patients with swallowing disorders are admitted to a hospital, they are at a higher risk of encountering nosocomial pathogens, i.e., multidrug-resistant bacteria. Therefore, protection against aspiration and prevention of lower respiratory tract infection by ensuring good oral hygiene may be the most practical and effective means for the prevention of pneumonia in the elderly.

**Key words:** Aspiration pneumonia; Hospital-acquired pneumonia; Depressed cough reflex; Anaerobic infections

## Introduction

Progressive aging of the society poses the problems of susceptibility of a significant section of the population to infections associated with age-related multiorgan dysfunction, and of dealing with the seriousness and refractoriness of the infections complicating various underlying diseases in this subject population.

Aspiration becomes clinically evident when the patient chokes or has a fit of coughing during a meal. In contrast, a less obvious form of aspiration, which may sometimes be associated with mild coughing but is more often largely asymptomatic, is called micro-aspiration. When food or drink, saliva containing oral flora, or regurgitated gastric acid is aspirated into the airway, severe inflammation of the lower respi-

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Table 1 Risk Factors for Nosocomial Respiratory Tract Infections<sup>3)</sup>

		Parenteral alimentation group (n = 26)*	Oral alimentation group (n = 54)	P-value
Gram-negative bacilli				
Rate of colonization of the upper respiratory tract (number of specimens with positive results/the number of specimens tested)		61% (106/175)	3.6% (4/111)	0.001
Number of episodes of respiratory infections		31 (average, 1.2)	1 (average, 0.02)	0.001
MRSA				
Rate of colonization of the upper respiratory tract (number of specimens with positive results/the number of specimens tested)		47% (83/175)	5.4% (6/111)	0.001
Number of episodes of respiratory infections		17 (average, 0.64)	3 (average, 0.06)	0.001
Total number of episodes of respiratory infections/month		1.5	0.2	0.001
Doses of antimicrobials (g/month)	Injectable penicillin	7.2	0.86	0.001
	Second-generation cephalosporins	8.9	0.44	0.001
	Third-generation cephalosporins	9.1	0.37	0.001
	Other $\beta$ -lactams	3.2	0.08	0.001
	Minomycin <sup>®</sup>	0.16	0.01	0.02
	Aminoglycosides	0.13	0.002	0.01
Hemoglobin (g/dl)		8.6	11.8	0.01
Serum total protein (g/dl)		5.9	6.5	0.02
Presence of decubitus ulcers		25 (96%)	5 (9%)	0.001

\* including 4 patients with tracheostomy.

Note: Preliminary testing revealed that the MRSA and Gram-negative bacilli colonization rates of the upper respiratory tract were higher in the parenteral alimentation group than in the oral alimentation group, and that the use of antimicrobials was more frequent in the former.

(This survey was conducted from February 1991 to September 1991 in a geriatric hospital)

ratory mucosa occurs, often complicated by pneumonia. Although aspiration by itself is one of the most important risk factors for pneumonia, the situation is obviously more serious when nosocomial multidrug-resistant pathogens, which cause hospital-acquired pneumonia, are contained in the aspirate.

Intensive effort to protect against aspiration and encourage maintenance of good oral hygiene in elderly patients could be expected to result in a reduction in the incidence of nosocomial pneumonia. How thoroughly can we take these preventive measures in the clinical setting in Japan? In this study, we attempt to discuss the clinical presentations of aspiration pneumonia and the measures adopted in Japan to prevent this condition, from the prevailing clinical setting.

## Lower Respiratory Tract Infection Caused by Pathogenic Bacteria Originating from the Upper Respiratory Tract

### 1. Decreased swallowing ability increases the risk of colonization of the upper respiratory tract by pathogenic bacteria

Cough is an important clinical manifestation of pneumonia. The cough reflex is, however, often compromised in elderly individuals. We previously examined whether colonization of the upper respiratory tract by pathogenic microorganisms is more frequently associated with the onset of lower respiratory tract infection in bedridden patients in geriatric hospitals.<sup>1-5)</sup>

The results indicated that the frequency of pharyngeal colonization by *Staphylococcus*

*aureus* strains, particularly methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative bacilli, was significantly higher in patients on parenteral alimentation than in those on oral alimentation. Furthermore, the incidence of lower respiratory tract infection caused by MRSA and Gram-negative bacilli was also higher in the parenteral alimentation group than in the oral alimentation group (Table 1). Both the frequency of MRSA colonization of the pharynx and the incidence of lower respiratory tract infection were about 10 times higher in the parenteral alimentation group than in the oral alimentation group.

These findings indicate that pathogenic bacteria are more liable to persist and grow in the oral cavity of patients with depressed swallowing function. It is also indicated that normal deglutition and salivary secretion may facilitate the smooth swallowing of saliva as well as food and drink, and act as self-cleansing mechanisms of the oral cavity.

## **2. Pharyngeal colonization by pathogenic bacteria following viral infection (common cold syndrome)**

In another study, we investigated the colonization of the pharynx by pathogenic organisms in healthy subjects, from children to the elderly. Healthy subjects were defined as people who had rarely consulted a physician, except for common cold, and in the case of adults and the elderly, also those who had no underlying disease that might predispose to infection, such as diabetes mellitus or chronic respiratory disease. The subjects were classified into two groups: those presenting with the common cold syndrome, including pharyngolaryngeal pain and running nose, within the week prior to commencement of the study (the acute respiratory tract inflammation group), and those without any symptoms of common cold during the corresponding period (the healthy group).

In the healthy group, the frequency of pharyngeal colonization by pathogenic bacteria was substantially higher in children and was

almost nil in adults and the elderly, except in those who frequently came in contact with children (mothers, school staff, etc.). On the other hand, the frequency of pharyngeal colonization by pathogenic organisms was about one and half to two times higher in children belonging to the acute upper respiratory tract inflammation group than in the children assigned to the healthy group. Pharyngeal colonization by pathogenic organisms, although at a low percentage, was also confirmed in adults and older adults assigned to the acute upper respiratory tract inflammation group.

These findings indicate that in healthy adults, systemic and local immune mechanisms might prevent colonization of the pharynx by pathogenic organisms with the help of the barrier established by the resident microbial flora on the surface of the pharyngeal membrane. However, when the defense of the membrane is weakened by viral infection, pathogenic organisms can easily establish themselves on the airway membrane and cause lower respiratory tract infection and pneumonia, especially in the immunocompromised elderly.<sup>6)</sup>

## **3. Destruction of the barrier of indigenous microbial flora on the pharyngolaryngeal mucosal epithelium by pathogenic organisms**

Indigenous microbial flora is believed to block adhesion of pathogenic organisms to the pharyngolaryngeal mucosal epithelium in healthy adults. Adhesion factors and receptors are known to be closely linked to the adhesion of bacteria to the host epithelium; the underlying molecular processes, however, remain to be elucidated in detail.

We previously clarified that the adhesion factors of *Haemophilus influenzae* and *Moraxella (Branhamella) catarrhalis* are sugar chains, and that several drugs effectively prevent these pathogenic bacteria from adhering to the mucosa of the respiratory tract. Easy adhesion of pathogenic bacteria to the pharyngeal epithelium may increase the risk of lower respira-

tory tract infection. Thus, proper gargling is useful in the prevention of adhesion of pathogenic bacteria to the upper respiratory tract. The aforementioned drugs can also be used to decrease the frequency of episodes of lower respiratory tract infections.<sup>7)</sup>

On the other hand, various types of non-pathogenic bacteria adhere to and grow on the surface membrane of the upper respiratory tract in healthy adults. The barrier formed by the non-pathogenic microbial flora inhibits the adhesion of pathogenic organisms to the surface membrane of the respiratory tract. These non-pathogenic bacteria strongly adhere to the membrane of the respiratory tract and their rate of proliferation is much higher than that of pathogenic bacteria.

Accordingly, destruction of the barrier formed by the resident microbial flora would be expected to increase the chances of pathogenic bacteria adhering to the airway membrane. Damage to the membrane of the respiratory tract by orotracheal and nasotracheal catheters, and decreased or increased oropharyngeal secretions related to advanced age or underlying disease, may directly or indirectly induce the adhesion of pathogenic bacteria to the surface membrane of the respiratory tract.

### **Mechanisms by which Aspiration Causes Severe Pneumonia**

Aspiration pneumonia is often a progressive or refractory disease. The following factors may be involved.

1. Aspirated saliva, gastric acid, and food debris injure the airway membrane and damage the mucociliary clearance system.
2. Microorganisms originating in the oral microbial flora can easily invade the lower respiratory tract and grow there.
3. Although aspiration induces infections by various types of pathogens, if the initial antibiotic treatment is inappropriate, multidrug-resistant bacteria, anaerobes, and fungi survive and exert pathogenicity.

4. Aspiration of regurgitated gastric acid, because of its strong acidity, frequently causes severe chemical pneumonitis.
5. Repeated aspiration, whether it is micro-aspiration, or a frank large-volume incident during a meal (macro-aspiration), causes inflammation that is often prolonged and refractory.

The lung segments involved greatly depend on the posture of the patient during the aspiration, and most often include the dorsal segments bilaterally. Extensive lobar pneumonia, pulmonary abscess, and pleural empyema may occur in severe cases. Airway obstruction by food debris or other materials in combination with aspiration pneumonia may manifest as atelectasis and obstructive pneumonitis, with a poor prognosis.

The following factors may influence the severity of aspiration pneumonia:

1. The number of episodes of aspiration. The more frequent the aspiration, the more severe the complications.
2. The degree of airway obstruction by the aspirated material and the amount of airway-injurious substances contained in the aspirate, such as gastric acid.
3. Aspiration of massive amounts of indigenous microbial flora alone, or of a mixture of pathogenic organisms, is associated with increased severity of complications.
4. Failure of initial therapy, including drainage procedures or the antibacterial chemotherapy, is associated with refractory complications.

### **Key Points in the Treatment of Aspiration Pneumonia**

The first step in the treatment of aspiration pneumonia is proper respiratory care and prevention of respiratory failure. Food debris and other materials that may cause airway obstruction should be removed through transbronchial suctioning or other appropriate methods at the earliest. After securing the airway, proper oxy-

genation (proper intervention, varying from nasotracheal intubation to mechanical ventilation, may be required, depending on the severity of the disease) should be ensured in patients with respiratory failure or hypoxia. In regard to antibiotic treatment, a broad-spectrum antimicrobial agent ( $\beta$ -lactam as the first choice) should first be administered intravenously.

