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## Consciousness and Psychological **Behaviors of Smokers**

## —Factors that cause people to start, continue, or stop smoking, and measures to be taken—

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**Abstract**: When implementing anti-smoking measures, we must consider factors such as the consciousness/psychology related to smoking. In Japan, despite legal restrictions, a lot of people start smoking as minors. While their motives for taking up the habit is not very clear, it seems to have to do with how the smoking habit has seeped into the society. The desire to feel connected with friends and availability of cigarettes also contribute to how people take up the habit. If we are to keep minors from smoking, it is important to provide anti-cigarette education that will not stimulate the curiosity of minors while also making adjustments to their social environment. For adults, on the other hand, it is important that we provide accurate knowledge on smoking to help smokers make decisions for themselves. Smokers must also understand the condition of nicotine dependency. When counseling smokers toward cessation, it is necessary to first conduct nicotine replacement therapy if there is marked nicotine dependence, and then help smokers to realize that the issue of smoking has to do with their own health so that they can make decisions for themselves. In the future, not only should changes be made to the social environment so that people are less inclined to smoke, but anti-smoking education should also be developed with the psychological aspects in mind.

**Key words**: Antismoking; Nicotine dependency; Antismoking guidance; Habitual smoking

## Introduction

Smoking has become a large issue across the world, as it is now known to have a significant negative health effect not only on a smoker but also on non-smokers nearby due to the secondhand smoke caused by smoking. Even in Japan, smoking has been selected as one of the target

This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol. 127, No. 7, 2002, pages 1015–1018). items for "Healthy Japan 21 (a framework of health promotion)," and measures have been taken gradually to this day. Programs to help people stop smoking are available at clinics, hospitals, municipal offices, and public health centers. Nicotine gums have become available as over-the-counter drugs since September 2001, and NRT (nicotine replacement therapy) has also become more readily available. However, it cannot be said that the non-smoking rate increase is at an adequate level. Nicotine dependency, one of the causes that keep people from getting rid of their smoking habits, is weaker than dependency on psychostimulants or narcotics, and demonstrates little withdrawal syndrome. Nevertheless, people seem to have difficulty to stop smoking. One of the reasons may be that it is socially acceptable. However, despite the fact that science has revealed the adverse effects on health in recent years, the incidence of smoking among young people has not gone down but rather it is on the rise among young women. This may suggest that the current anti-smoking education is not very effective in preventing people from taking up smoking habits. Therefore, the consciousness and psychological behaviors of smokers are herein examined.

# Psychology of People Who Take Up Smoking Habits

Despite the fact that there is a law that prohibits the use of tobacco products by minors in Japan, the common time for people to taking up smoking habits has been know to be when they are still minors.

Since there has not been enough studies on smoking habits among minors, and there are large differences among minors, depending on region, sex, age, school, and timing of survey (before or after summer vacation), the actual situation of smoking among minors has not been adequately understood. Nevertheless, the following has been identified from the results that have been obtained thus far.

Surveys of senior high school students<sup>1)</sup> have shown that most smokers started smoking while they were in junior high school, and that reasons for taking up the habit were "no reason in particular," "encouraged by friends," and "curiosity." Surveys of college students revealed that most smokers started smoking while they were in senior high school, and common reasons for taking up the habit were "curiosity," "no reason in particular," and "fellow feeling." The fact that many responded "no reason in particular" may suggest that the motive for taking up the habit was not exactly a conscious one, which seems to have to do with how cigarettes might have had already integrated into their lives. The second most common responses, which were "encouraged by friends" and "fellow feeling," suggest that sense of connectedness and imitation are motivating factors for smoking. Furthermore, initial survey results for junior high school students have revealed that they gained access to cigarettes because they were "found at home," "given by a friend," or "purchase at a vending machine." This shows how smoking by family members and availability of cigarettes can contribute to the taking up of smoking habits by minors. Other investigations<sup>2,3)</sup> have shown that smoking by fathers and older brothers increases the chances of smoking by boys, and smoking by mothers and older sisters increases the chances of smoking by girls, suggesting that minors are greatly affected by same-sex smokers who are older than themselves. Moreover. moral decline in the society and the tolerant attitude of adults, particularly smokers, toward underage smokers are also adding momentum to smoking by minors.