The selection of antibiotics should be based on a consideration of the following points: 1) broad spectrum of activity (preferably covering both Gram-positive cocci and Gram-negative bacilli), 2) stability against  $\beta$ -lactamase, 3) awareness of the fact that more and more strains of bacteria are acquiring resistance that does not depend on the production of  $\beta$ -lactamases (e.g., alteration of penicillin-binding protein), 4) the extent of drug penetration into airway foci (confirmed by the sputum levels of the drug), and 5) the severity of adverse effects. In patients with severe airway damage caused by gastric acid or other injurious substances, however, the medication administered should also provide coverage for less virulent species within the hospital environment, including Gram-negative bacteria such as *Pseudomonas aeruginosa*, *Serratia*, *Citrobacter*, enterococci, *Staphylococcus aureus*, and *Staphylococcus epidermidis*.

Before the commencement of therapy with a  $\beta$ -lactam antibiotic in elderly patients, it is essential to check the renal and liver functions. In principle, the drug dose should be decreased to 1/2 to 1/3 in the elderly, while ensuring that therapeutic concentrations are achieved at the foci of damage.

The efficacy of the initial treatment should be determined on the 3rd day of treatment. If neither clinical nor radiographic improvement is noted, the medication should be modified based on a consideration of the following:

- 1) If no improvement in oxygenation is observed, it must be ascertained that the airway is patent; the necessity of thorough drainage should also be considered.
- 2) When the disease has advanced to the stage

of lung abscess or pleural empyema, the involvement of tissue-invasive bacteria, such as *Staphylococcus aureus* and *Streptococcus pneumoniae*, or anaerobes should be suspected. In the case of anaerobic infection, combined therapy with clindamycin is widely adopted.

It should be noted that if proper specimen collection, be it sputum or bronchial aspirate, has been ensured, and the causative bacteria have been appropriately identified, the drug of second choice will be self-evident even if the initial therapy has failed.

Most elderly patients with aspiration pneumonia have underlying cerebrovascular disease. Therefore, as described in the section on the mechanism of development of aspiration pneumonia, measures to prevent reinfection and superinfection should be adopted in concert with antimicrobial chemotherapy.

### Measures to Prevent Aspiration Pneumonia

It is known that a depressed deglutition reflex or cough reflex often predisposes elderly individuals to aspiration, including micro-aspiration. Sasaki *et al.* reported that damage of the cerebral cortex by cerebrovascular disease impairs the synthesis of substance P, which is distributed to the pharynx and airway through sensory nerves, associated with suppression of the deglutition and cough reflexes. They indicated that Symmetrel® (amantadine hydrochloride), an antiparkinsonian drug that stimulates the synthesis of substance P, as well as ACE inhibitors, which inhibit neutral endopeptidase known to be involved in the degradation of substance P, are helpful in reducing the frequency of aspiration.<sup>8,9)</sup>

We previously reported that measures for the prevention of nosocomial infections focusing on a thorough cleaning of the oral/nasal cavity with povidone iodine in patients dramatically decreased the incidence of hospital-acquired pneumonia caused by MRSA and

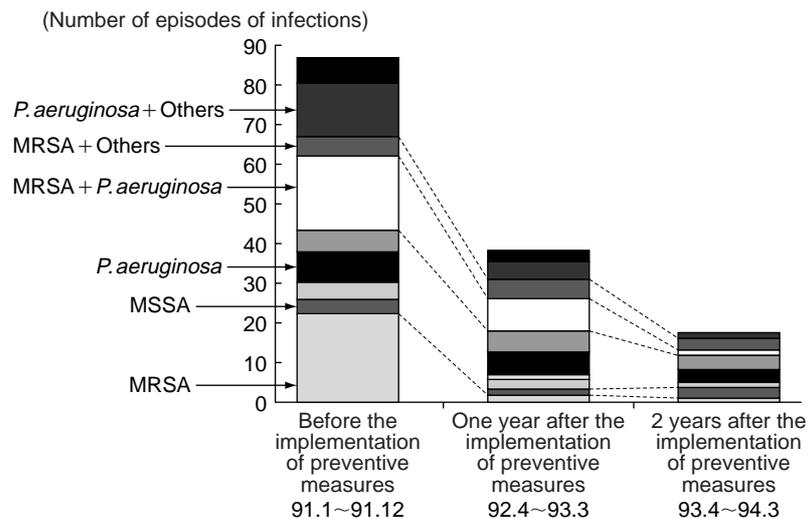


Fig. 1 The usefulness of measures adopted to prevent nosocomial pneumonia<sup>10)</sup>

Gram-negative rods in a geriatric hospital (Fig. 1).<sup>10)</sup> Sasaki and associates also emphasized the importance of good oral hygiene in the prevention of aspiration pneumonia in elderly patients.<sup>11)</sup>

The method of feeding may need to be modified in patients with normal appetite who have repeated episodes of aspiration. It is important to balance the patient's nutritional status and the measures needed to reduce the risks of aspiration and infection. Gastrostomy has been considered as an alternative for the prevention of aspiration in several institutions.

The use of intravenous hyperalimentation (IVH) immediately after aspiration may sometimes be unavoidable for the prevention of the onset of aspiration pneumonia, since the clinical course of aspiration pneumonia is more prolonged than that of other bacterial pneumonias. Thus, a patient care program that incorporates preventive measures against aspiration as an integral part of the management should be implemented in elderly patients in both institutional care and home care.

## Conclusion

Aspiration pneumonia occurs mainly in elderly

people, particularly in those with underlying disease, such as cerebrovascular disease. Although the case-fatality rate is very high, patient care embracing preventive measures against aspiration can reduce the risk of protracted and refractory disease.

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# Home Respiratory Care of the Elderly with Chronic Respiratory Failure

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**Abstract:** It is expected that the 21st century will see significant advances in home care. Home oxygen therapy and home mechanical ventilation are often administered to chronic respiratory failure patients, and are highly rated as the best functioning lines of home medical care in Japan. Coordination in a community medical care team is essential for the effective and smooth implementation of home respiratory care. It is important for the team members to hold a common concept of care. Respiratory diseases that are common in the elderly are different from those occurring in younger populations in various aspects, including clinical features and complications. It is not appropriate in the management of patients to set prolongation of life as the only goal of treatment. Instead, patient care and rehabilitation programs should aim at providing a better quality of life to patients in the course of illness. These programs should have a sound scientific ground. It is of great concern that treatment policies based solely on a consideration of patient care may lose a scientific perspective. To promote the development of home respiratory care as a new and reliable form of medical care, it is an urgent need to incorporate scientific elements into patient care.

**Key words:** Chronic respiratory failure; Home respiratory care; Patients with impairment; Coordination in the medical care team

## Introduction

Home treatment of respiratory diseases centering on oxygen therapy and mechanical ventilation is called home respiratory care. This form of treatment has developed rapidly over the past decade as a new type of medical care

for chronic respiratory failure. Home oxygen therapy is aimed at patients with chronic respiratory failure in the stable stage. This therapy has been covered by the National Health Insurance in Japan since 1985. The number of patients receiving home oxygen has increased steadily, and about 90% of patients are aged

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65 years or older. Home mechanical ventilation using a nasal mask began to be covered by the National Health Insurance in 1998, after the recent development of useful equipment. More recently, home oxygen therapy and mechanical ventilation have often been used in combination.

It is believed that a great part of conventional hospital care will most certainly shift to home medical care during the 21st century. Home oxygen therapy, in particular, has been rated highly as a well-functioning form of home care. However, this therapy is based on limited evidence, and its usefulness has not yet been fully established.

This paper describes the author's view to "home respiratory care" of elderly patients with chronic respiratory failure. For more detailed information, readers are referred to the author's recent work on home respiratory care that provides a summation of currently available information.<sup>1)</sup>

## Home Respiratory Care of the Elderly

### 1. Development of home care

In Western countries, hospital care focuses only on specialized care in the acute stage of diseases. In contrast, hospital care in Japan includes treatment of chronic diseases. As a result, it is not uncommon to encounter patients staying at hospitals for several months, and not uncommonly, the family of a patient is not ready for the patient's return even when the patient is ready to go home. In addition, prolonged hospital stay reduces the quality of life of a patient, and the health care cost of the elderly increased steeply, arousing criticism from both aspects. Reconsideration of the health care system therefore became necessary to enrich patient-centered home care. In this context, the Medical Service Law was revised in 1992, and then in 1994, the health insurance system was revised. With these advances, home care was developed as a new form of medical care.

### 2. Home care using high-tech equipment

The fundamental idea of home care is to provide the necessary care at a patient's home or living environment, with the aim of returning the patient to the social mainstream and to improve the quality of life (QOL) of the patient and his/her family (caregiver). However, since home care is more often targeted at the elderly, the basic concept of home care becomes more complicated.

On the one hand, many researchers consider home respiratory care of the elderly as a form of terminal care, while on the other, there is a new view that it should be regarded as a part of rehabilitation using high-tech equipment, such as oxygen therapy and mechanical ventilation. For some, the goal falls somewhere in between these two ends. In Western countries, home oxygen therapy, as a fundamental rule, is applied as a respiratory rehabilitation procedure.<sup>2)</sup> In contrast, in Japan, home oxygen therapy is often used as a form of terminal care. The position of home mechanical ventilation is even more dubious.

In general, home care of the elderly is implemented as a combination of medical and nursing care, and as assistance to the patient. Both home oxygen therapy and home mechanical ventilation involve medical and nursing care, and provision of assistance to the patient, even though the emphasis is on medical care, in view of the use of high-tech equipment.

Respiratory diseases in the elderly are markedly different from those in younger populations in various ways, including in the clinical features and complications. It is not appropriate in the management of patients to set prolongation of life as the only goal of treatment. Instead, patient care and rehabilitation programs should aim at providing a better quality of life to the patient in the course of illness. These programs should have a sound scientific basis. It is of great concern that treatment policies developed focusing only on patient care may lose scientific perspective.