# Psychology of People Who Continue to Smoke

Smoking a cigarette once does not turn all people into regular smokers. Surveys of junior high school students<sup>4)</sup> showed that the reason why they continue to smoke is because cigarettes "produce a sense of exhilaration/satis-

Table 1 Fagerstrom Tolerance Questionnaire (FTQ) (Fagerstrom, 1978)

| Questions   | Answers (Score)   |  |
|---|---|--|
| How soon after you wake up do you smoke your first cigarette?   | Within 30 minutes (1), After 30 minutes (0)               |  |
| Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in churches, libraries and movies)? | Yes (1), No (0)   |  |
| What cigarette would you most hate to give up?  | The first one in the morning (1), Any other (0)           |  |
| How many cigarettes per day do you smoke?   | 26 or more (2), 16 to 25 (1), 15 or less (0)              |  |
| Do you smoke more frequently during the first hours after waking than during the rest of the day?                           | Yes (1), No (0)   |  |
| Do you smoke when you are so ill that you are in bed most of the day?   | Yes (1), No (0)   |  |
| What is the nicotine content of the cigarette brand you usually smoke?  | 1.3 mg or more (2), 1.0 to 1.2 mg (1), 0.9 mg or less (0) |  |
| How often do you inhale the smoke from your cigarette?  | Always (2), Sometimes (1)                                 |  |

Table 2 Fagerstrom Test for Nicotine-Dependence (FTND) (Heatherton, 1991)

| Questions  | Answers (Score)   |
|--|---|
| How soon after you wake up do you smoke your first cigarette?  | Within 5 minutes (3), 6–30 minutes (2), 31–60 minutes (1), After 61 minutes (0) |
| Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in churches, libraries, and movies)? | Yes (1), No (0)   |
| What cigarette would you most hate to give up?   | The first one in the morning (1), Any other (0)                                 |
| How many cigarettes a day do you usually smoke?  | 31 or more (3), 21–30 (2), 11 to 20 (1), 10 or less (0)                         |
| Do you smoke more frequently during the first hours after waking than during the rest of the day?                            | Yes (1), No (0)   |
| Do you smoke when you are so ill that you are in bed most of the day?  | Yes (1), No (0)   |

faction," "have a calming effect," and "smell or taste good." Reasons among adults are because it is "a habit" or because they would "not have any distraction," "become irritable," or "become bored" if they abstained from smoking.5) These results seem to show dependence on excitatory and inhibitory effects of nicotine that results from the pharmacological actions of nicotine. However, in addition to dependence on the pharmacological actions of nicotine, psychological dependence on cigarettes is also seen in responses such as "a habit" and "become bored." Whether smoking is habitual and largely attributed to psychological factors or largely attributed to nicotine dependence can be determined by Fagerstrom Tolerance Questionnaire (FTQ; Table 1) and Fagerstrom Test for Nicotine Dependence (FTND; Table 2). When a person scores at least 6 points on the tests, smoking can be largely attributed to nicotine dependence, and when the score is low, smoking can be largely attributed to psychological factors. A survey of company workers and city employees conducted by a public health center showed that nicotine-dependent smoking with a score of at least 6 points was relatively uncommon and that the habitual factor had to do more with smoking in most cases. This suggests the importance to examine the issue from a psychological perspective.

# Psychology of People Who Stop Smoking

Many surveys have shown that ex-smokers who successfully quit smoking did so because of the effects on themselves, with reasons such as "it is bad for health," "health condition was poor at the time," and "it does not taste good." Smokers who wish to quit smoking gave reasons other than for themselves, such as "it is bad for health," "it inconveniences others," and "it costs too much." While many reported a 20–30% success rate in relinquishing the habit of smoking, 60 it seems that one of the keys to success is dependent on whether or not they can convince themselves that cessation would be good for themselves.