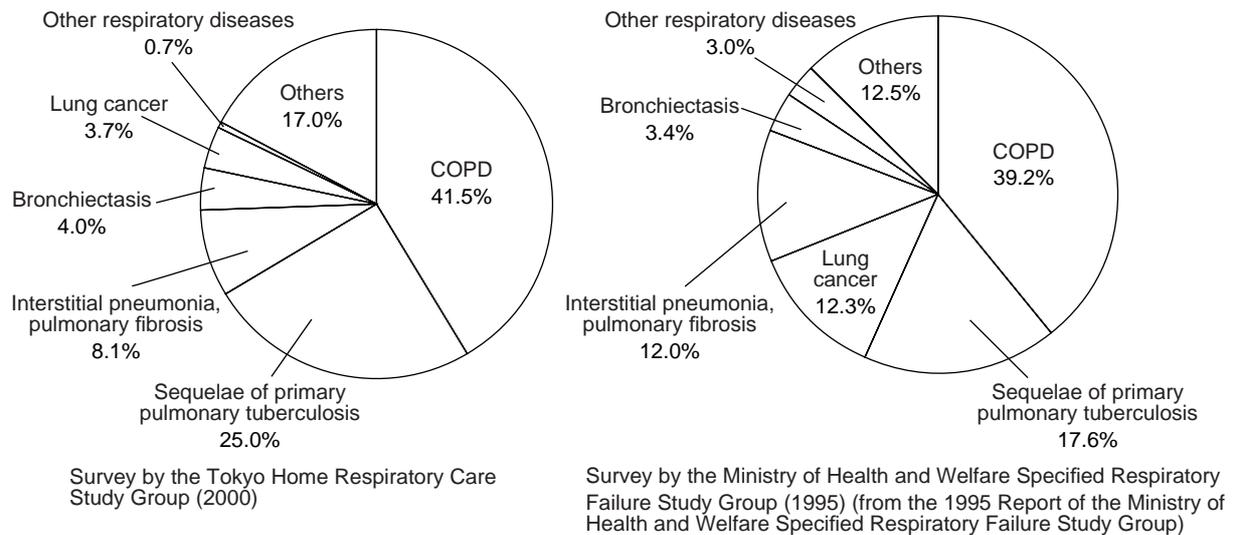


Fig. 1 Underlying diseases in patients on home oxygen therapy

## Chronic Respiratory Failure as an Internal Impairment

### 1. Annual changes in the incidence of chronic obstructive pulmonary disease

National statistics on the number of patients with underlying diseases potentially complicated by respiratory failure had been obtained until 1995, because regular annual surveys were conducted by the Ministry of Health and Welfare Specified Respiratory Failure Study Group. Thereafter, the Tokyo Home Respiratory Care Study Group has been studying the status of home oxygen therapy and home mechanical ventilation in Tokyo, using a questionnaire survey. Until 1995, the number of patients in Tokyo accounted for about 1/10 of all the patients nationwide in Japan; however, the pattern of the underlying diseases were similar in Tokyo and elsewhere in the nation. Figure 1 shows the results of the survey conducted in 2000 by the Tokyo Home Respiratory Care Study Group. In Japan, about 90,000 individuals received home oxygen therapy, and about 40% of these patients had chronic respiratory failure due to an advanced stage of chronic obstructive pulmonary disease (COPD).

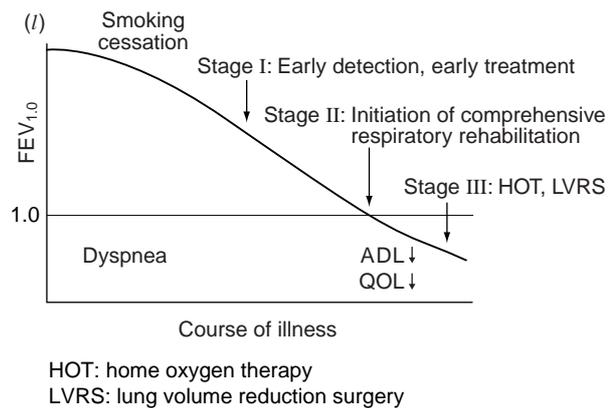


Fig. 2 Decrease in forced expiratory volume in one second ( $FEV_{1.0}$ ) in the course of COPD and the corresponding treatment<sup>1)</sup>

The severity of COPD is graded by pulmonary function testing as shown in recent guideline, global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (GOLD) (<http://www.goldcopd.com>). Drug therapy is administered based on these test data. Among the pulmonary function test items, forced expiratory volume in the first second ( $FEV_{1.0}$ ) is the most useful for therapeutic decisions. The possible course of illness from the onset to the terminal stage according to GOLD is shown in Fig. 2.

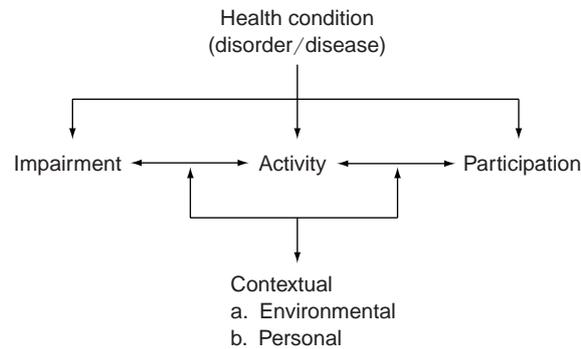


Fig. 3 WHO International Classification of Functioning, Disability and Health<sup>1)</sup> (1999)

Home care of COPD patients consists of early detection and early treatment (stage I), comprehensive respiratory rehabilitation (stage II), and home oxygen therapy, home mechanical ventilation or lung volume reduction surgery (LVRS) (stage III). Exertional dyspnea progresses rapidly as the FEV<sub>1.0</sub> decreases below 1L. In parallel, the activities of daily living (ADL) are lowered, and the QOL of the patient and his/her family deteriorates markedly. COPD worsens in severity year after year, and characteristically, the QOL also becomes progressively worse. The QOL is reportedly inversely correlated with the number of repeated admissions of a patient to the hospital.<sup>1)</sup> It is uncertain that various medications currently available cease or change the outcome. It is important to note that patients with COPD have an internal impairment. Usually problems characteristic to the elderly are intertwined with the impairment in these patients.

## 2. New concept of the disabled

In 1980, WHO published the International Classification of Impairments, Disabilities, and Handicaps (ICIDH-I). Over the 20 years since then, a new direction to construction of a new life with disability, rather than regarding the disability as negative, has been developed. Figure 3 shows the recent WHO concept on the International Classification of Functioning, Disability and Health (ICIDH-II: <http://www.who.int/icidh/brochure/content.htm>). The basic idea is that persons with disabilities resulting from chronic illness should be encouraged to participate actively in the society and to partake in higher levels of activity.

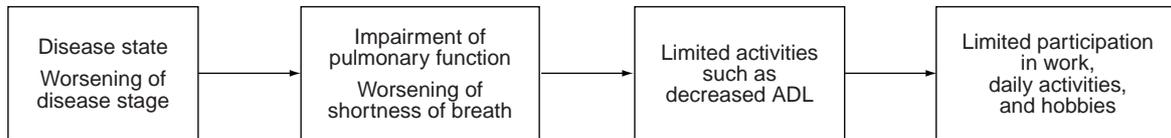
who.int/icidh/brochure/content.htm). The basic idea is that persons with disabilities resulting from chronic illness should be encouraged to participate actively in the society and to partake in higher levels of activity.

## 3. COPD patients as disabled persons

The time-course of the decrease in ADL after the onset of COPD and the corresponding new views on the management of these patients can be reconstructed as shown in Fig. 4. Formerly, the onset of COPD caused a gradual decrease in ADL, associated with marked limitations in the ability to participate in any occupation, daily activities, and hobby activities. In contrast, in accordance with the new concept, the implementation of home oxygen therapy, home mechanical ventilation, home respiratory rehabilitation, and appropriate drug therapy, the patient's life can be reconstructed so as to achieve the highest possible quality of life.

Table 1 shows the therapeutic and prophylactic aspects of home care in patients with COPD who are regarded as disabled persons. Impairment occurs according to the severity of the disease, leading to limitations in the ability of the patient to participate in any occupation and in the activities of the patient. To cope with this, both therapeutic and prophylactic measures are necessary.

## Conventional concept



## New concept

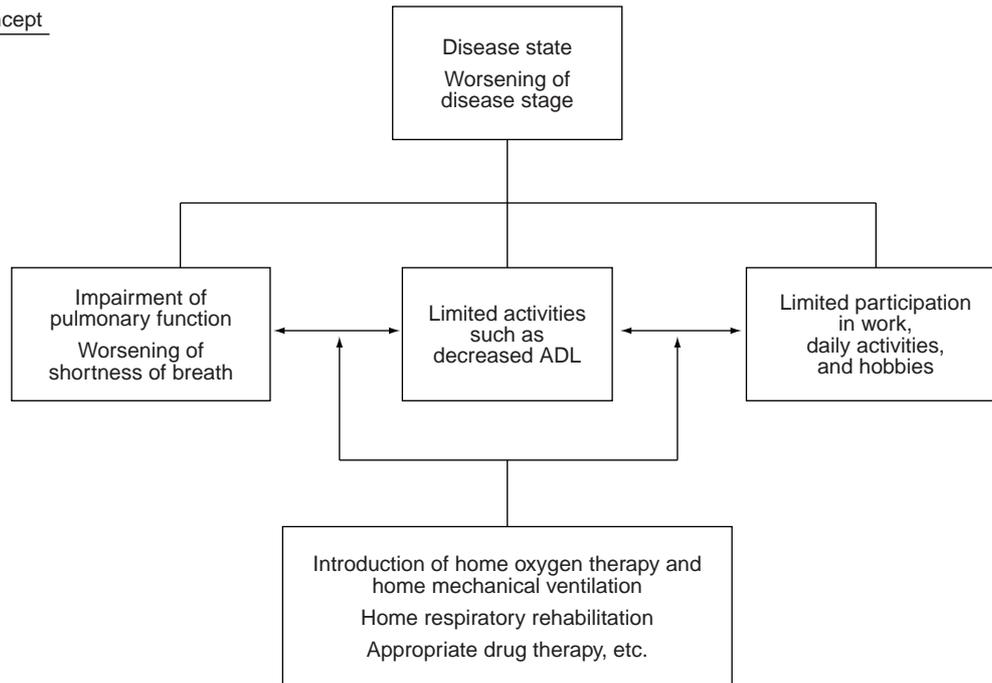
Fig. 4 Problems arising from the development of COPD<sup>1)</sup>

Table 1 Treatment and Prophylaxis in Home Care of Chronic Respiratory Diseases

Changing process	Measures	
	Treatment	Prophylaxis
Disease state	Medical treatment, scientifically based care Drug therapy	Health campaign Nutrition improvement Vaccination
↓		
Development of impairment	Medical treatment, scientifically based care Drug therapy	Prevention of limitations on activities
↓		
Limited activities	Home oxygen therapy, home mechanical ventilation Visiting care, involvement of helpers Respiratory rehabilitation	Prophylactic rehabilitation Prevention of limitations on participation in society
↓		
Limited participation	Improvement of residential environment Enlightenment of the public about acceptance of patients Elimination of discriminating people having illness	Change to better living environment Consideration to avoid disadvantages in employment and participation in society Ensuring easily accessible services

Table 2 Complications and Problems Occurring in Home Respiratory Care of Severe COPD

- 
- Poor efficacy of drug therapy and oxygen therapy, Adverse effects of drug therapy
  - Symptoms of severe dementia
  - Marked depressive symptoms
  - Overt misswallowing
  - Sequelae of cerebrovascular disorder
  - Insufficient response to treatment of physical pain in cases of osteoporosis or arthritis
  - Pressure sore
  - Exhausted family (caregiver)
- 

#### 4. How home care of elderly patients with severe COPD should be

Various complications and problems may occur during the course of home respiratory care of the elderly. Table 2 shows the possible complications and problems. To achieve success in providing prolonged home care of a patient with a high QOL, some important measures need to be taken in parallel with respiratory care. For efficient achievement of this purpose, the involvement of a medical care team would be most desirable.

### Desirable Home Care of the Elderly

There are basic rules to implement home care of elderly persons smoothly and effectively. Major rules will be described below.

#### 1. Holistic and comprehensive medical care should be provided

Elderly patients commonly have comorbidities, which often follow a chronic course with minimal chance of complete cure. Acute exacerbations of illness during the clinical course would result in a stepwise decrease in the ADL. For medical care of the elderly, information about the disease as collected in younger adult patients is not sufficient, and a wide range of information, extending from the changes associated with aging to the status of diseases of old age and health/well-being, must be sought.

Medical care in the elderly should be holistic and comprehensive. Focusing only on the disease is to treat the disease, but not the patient, particularly when the patient is an elderly. Such act is far from providing proper medical care.

COPD is a progressive disease, with reversibility of airway obstruction being lowered with increasing severity of the disease. In this process, acute exacerbation may occur due to respiratory infection or other events. When drug therapy or home oxygen therapy is administered, the presence/absence of dementia and the role of the family (caregiver) that the patient is living with are extremely important.

#### 2. Doctors should take the central role in coordination among health care, medical care, and welfare services

The important prerequisite in medical care of the elderly is coordination of health care, medical care, and welfare services. To maintain and prevent a decrease in the ADL as effectively as possible, holistic and comprehensive care of the patient involving medical care and welfare services is required, including early detection, early treatment, rehabilitation, and nursing care. Comprehensive respiratory rehabilitation is consistent with this concept.<sup>3)</sup>

United Nations (UN) designated the year 1999 as the International Year of Older Persons, and promoted the Active Aging Initiative to facilitate active aging, devoid of diseases, and with only slight impairment, if any (Active aging; *JAMA* 1999; 281: 1262). In this process, five goals, i.e., “independence, participation, care, self-actualization, and dignity” are laid down. Medical care is closely involved in attaining each of these five goals. Physicians should take the central role in maintaining orderly coordination of health care, medical care, and welfare work.

#### 3. Characteristics of the elderly should be understood

In providing medical care for the elderly, it is necessary to understand the characteristics

of the elderly. A barrier to success in the prolonged management of elderly patients is loneliness. The feeling of loneliness interferes significantly with successful treatment. About 10% of elderly patients are pointed out to be in a depressive state requiring treatment.<sup>4)</sup> Such loneliness often becomes an even greater issue in elderly patients with some disability, e.g., disability that causes them to be housebound, or dementia. It should also be noted that many elderly subjects are in a malnutritional state, which also poses a problem in therapeutic management.<sup>4)</sup>

Loneliness often makes a patient a complainer. A tendency towards a depressive state is said to be seen in nearly half the patients with chronic respiratory failure. It is therefore important to collect detailed information about the patients' complaints. Only prescribing drug therapy for psychosomatic disorder or depression is not a proper way to manage these patients.

#### **4. Informed consent should be obtained in a strict manner**

Clinical signs and symptoms in the elderly show some characteristic features. Elderly patients may show disproportionate worry about a certain symptom or sign, or regard a trifling disease as a serious disease because of anxiety about impending death. On the other hand, some elderly patients may feel no anxiety about death, but accept the disease as destiny and show a negative attitude toward medical care. These patients are reluctant to receive treatment, saying that they are too old, even if the disease was treatable and not serious. Thus, the thoughts of the patient and the medical care provider often do not go hand in hand. In general, it is very important to obtain consent from these patients after providing full information about the disease and its signs and symptoms. However, there are wide variations in thinking, disease states, and the content of complaints among elderly patients, and it is difficult to know the degree of the patients'

understanding during short interviews. Providing the patient with information is often difficult when the patient has dementia. Elderly patients with diminished concentration may perplex a medical care provider at a later day, and complain that they have not been told enough about a disease.

Although medical services are a type of commodity in a sense, many patients do not have sufficient information about the services given in Japan, and this has aroused criticism. Several problems remain to be resolved concerning informed consent in the medical care system for the elderly, including handling of terminal care and patients with dementia.

A large volume of information thus needs to be handled while dealing with COPD patients. Before proceeding with the management, all members of the team should have a full knowledge of the basic concept of the care that is to be provided.

#### **5. "Self-contained" medical care should be criticized**

In most patients with chronic respiratory failure, exertional dyspnea is the major clinical symptom. In the terminal stage of the disease, the patient is usually housebound due to dyspnea and decreased ADL, and eventually becomes bedridden. It is necessary to develop a program to support the general care and home medical care of the patient, bearing in mind the QOL. On the one hand is the large- hospital-oriented attitude of the patients, and on the other, there is the need for building a new medical care team to handle individual patients in the community, which is still largely under development.

"Self-contained" medical care, by which a physician deals with a particular patient continuously throughout the course of illness, is commonly encountered. However, this should be replaced in the future by team medical care in the community, to provide high-quality care and present various care options to the patient. Introduction of the long-term care insurance system in this country has diversified the sys-

tem to support medical care in the community, and resulted in an increase in related occupations. Daily care of the patient should be directly linked with professional medical care, but this is not necessarily the state of things seen at present. It is wrong to administer home oxygen care in the package of “self-contained” medical care, regarding it as medical treatment of the patient in the terminal stage. It should be provided under a system of team care, while maintaining efficient highly specialized medical care, without lowering the quality of life.

#### **6. Avoidance of mishaps in home care**

In home care using high-tech equipment, there is the risk of ineffective care and mishaps if the patient and family are not well educated and instructed. Fire accidents and burns related to home oxygen therapy are prominent examples; they are seen sporadically nationwide.<sup>1)</sup> In cases of such mishaps in home care, the patient/family, equipment provider, and/or medical facility may be responsible. In particular, the propriety of instructions and supervision of the medical facility that obtains the supervising charge may be questioned. Attention to this matter should be addressed.

#### **Conclusion**

It is expected that home care will play a central role in medical care of the elderly in the 21st century. Highly specialized medical care in university hospitals and core hospitals has been developed scientifically according to the principle of evidence-based medicine. For the steady development of home care as a new efficient form of medical care, it is an urgent need to incorporate scientific elements into home care. From this viewpoint, the role of physicians would seem to be critical.

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# Visual Disorders in Middle-Age and Elderly Patients with Diabetic Retinopathy

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**Abstract:** The risk of combined diabetic retinopathy is relatively high in elderly diabetic patients. The primary reason for this is that many elderly diabetic patients suffer from physical and mental ailments and often take poor control of their blood sugar, especially in consideration of their social background. Additionally, long-term elderly diabetic patients frequently have an increased incidence of diabetic retinopathy. Generally, the activity level of retinopathy in elderly diabetic patients is low. On the other hand, maintenance of the visual function by ophthalmologic treatment is more difficult in elderly patients than in those who are younger. Therefore, given these characteristics, elderly diabetic patients require a greater degree of ophthalmologic management.

**Key words:** Diabetic retinopathy; Visual disorder; Elderly patients; Vitreous surgery

## Introduction

Visual impairments in the elderly are due to physiological aging phenomena and diseases to which the elderly are susceptible. Among such diseases are senile cataracts and age-related macular degeneration, and diabetic retinopathy is cited along with glaucoma as a disease to which middle-age and elderly patients are susceptible.

A fact-finding study on diabetics conducted by the Japanese Ministry of Health & Welfare in 1997 found the diabetic population of Japan to number around 6.9 million, or 13.7 million if

a “reserve population” is included. The breakdown of this group by age shows that about 5% are in their 40s, about 10% are in their 50s, and about 14% are in their 60s, indicating that the percentage increases with age. The males in their 60s account for about 17%, the highest percentage among the entire patient population. This figure means that about half of all diabetics are elderly.

Diabetic retinopathy is one of the complications of chronic diabetes mellitus. Thanks to recent advances in medical management and treatment techniques, the mean life expectancy

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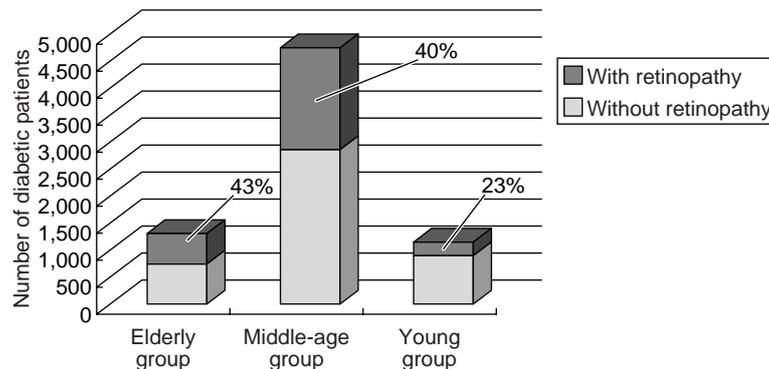


Fig. 1 Prevalence of diabetic retinopathy in three age groups

of diabetics has been increasing. However, with the extension of the mean life expectancy, an increasing number of elderly patients have developed diabetic retinopathy. It is therefore essential that we study the characteristics of diabetic retinopathy in elderly patients and the care that is required in its management.

### Blood Sugar Control and Duration of Morbidity in Diabetics

Blood sugar control and the duration of the disease are very much involved in the onset and progress of diabetic retinopathy.<sup>1)</sup> In other words, the poorer the control of the blood sugar level and the longer the duration of diabetes, the more likely it is that the patient will develop diabetic retinopathy.

The nine-year Diabetes Control and Complication Trial conducted in the United States clearly showed that strict control of blood sugar significantly restrains the onset and progress of diabetic retinopathy.<sup>2)</sup>

It is reported that fasting blood glucose is usually below 140 mg/dl in elderly diabetics,<sup>3)</sup> but their blood sugar control is not necessarily easy. This results from diverse physical and mental ailments including heart disease and complications of other diseases. In addition, the level of their daily activities and cognitive abilities are lowered, they have tendencies

toward depression, and suffer the risk of hypoglycemia, all of which contribute to somewhat lenient management of their blood sugar control. There are concerns that poor blood sugar control may help develop diabetic retinopathy.

Among elderly diabetic patients, there are naturally those whose duration of morbidity is extended because of the onset of the disease at a young age. At the other end of the spectrum, there are those who are diagnosed as diabetics for the first time after they have reached old age because of lowered glucose tolerance caused by aging. The fact that the onset and progress of diabetic retinopathy are affected by the period of morbidity suggests that the number of elderly patients with diabetic retinopathy is largely dependent on their age at the onset of diabetes mellitus.

When diabetic patients were initially seen at the author's clinic, they were classified into three groups, those younger than 40, those aged between 40 and 65, and those older than 65. The percentage of diabetic retinopathy was 23% for the young group, 40% for the middle-age group, and 43% for the elderly group<sup>4)</sup> (Fig. 1). The older the patient, the greater the tendency for developing diabetic retinopathy.

Since the period of morbidity for elderly diabetic patients is naturally longer than others, the subjects were matched by duration of the disease. In those whose period of morbidity

was between 6 and 15 years, diabetic retinopathy was significantly lower in the younger group. Among those whose period of morbidity ranged between 16 and 25 years, there was no significant difference between the age categories. In other words, the prevalence of diabetic retinopathy was higher in the older group when all groups were compared, but the influence of the length of morbidity was the apparent cause. When the subjects were matched by duration of morbidity, there were no apparent age-related differences in the prevalence of diabetic retinopathy.

### Characteristics of Diabetic Retinopathy in the Elderly

Diabetic retinopathy in elderly diabetic patients should be examined by changes attributable to aging in addition to the effects of diabetic microangiopathy. Age-related changes in the choroid and vitreous body are considered to affect the clinical model of diabetic retinopathy.

Elderly patients develop so-called "senile tigroid fundus" in which the retinal reflex is limited, the hue is dark, and the great choroidal vessels are visible. The nerve fiber and ganglion cell layers of the retina become thin, and the number of ganglion cells decreases with aging.<sup>5)</sup> Surprisingly, age-related changes in the retina itself are usually minimal and do not affect vision.

Arteriosclerotic changes in the retinal vessels become evident with aging. These changes become even more pronounced if hypertension or diabetes is present. Arteriosclerosis, in turn, promotes the onset and progress of diabetic retinopathy.

Just as there is a blood-brain barrier in the brain, there is a blood-ocular barrier in the eye to prevent an unchecked influx of substances from the blood and to maintain physiological homeostasis. The blood-ocular barrier consists of the blood-aqueous barrier and the blood-retina barrier. Both retinal pigment epithelium

and retinal vascular endothelium play important roles as components of the blood-retina barrier. With aging, the hexagonal cell structure in the retinal pigment epithelium disassembled, and the phagocytic capacity of the outer segments of the photoreceptor cells is lost.<sup>6)</sup> Bruch's membrane, between the retinal pigment epithelium and the choroid, becomes thickened with aging.<sup>7)</sup>

These changes appear to be involved with the increased permeability of the blood-retina barrier caused by aging. In vitreous fluorophotometry, the increased leakage of fluorescein from retinal vessels to the vitreous body is actually observed with advances in age.<sup>8)</sup> Accelerated permeability of the blood-retina barrier possibly affects the morbidity of diabetic retinopathy, particularly that of macular edema, which often accompanies diabetic retinopathy.

Age-related changes in the vitreous body include liquefaction of the gelatinized vitreous body and subsequent posterior vitreous detachment. In patients in their 40s, the incidence of posterior vitreous detachment is reported to be 8%. It is 22% for those in their 50s, 43% for those in their 60s, 71% for those in their 70s, and 85% for those in their 80s.<sup>9)</sup> Retinal traction by posterior vitreous detachment is said to affect the progress of diabetic retinopathy in a variety of ways.

If there is a strong adhesion between the retina and the vitreous body, the proliferative membrane of fibrous blood vessels that develops along the posterior vitreous membrane breaks to cause vitreous hemorrhage and tractional retinal detachment due to its contraction. Conversely, there are many cases where the eye that is free of adhesion between the retina and the vitreous body, having almost complete posterior vitreous detachment, works to control and ameliorate diabetic retinopathy. In other words, as the patient gets older, the incidence of posterior vitreous detachment increases and tends to restrain the progress of diabetic retinopathy.

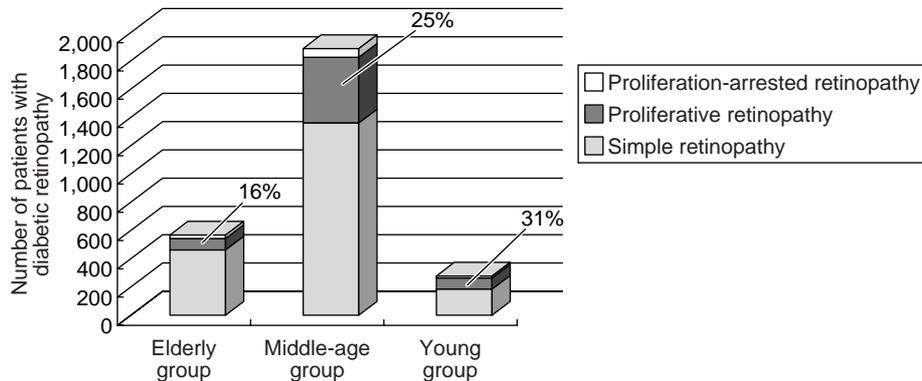


Fig. 2 Prevalence of diabetic retinopathy in three age groups broken down by stages of morbidity

### Incidence of Elderly Diabetic Retinopathy Classified by Morbid Stages

For the purposes of comparison, patients with diabetic retinopathy were classified by their stage of morbidity into simple retinopathy, proliferative retinopathy, and quiescent proliferation retinopathy. The incidence of proliferative retinopathy with more severe visual impairment was 16% in the elderly group, 25% in the middle-age group, and 31% in the young group, indicating that the incidence decreases with advanced age<sup>4)</sup>(Fig. 2).

Although patients with an extended history of diabetes are considered to be more likely to develop diabetic retinopathy, the ratio of proliferative retinopathy was lower in the elderly group when compared with the younger group by duration of morbidity of either 6 to 15 years or 16 to 25 years. The ratio of those who developed diabetic retinopathy or whose diabetic retinopathy progressed during the observation period was significantly lower in the younger group when all groups were studied. When the periods of morbidity were matched, however, the ratio was significantly lower in the elderly group. The ratio of those not suffering from diabetic retinopathy or whose simple retinopathy progressed to proliferative retinopathy during the observation period was significantly

lower in the elderly group: 5% in the elderly group, 14% in the middle-age group, and 23% in the younger group.

The above results suggest that the risk of elderly diabetic patients developing proliferative retinopathy is less than for younger patients. In particular, those patients whose glucose tolerance lessened with aging and whose onset of diabetes mellitus occurred in old age had fewer risks of onset and progress of diabetic retinopathy. No elderly patients developed proliferative retinopathy during the observation period.

Diabetic retinopathy in the elderly is characterized by an extended period of morbidity as a background factor and a higher prevalence, both of which influence onset and progress. In contrast, however, the incidence and ratio of developing proliferative retinopathy are low.

### Ophthalmic Treatment of Diabetic Retinopathy in Elderly Patients

Currently, no medicine is considered specific and effective for treating diabetic retinopathy. The presently available treatment consists primarily of photocoagulation of the retina and vitreous surgery.

The efficacy of retinal photocoagulation for diabetic retinopathy has been established in many reports. Its main purpose is to prevent or to arrest the progress of proliferative retino-

Table 1 Results of Vitreous Surgery for Proliferative Retinopathy

Although no difference was observed in the number of patients aged 65 or over for whom vitreous surgery improved vision by more than two steps, significantly few had post-operative vision of 0.5 or higher.

Age	Vision improved by more than 2 steps		Post-operative vision is more than 0.5	
	Yes	No	Yes	No
Younger than 65	95	22	47	70
Older than 65	14	2	2	14

 $\chi^2$  test $p = 0.539$  $p = 0.031$ 

pathy.<sup>10)</sup> A review of effective control of the formation of new vessels by retinal photocoagulation in diabetic retinopathy reveals that the treatment is more than 80% successful if conducted at appropriate times.<sup>11)</sup>

A review of the effectiveness of retinal photocoagulation in elderly patients according to age did not reveal any difference regarding angiogenesis control. This is because the incidence and ratio of progress to diabetic retinopathy in the elderly are low even though many patients have accelerated vascular permeability that tends to resist retinal photocoagulation. The incidence of macular edema, a complication of retinal photocoagulation, is expected to be high because vascular permeability is promoted in many elderly patients.

Vitreous surgery is performed when a patient with proliferative diabetic retinopathy develops visual impairment caused by vitreous hemorrhage or traction retinal detachment.<sup>12)</sup> Because of advances in surgical instruments and techniques in recent years, the performance of vitreous surgery has improved dramatically, contributing to increases in the prevention of blindness by diabetic retinopathy. The success of vitreous surgery for diabetic retinopathy, particularly regarding postoperative vision, is much higher among elderly patients than among younger patients.

Diabetic retinopathy in the elderly is less active than in the younger group and, since proliferative lesions are comparatively mild and the posterior vitreous body is already

detached, the surgery itself is not so difficult. However, since only about half of the patients recover vision of more than 0.1 after the operation and significantly fewer recover vision above 0.5, the results cannot be characterized as excellent when compared to younger patients<sup>13)</sup>(Table 1).

This means that while diabetic retinopathy progresses rapidly and its activity level is higher among younger patients, many of these patients retain their macular functions comparatively well, so that once the active lesion is removed by vitreous surgery, the prognosis regarding vision is comparatively good. Conversely, in elderly diabetic patients the macular functions are likely to be poor due to degenerative changes in the retina caused by extended hemorrhage and edema. Therefore, the post-operative quality of vision will be poorer for elderly diabetics although the success ratio of surgery *per se* may be the same.

The problems faced by elderly diabetics include psychosomatic ones, limitations in blood sugar control because of social background, and higher risk for complications of diabetic retinopathy due to the extended period of morbidity. While the activity level of diabetic retinopathy is generally low among elderly patients, maintaining their visual functions is characteristically difficult, warranting further studies of innovative ophthalmic treatments and indications for surgery by considering these characteristics.

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# DRG/PPS-Conforming Clinical Laboratory Test Guideline

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**Key words:** DRG/PPS; Laboratory tests; Guideline

Recently, the environment of medical economics has become harder. In the field of medical insurance systems, the implementation of comprehensive medicare has spread, resulting in National Health Insurance (NHI) points for clinical laboratory tests being calculated on a lump-sum payment basis.

The DRG-PPS (diagnosis related group/prospective payment system) is one of the measures of comprehensive medicare, and its probable introduction this fiscal year to inpatients of advanced treatment hospitals, such as university hospitals is indicated. Should this system be determined to apply to outpatients in the future is expected to have a considerable impact on what clinical laboratory tests should be performed, and physicians will be obliged to adequately deal with it.

In dealing with the DRG/PPS, the first thing to be done is to secure high-quality clinical laboratory tests for patients. For this purpose, it is necessary to understand and practice the proper uses of tests, and for this, it is critical to prepare a guideline for the proper uses of tests conforming to the DRG/PPS. Presently, the Japanese Society of Laboratory Medicine (JSLM) is preparing the guideline for the effi-

cient uses of tests according to the health system that meet such needs of the age. In this article, the progress of the preparation is explained for physicians.

## **Preparation of the “DRG/PPS-Conforming Clinical Laboratory Test Guideline”**

The JSLM has set up the “Subcommittee on the Uses of Clinical Laboratory Tests in Daily Primary Medical Care” in 1998 to become active in establishing the proper tests conforming to the comprehensive medicine including the DRG/PPS. The subcommittee has been subsidized by the Ministry of Health, Labour and Welfare (MHLW) from 1998, for its activities as the “Research Study Project on the Flat Payment System for Inpatient Acute Treatment” covered by the Ministry of Health and Welfare (MHW) expenditure for entrusted basic studies on the social insurance system.

The subcommittee has proceeded the study for about a year, with the objective of preparing “clinical laboratory test guideline that conforms with DRG/PPS.” In April 1999, the primary draft guideline was prepared and issued

Table 1 Disease groups selected for the guideline

1. Pneumonia	18. Multiple myeloma
2. Chronic hepatitis or liver cirrhosis	19. Ovarian cancer
3. Pancreatic diseases	20. Cerebral hemorrhage
4. Gastric or duodenal ulcer	21. Cerebral infarction
5. Rheumatoid arthritis or other kinds of inflammatory multiple arthrosis	22. Acute myocardial infarction
6. Collagen disease or related diseases	23. Cardiac incompetence
7. Diabetes	24. Essential hypertension
8. Lymphoma	25. Allergic rhinitis
9. Hemorrhagic disorders	26. Pulmonary tuberculosis
10. Asthma	27. Malignant neoplasm of the stomach
11. Primary malignant neoplasm of the bronchus, bronchial tube or lung	28. Chronic obstructive pulmonary disorders
12. Cholelithiasis	29. Urinary tract infection
13. Ulcerative colitis	30. Hyperlipemia
14. Malignant neoplasm of the thyroid gland	31. Carcinoma of the colon and rectum
15. Primary nephrotic syndrome	32. Infectious diseases of the digestive tract
16. Chronic renal failure	33. Anemia
17. Acute or chronic leukemia	34. Arrhythmia
	35. Abnormal thyroid function
	36. Albuminuria or hematuria

1–9: Disease groups included in the primary draft 10–23: Disease groups added in the secondary draft  
24–36: Disease groups and medical conditions added in the tertiary draft

as follows.

## Content of the Guideline

### 1. Disease groups

Disease groups selected in the primary draft schedule are as listed in Table 1 as 1–9. They were selected, with the intention of assigning typical diseases first of all, out of the classification of diagnosis related groups in the coding guide for diagnosis related groups of the MHLW “A Flat Payment System for the Acute Treatment of Inpatients.”

### 2. Description

The guideline described here is not a final plan, but a draft. It is to be read by as many physicians as possible, especially internists, and based on their advice and opinions, to be rectified and rewritten to provide a better version. For this reason, it was carefully arranged that the description would be an intelligible, lucid explanation. To be accurate concerning tests

required for defining diagnoses, the minimum of tests necessary for follow-up purposes, and tests to be done before discharging a patient from the hospital, the subcommittee has made it a rule to select those tests from a scientific perspective so that the quality of medical services is not compromised, as well as to explain test processes using flow charts.

### Feedback on the Primary Draft Guideline

The primary draft guideline was issued in April 1999. In the four months after it was issued, a questionnaire survey was conducted in order to sufficiently incorporate opinions of the councillors of the Japan Society of Clinical Pathology (JSCP), and physicians of the DRG/PPS-designated hospitals, the Japan Medical Association (JMA) and the member societies of the Japanese Association of Medical Sciences (JAMS). Valuable opinions were given from many physicians, among whom more than 70

percent conceived the primary draft schedule practical and readable, and some gave words of encouragement.

General requests and opinions were: more consideration of cost-related matters including the NHI points to be desired; items, the number of times, frequency of use, etc. of tests to be indicated more clearly; to define the application of the respective items to specialized physicians or general physicians; to assign many fewer test items; to add many more diseases; to make the retrieval of these data available from personal computers; further notification of this matter to the member associations and societies of the JMA and JAMS to be mandatory; and to adopt this guideline as a guiding principle of clinical laboratory tests to a critical path. As for respective disease groups, points to be altered or improved were advised in detail, which were very helpful toward the future rectification of the guideline.

### **The Secondary and Tertiary Draft Guidelines**

In response to the primary draft guideline that was favorably received, the subcommittee prepared and issued a secondary draft guideline based on the physicians' opinions after the spring of 2000. In the secondary draft, 14 disease groups listed in Table 1 as 10–23 were

added as diagnosis related groups. Because of the importance of gathering many more opinions, the number of copies was increased to three thousand, and the printed copies were distributed to various medical institutions and physicians. Consequently, many more valuable opinions were given.

Based on the opinions given on the secondary draft guideline, the tertiary draft was issued at the end of August 2001. The merits of the tertiary draft guideline are the following two points: 1) In addition to the previous issues dealing with inpatients, the use of tests for outpatients are also described; and 2) diseases with a high incidence, such as essential hypertension, were added from the MHLW Evidence-Based Clinical Practice Guideline. The number of the disease groups added to the tertiary draft guideline was 13, which brought the total number of disease groups to 36. As a result of both quality and quantity having increased, the tertiary draft was of considerable length, consisting of nearly 150 pages.

It is now important to examine the tertiary draft with meticulous attention in the respective specialty societies of the JAMS, however, physicians are highly encouraged to give their opinions, because the best point of this guideline is that it is prepared based mainly on the opinions of clinicians.

# Prospects for the Health Care System in the 21st Century

## —Suggestions on the importance of risk management—

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**Abstract:** This paper constitutes considerations on methods of bringing the health care system of the 21st century to a state of maturity by posing the issues surrounding the high frequency of medical accidents and the growing prosperity of alternative medicine. There is a tendency to stress only the remarkable aspects of modern medicine, however, it harbors another aggressive, invasive side. This offensive is not only directed at the bodies of patients, but can at times be both a psychological and financial assault. Risk management is crucial to addressing this aggressive side of medical care. Studies in support of forefront medical science are necessary if medical technology is to be safely employed. This is linked to the establishment of the safety sciences in modern medical care. Moreover, medical professionals need to endeavor to ease the financial and psychological burdens of medical technology by making commonsense judgments from the perspective of those on the receiving end of such technology (the patient side). This paper presents examples of methods for lessening the three aggressive aspects of modern medical science (physical, financial, and psychological) that can be established within the health care system, in what can be referred to as the work of causing the tree of modern medical science to put down firm roots.

**Key words:** Health care system; Aggressive; Biomedical model; Risk management; Safety science

### Introduction

#### —Outbreak of Medical Accidents—

The health care system of Japan, with its system of universal insurance, benefits in kind

and free access, is a superlative system that is unparalleled the world over.<sup>1)</sup> Even the World Health Report (WHO) 2000 acknowledges Japan to have the world's longest life expectancy. Accordingly, one would expect to be able

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to state that the country's health care system is completely problem-free.

Unfortunately however, a spate of medical blunders at medical institutions has filled the pages of the newspapers. Medical incidents that run counter to all wisdom, such as the patient misidentification at Yokohama City University Hospital and the accidental injection of a patient with disinfectant at Tokyo Metropolitan Hiroo Hospital, have been occurring repeatedly at forefront medical institutions. According to a report compiled in 2001, among national university hospitals, which are vanguard providers of health care, a mere two hospitals were not embroiled in medical malpractice litigation. Medical blunders have become so commonplace that the health care system is undoubtedly being dogged by "shadows." It is ironic that whilst Japan's state-of-the-art health care system has boosted life expectancy in this country to the highest level in the world, it is, on the other hand, engendering numerous medical accidents.

This paper presents the issues surrounding these medical blunders and considers methods of resolving them via an analysis of the current health care system from the standpoint of scientific philosophy. Key words in this discussion are aggressive and risk management.

## The Modern Model of Medicine

### —Aggressive—

Modern medical science affords tremendous benefits. On the other hand, it is also becoming a hotbed for medical mishaps. What type of model<sup>(Note 1)</sup> then is modern medicine, which incorporates these two aspects, based upon? This can be considered in terms of scientific

philosophy.

As in other scientific fields, the foundations of modern medicine are reflected in the paradigm<sup>(Note 2)</sup> of elemental reductionism. Elemental reductionism can be understood as the breaking down of matter or phenomena into the component elements for analysis.<sup>2)</sup> This philosophy was triggered by the mechanistic worldview originating in Decault's rationalism and the classical dynamic model of Newton. The form of elemental reductionism that is applicable to medicine is the biomedical model. Engel offers the following explanation of this model. "The dominant model of disease today is biomedical, with molecular biology its basic scientific discipline. It assumes disease to be fully accounted for by deviations from the norm of measurable biological (somatic) variables."<sup>3)</sup>

In modern medicine, digitized laboratory data is unquestionably given precedence over analog data, and diseases are diagnosed on the basis of quantitative deviations from the standard values yielded by a comparison with such digital laboratory data. Even psychiatry, the medical field employing the most analog approach, has been subject to digitization. In psychiatry, which deals with the human mind, the biomedical model requires that the causes of mental disorders be explained in terms of abnormalities of the neurotransmitters within the brain as opposed to a diagnosis encompassing the variability of the mind as a whole. It goes without saying that phenomenological psychiatry and dynamic psychoanalysis are also being studied, nonetheless, the mainstream at universities is the study of biopsychology.<sup>(Note 3)</sup> Meanwhile a succession of new serotonin-dopamin antagonists and selective reuptake inhibitors has been introduced in the receptor

<sup>Note 1)</sup> **Model** A model uses a compound system of meanings to examine, explain, and comprehend reality. In other words, it provides a theoretical framework for the ethical handling of various social phenomena.

<sup>(Note 2)</sup> **Paradigm** Originating from the Greek *paradeigma* meaning pattern, and referring to a consistent theoretical system (theoretical framework).

<sup>(Note 3)</sup> **Biopsychology** Falling within the domain of psychiatry, biological psychiatry is a discipline used to explain mental disorders by way of biology and natural science. Psychoneuropharmacology, imaging diagnosis, molecular genetics are currently attracting attention in this field.

theory of psychiatric medication. Although this is conceptualized in terms of the derangement of neurotransmitters, it is in fact none other than the paradigm of elemental reductionism. Engel offers the following sardonic explanation of the role of medical practitioners in terms of the biomedical model.

“Under the biomedical model, the human body is a piece of precision machinery and disease a malfunction of this machinery. Accordingly, the duty of medical practitioners is to repair the machinery”.<sup>3)</sup>

If medicine is perceived in metaphorical terms as the maintenance or repair of machinery, then disease is necessarily based on the law of causality and can be reconciled by the removal of such causative factors. Modern medicine therefore seeks a comprehensive triumph over disease by ascertaining said causative factors. In this instance, the targets of such attacks are pathogenic microorganisms or cancer lesions. Furthermore, although this is an issue of medical terminology, expressions such as killer T-cells are disturbing. Jargon such as “cancer missile treatment” from a decade ago, are personifications of warfare terminology, and infer the powerful stance of disease as the enemy of modern medicine to be smashed by a single blow. Surgical maneuvers likewise. Like surgery, physical examinations also represent an invasion of the human body. The more spectacular the surgery, the greater the offensive on/invasion of the living body. In this sense, forefront medical institutions resemble a war zone and the doctors valiant soldiers.

In short, it is necessary to recognize this aggressive aspect as one of the characteristics of modern medicine. No consideration of the health care system in the 21st century can afford to refute this reality, and it is essential that

we formulate countermeasures to address this aspect whilst continuing to receive the benefits.

## The Boom in Alternative Medicine

While investigating the issue of mushrooming medical accidents in modern medicine, I came to the realization that aggression lies at the heart of the models of scientific philosophical theories. An examination of the aspects of aggression and invasion that are inherent to modern medicine from a different perspective that focuses on the health seeking behavior<sup>(Note 4)</sup> of patients, reveals that beneath the surface of modern medicine a large number of patients are using alternative medical therapies.

Alternative medicine is a generic term for traditional medicine that has been derived from folk remedies and unique (healing) theories. The opportunity for discussion of alternative medicine to take center stage was generated by a 1993 article published by Eisenberg. The paper revealed an estimated 34% of Americans to be using alternative medical therapies at their own expense at the time of reporting. Of these, approximately 70% of patients who acknowledged using alternative therapy never mentioned it to their attending physician.<sup>4)</sup> In the US, an entirely different system of medical treatment is being practiced behind the scenes of modern medicine. In Japan also, much has been made of various folk remedies in recent years, and dozens of ‘such and such’ new health cultures have emerged. Moreover, there is marked interest in health foods among patients, with numerous dietary fads emerging including the ‘wine boom’, the ‘cocoa boom’, and the ‘mushroom boom’, to name but a few.

The term alternative refers to a substitution. It goes without saying that in this instance it is

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Note 4) **Health seeking behavior** According to the medical anthropologist, Arthur Kleinman M.D., the health care system comprises three overlapping sectors (specialist health care, private [non-government] health care, and folk remedies), which patients can use selectively or simultaneously. The behavior adopted by the patients when they wish to resolve a medical problem is referred to as health seeking behavior. Consulting a medical specialist is one type of health seeking behavior, others include self-care by the patients and the use of private health care.

modern medicine that is being substituted. If we examine the etymology of the word 'alternative' in terms of scientific philosophy, it becomes clear that the word was born out of the New Science movements<sup>(Note 5)</sup> of the 1970s. In consequence, aside from its meaning of substitution, the term 'alternative' also refers to more ecological practices. For example, when discussing alternative energy sources, this is not a reference to finding alternatives to fossil fuels or nuclear power, but to energy sources whose use encompasses environmental considerations such as wind power and solar energy. By the same token, alternative medicine refers to ecological treatments that take the manifest power of natural healing into consideration as opposed to mere substitutes for modern medical treatments.

The problem of soaring health care costs has additionally helped to focus attention on alternative medical therapies. The development of increasingly sophisticated diagnostic equipment in modern medicine has sent costs skyrocketing. Pressure on health insurance resources has exposed the necessity of conducting research into non-invasive treatments which have low unit costs, and it is this medical economics aspect that has served as the driving force behind the flourishing research into alternative medicine therapies in the US in recent years.

Does alternative medicine thus have the leverage not just to replace modern medicine but to transform the health care system? In the final analysis, alternative medicine therapies and modern medicine are not in confrontation, instead the relationship should be seen as one of complementarity or supplementation. That is why the practice of alternative medicine has essentially continued unbroken beneath the surface of modern medicine. The reason that the spotlight has suddenly been turned on the field of alternative therapies in recent years can

be perceived as a reaction to the aggressive nature of the modern health care system. As medical professionals, we need to adopt a humble attitude to the current interest in alternative medicine, and to consider methods of easing the aggressive/invasive aspects of modern medicine.

### The "Tree" of Modern Medicine

To summarize the discussions cited above, modern medicine can be compared to a tree; a large tree that has grown concomitantly with the history of modern medicine. A large tree has a trunk, flowers and leaves; it also has roots, though these are concealed. When all is said and done, the brilliance of state-of-the-art health care is equivalent to the beautiful flowers and leaves of this tree. These have served to support the trunk of medical science in the past. The flowers, leaves, and trunk of a big tree are immediately visible. However, the roots that are crucial to sustaining this tree are hidden from view. If these roots are not strong, the tree cannot take sufficient nourishment and will be unable to provide sustenance to the flowers and leaves. Moreover, a tree with weak roots is liable to topple over in strong winds.

When compared with the brilliance of the flowers and leaves, the roots of the tree of modern medicine have failed to keep pace with the rapid growth of medical science. The health care system of the 21st century calls for the creation of sturdy roots to support the organ-specific departments of medicine (the flowers and leaves). In short, it is now necessary to enrich the areas of the health care system that are out of sight in the earth. The 20th century was an era of specialization in the field of medicine. As is shown in the table, medicine in the 20th century was a vector that aimed to reach the frontiers of medical science through the

<sup>(Note 5)</sup> **New science** Falling under the domain of scientific philosophy and embracing the series of social movements that occurred in the United States in the 1960s and 1970s, the return to Eastern thought and the post-modern movement. The philosophy of the new scientist advocates a paradigm shift from competition to symbiosis, from stratification to interdependence, and from atomic theory to contextual understanding.

Table 20th Century Medicine &amp; 21st Century Medicine — The differences

20th Century Medicine	21st Century Medicine
Division of specialties	Supporting specialist fields
Aggression	Safety
Reaching the frontiers of medical science	Supporting the frontiers of medical science
Law of causality	Factoring in an ecological viewpoint
Elemental reductionist paradigm perspective	General systems theory perspective
Emphasis on direct vision/experimentation	Incorporating sensitivity
Evidence (proof)	Evidence + narrative (stories)
Flowers and new leaves	Working to put down roots

elemental reductionist paradigm, which was in turn based on the law of causation. It emphasized direct vision and experimentation, and required constant proof and authentication (evidence).

Against this, the 21st century must be an era that advances learning in support of forefront specialist fields. It is necessary to build this learning to support forefront medical care, integrating a more ecological perspective and which incorporates sensitivity and the ‘stories’ of individual patients in evidence. This is a low-key process that has none of the brilliance of state-of-the-art medical science. It is, nonetheless, essential to stabilizing the health care system. In this sense, it can be likened to the tree of medicine putting down roots into the ground as it grows. So, what are the aspects of health care that can be considered to correspond to its roots? If forefront medical science is considered in terms of its aggressiveness, then in order to alleviate that risk its roots must surely be in risk management. If the tree of modern medicine is to be nourished then the role of the health care system of the 21st century must be to put down roots in risk management.

## Risk Management

The Japan Medical Association (JMA) was

quick to adopt risk management into the health care system. In 2001, the JMA started offering a training course on medical safety promotion recommending the widespread application of risk management practices within the health care system. The following is an excerpt from the outline for prospective students.

“Jobs in the medical field require the constant acquisition of new knowledge. Advances in medical science have expanded the scope of diagnostic treatment, whilst progress in the highly sophisticated information society has led to increasing diversification of people’s needs. Under such circumstances, the need to find ways to ensure patient safety has become an urgent task for medical institutions. The aim of this course is to promote the establishment of systematic safety management systems within medical institutions by cultivating/training personnel to be able to take appropriate measures in dealing with the cardinal background issues of medical accidents and medical disputes.”<sup>5)</sup> This course advocates the necessity of the safety sciences as a way of protecting patients from the aggression that lies in the background of modern medicine.

Specifically, those involved in the promotion of medical safety have the following four duties: (1) planning safety measures for patients and medical professionals; (2) imple-

menting risk management at medical institutions; (3) coordination for handling accountability at medical organizations; (4) monitoring of medical safety management. The course curriculum comprises nine components designed to facilitate the realization of these duties. This being the case, what do we as practitioners of medicine need to consider in order to incorporate the concept of risk management in the health care system?

### Errors and Rule Violations

The ultimate goal of medical risk management is to eradicate accidents. Thus, it follows that if problem staff can be removed from the site of medical practice then dangerous errors will no longer occur. Are medical accidents in other words caused by “problem” practitioners? In the past, attempts were made to reduce the incidence of medical accidents in the US, by using disciplinary measures to rid the system of the doctors responsible for such accidents. This represents the so-called method of weeding out bad apples (bad apple picking). However, the incidents continued to occur despite the elimination of culpable individuals because the average doctors make numerous errors as opposed to such being caused only by the doctors who can be pinpointed as poor (bad apples). The aggressive nature of modern medicine, the result of its increasing complexity, means that the average doctor is the culprit in medical accidents.

Leeson explains the risk-taking behavior that results in errors as falling into two categories, “errors” and “rule violations.”<sup>6)</sup> Errors include oversights, mental blocks, and mistakes, and their occurrence at a certain level of probability is inevitable. Rule violations are the result of procedural decisions and represent deliberately aberrant behavior. Endeavors to minimize the probability of errors being generated are essential. In the case of rule violations, since such are willfully undertaken, it is protocol and psychology that are deemed to be

involved as opposed to the theory of probability. Accordingly, I intend to divide medical accidents into “errors” and “rule violations” and to offer concrete proposals on countermeasures to prevent their occurrence (the work of putting down roots for the tree of modern medicine).

### Reducing Errors

#### — The Necessity of the Safety Sciences —

Errors will occur at a fixed probability. Those occurring in state-of-the-art medical practice are liable to have far-reaching consequences. For example, advances in respiratory management mean that artificial respirators are used frequently, even in general hospital wards to treat various pathological conditions. However, a single circuitry leak will have lethal consequences. Incidents involving artificial respirators continue to occur despite the existence of alarms and back up systems. The need for learning to support the introduction of highly sophisticated technologies and equipment is increasingly palpable.

Forefront medical care can be supported “within the framework of medical science” or “outside the framework of medical science”. Both will reduce the incidence of errors, both contribute to the establishment of the safety sciences in the medical domain. The JMA training course on medical safety promotion may be cited as an example of the latter type of support.<sup>5)</sup> By providing interdisciplinary knowledge through introductions to the law, data, and risk management, all outside the field of medicine, the course is helping to reduce the incidence of error in the modern health care system.

Developments in anesthesiology can be cited as an example of support for forefront medicine from within the framework of medical science. Safe invasive surgical operations are possible largely as a result of developments in general systemic management technologies within the field of anesthesiology. Moreover,

this direction has also been applied in the fields of emergency and critical care medicine and intensive care, resulting in the development of organ-specific fields. In the 21st century it will be necessary to create learning (within the framework of medical science) in support of organ-specific medical technologies in various clinical settings.

The treatment of mental disorders, for example, has expanded variously to encompass psychotherapy, pharmacotherapy, and electroconvulsive therapy. Each of the techniques is in its own way physically or mentally invasive, and general systemic management is indispensable if the numerous patients with psychological disorders are to be able to undergo such therapies safely. This is not limited to the patients with mental disorders accompanied by somatic diseases (psycho-somatic). In terms of reducing invasive surgery and adverse drug reactions (the aggressive aspect), and of mitigating the probable occurrence of unforeseen situations, this includes all patients with mental disorders. However, current treatment of mental disorders continues to stay within the domain of internal medicine such as consultation, and is essentially no more than external support for psychiatric treatment. In some instances, it is not possible to indicate a satisfactory somatic treatment because the patients have mental disorders.

Internally, namely in psychiatric hospitals, the study of somatic management to facilitate effective psychiatric treatment has yet to be conducted systematically. The necessity for such systemization is based on (1) the singular relationship between patient and psychiatrist, (2) the singular nature of the setting, and (3) the singular nature of the pathology and technologies involved. In psychiatric treatment, an "intersubjective relationship" between the patient and psychiatrist is crucial, with this relationship of mutuality between the two parties being more significant than in any other branch of medicine. Accordingly, under somatic management, when a non-psychiatric physician is

added to the equation ideally, there should be no adverse impact on the dynamics of this relationship between patient/psychiatrist. Instead of entering the relationship between patient/psychiatrist, the physicians in psychiatric hospitals are required to use advanced techniques to treat somatic disorders and manage adverse reactions whilst behaving as a separate entity.

Regarding the singular nature of the setting, the press frequently reports mass outbreaks of tuberculosis or influenza resulting from the living habits in closed hospital wards. It is important to understand the singularity of the clinical setting and to implement care in consideration of the prevention of infection and environment management. Moreover, it is necessary to provide knowledge and technology to reduce the adverse reactions induced by electroconvulsive therapy and pharmacotherapy, and to develop techniques to facilitate this. Adverse reactions such as water intoxication and malignant syndrome, that are characteristic of psychiatry, need to be detected in the early stages and treatment management techniques must be developed. The issue of obesity and hyperlipidemia apparently caused by long term administration of psychotropics is poorly understood and only serves to increase the significance of somatic management.

In forefront psychiatry, there is marked indifference to the above-mentioned physical and environmental conditions, and psychiatric care is frequently disrupted as a result. In order for psychiatrists to be able to look at the overall picture of patients' minds with confidence, it is necessary to promulgate specialized study of the health problems that arise due to somatic management and the environment/habits of psychiatric hospitals. This will be difficult to accomplish, however, if the three singular characteristics of this field outlined above are simply given somatic applications, such as internal medicine. If psychiatric care is compared to a surgical operation, in order for it to be implemented safely and successfully, it needs to be studied in an equivalent way to anesthesiology

as providing general systemic management.

Anesthesiology and novel somatic practices in psychiatric hospitals are merely examples. If new medical fields can be created in various clinical settings in support of spearheading medical science then this will facilitate the development of the safety sciences within the health care system of the 21st century.

### **Becoming Sensitive to Rule Violations** —The Importance of the Untrained Eye—

To protect patients from the aggressive/invasive aspects of modern medical practices it is necessary to reduce the incidence of errors and to introduce the safety sciences. Considered within the context of the framework of medicine, the safety sciences should be developed as a specialist branch of medicine in support of forefront health care. However, this in isolation will not be sufficient to eliminate medical accidents. It is also necessary to contemplate countermeasures to address an additional factor, rule violations.

Since rule violations are undertaken consciously it is not possible to interpret them through the development of learning. Leeson points out that “behind the scenes of a medical incident rules will have been broken or procedures deliberately omitted.”<sup>6)</sup> This would seem to imply that specialist medical professionals willfully break the rules. On the contrary, it is the psychological makeup intrinsic to specialists that permits rule violations to be easily undertaken.

Experience is a formidable thing. The gap between qualifying as a doctor and being able to go out after operating on a colon cancer patient and devour guts at a Korean barbecued beef restaurant is not as long as one would imagine. In order to become a medical specialist it is necessary to learn to close one’s eyes to the accepted norms and perspectives of society. This isolation is effectively a psychological defense mechanism. The process of acquiring expertise requires that you become able to

trust in the group to follow established routines, closing oneself off from one’s surroundings in order to avoid mental confusion. In one sense, the process of becoming a leading medical practitioner is the process of learning to avert one’s eyes from accepted perspectives (sensitivities) and accept, without question, the norms of the specialist group (which may not always be correct/standard). Leading medical specialists who work continuously in an environment that is far-removed from the generally accepted norms of society are prone to violate the rules without thinking, and to do so repeatedly. It is precisely because they are specialists that they do not follow accepted procedures and commit rule violations. This psychology is linked to the occurrence of numerous medical incidents.

It is for this reason that it is important for medical practitioners to pause for breath occasionally, and take the time to reconsider forefront medical technologies from the perspective (position) of patients (amateurs). If, for example, the world of doctors were to be ranked, the doctors of the 20th century regrettably paid little regard to humanity and common sense. This is summarized in the review of Mizuta as follows.

“After qualifying, even if a doctor does not study ethics and philosophy, their reputation as a doctor will not change. Doctors are currently evaluated in terms of how many scientific reports they have published.”<sup>7)</sup>

How many doctors recognize the need to prevent their own cultural and social background from becoming an absolute standard? The ability of medical practitioners to liberate their minds from their experience as specialists is the key to their potential to becoming sensitive to the simple rule violations that are the main culprits of medical accidents. If the process of becoming a specialist involves the work of closing one’s eyes, then the work of opening one’s eyes wide is necessary after achieving that goal. This is the process of becoming sensitive to the perspectives of amateurs.

In the state-of-the-art medical practice, a doctor will assign all patients with the same pathological condition to a patient group for that disease and will erase all individual patient factors. The doctor will then provide each of the patients in this group with the same protocol. Naturally enough, however, the personal pain experience of a disease is unique to each patient and will have its own background of despair, pessimism and/or moral pain (existential pain).<sup>8)</sup> It would not be excessive to state that the ability to handle the suffering of individual patients will determine the success of the health care system of the 21st century.

## Conclusion

### —Aggression Does Not Stop at the Body—

I have emphasized the aggressiveness of the forefront medical technologies that were developed in the 20th century. This aggressiveness can justifiably be considered as being virtually synonymous with invasiveness. Aggressiveness within the context of health care is generally understood to be aggression against the body. However, in the case of the state-of-the-art medicine, this aggressiveness does not just stop in the physical domain.

Within the frame of reference of reproductive medicine, for example, recent developments in this field have been astonishing. One of the biggest advances in IVF in recent years has been the introduction of a technique called ICSI — intra-cytoplasmic sperm injection, which is a microsurgical procedure involving injecting a sperm directly into an egg to achieve fertilization. It has brought good news to many couples who were previously unable to conceive. Oocyte retrieval (OPU) is achieved via the method of hormone stimulation or through paracentesis under ultrasonography. This is a highly invasive technique. In certain cases, the hormone stimulation is excessive and results in retention of peritoneal fluid, or may induce lung edema. Accidental puncture of the bladder may result in complications. Ectopic pregnancy may be

induced leading to an emergency laparotomy. The technique brings joy to otherwise infertile parents, but the treatment method comprising hormone adjustment therapy for OPU is physically invasive and is followed by the microscopic injection of a sperm into the ovum thus retrieved. In short, the ovum is pierced by a needle, and if the ovum is anthropomorphized, this technique can be said to be highly aggressive/invasive to the ovum.

This technique also involves the following psychological problems. The ICSI technique has a success rate of around 20%, however, if the treatment is undertaken repeatedly the success rate is said to approach 100%, without exception. It has been branded as the ultimate infertility treatment; i.e. if you don't utilize ICSI you are not undergoing infertility treatment. In addition, the couples introduced to this method are liable to become psychologically mesmerized, unable to abandon the quest until success is achieved. However, even if the technique results in successful conception, the cost of the treatments accumulates and considerable sums are involved. This technique is also financially (economically) invasive. Moreover, for all the couples who have achieved success, several, if not dozens have abandoned ICSI without their wishes being fulfilled despite having invested both time and money into the process. It is also said to be an exceptionally invasive treatment in emotional terms and in certain cases, patients can undergo trauma (mental injury), or lapse into psychological conditions such as depression, nervousness or anxiety.

There is a tendency to stress only the remarkable aspects of modern medicine, however, it in fact harbors another aggressive, invasive side. The significance of risk management to forefront medicine can be understood by way of this bilateral character of state-of-the-art medicine. In the first instance, studies in support of forefront medical science are necessary if medical technology is to be safely employed. This is linked to lessening the physically aggres-

sive aspects of modern medical care. Moreover, those engaged in the provision of health care need to make efforts to ease the financial and psychological burdens of medical technology by making commonsense judgments from the perspective of those on the receiving end of such technology (the patient side).

This paper has presented examples of methods for alleviating the three aggressive aspects of modern medical science (physical, financial, and psychological) that can be established within the health care system, in what can be referred to as the work of causing the tree of modern medical science to put down firm roots.

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