#### Measures for Successful Cessation

Based on the points mentioned above, the following measures may be beneficial.

## 1. Measures to prevent people from taking up smoking habits

Since a lot of people start smoking before they are of age, and since it is clear that they are initially not dependent on nicotine, a psychological approach may be effective. For this purpose, it is necessary to provide scientific knowledge concerning smoking to minors in a way so that it would not stimulate their curiosity. Sketchy knowledge may have the reverse effect of rousing their curiosity. Along with scientific knowledge, they also need to learn how to tact-

fully decline invitation from friends to smoke together. In addition, when there are smokers in the family, due to the tolerant attitude toward smoking and availability of cigarettes, it is important to ask for the cooperation of the family. Besides just families, communities should also get involved in anti-smoking measures, such as by making it difficult for minors to purchase cigarettes.

Educating minors alone tends to only produce temporary effects, and reportedly lacks durability of effects, which suggest that cooperation of people around minors is essential. Considering the fact that the target adult smoking rate has not been decided for the regional policy of "Healthy Japan 21" in most cities and towns, it is undeniably difficult to obtain the cooperation of the local community. However, the issue of how to establish cooperative relationships with the local society must be dealt with nonetheless if we are to keep minors from smoking. Issues such as when anti-smoking education should be started, what the content should be, and how to raise up educators are still at an exploratory stage, and will require cooperation of the local community and further examination.

In order to keep adults from smoking, we must present sufficient scientific knowledge regarding tobacco. It would also be effective to show how to effectively reduce stress by means other than smoking. Although smoking can threaten health, it would be most effective to help a person fully understand the effects smoking has on both body and mind, and to let the smoker make a decision for himself/herself, rather than if the smoker tried to refrain from smoking out of fear of illnesses.

#### 2. Anti-smoking measures

Since smoking involves psychological factors and nicotine dependency, as mentioned earlier, tests such as FTQ and FTND should be conducted to determine which factor is dominant in each case. When the aspect of nicotine dependency is stronger, NRT should be conducted, and withdrawal symptoms should be alleviated. For the psychological aspect, effective methods to help people feel better or to reduce stress should be taught. Smokers should also be advised to refrain from occasions where alcoholic beverages are served to keep themselves from falling into situations where their judgement tends to be impaired.

Although smoking has been socially acceptable in Japan, it has gradually been restricted in recent years, making this country a better environment in which to abstain from smoking than how it used to be. Encouraging each other as a group is also effective, as seen from examples such as "Anti-smoking Marathon using Internet." However, in such cases, one must make sure that everyone in the group has the objective of relinquishing the habit of smoking. Participation by people with other objectives may cause disturbance to people who wish to quit smoking. Although many people who have experienced smoking cessation have often experienced several failures to abstain from smoking, such failure stories may also have an effect to lower the threshold for people to challenge smoking cessation.

While these things are effective for people who have made some form of decision to abstain from smoking, such as those who are in the preparatory phase or the implementation phase, we still need to solve a large problem of how to make smokers who are in the indifferent phase to consider getting rid of their habit if we are to figure out how to further reduce the smoking rate.

Currently, anti-smoking education places its primary focus on how to help people in the implementation phase to quit smoking, and there is insufficient emphasis on how to help people in the indifferent phase or the preparatory phase to move toward the implementation phase.

Lectures on smoking tend to place its emphasis on negative health effects on the smoker and the people nearby, and often lack information on the aspect of psychological dependency on smoking. Not only are encouragement toward cessation based on fear of illnesses and cessation for the sake of people around them not effective enough, but they can also cause smokers to feel resistant to the idea of abstaining from smoking. We must be very careful about these points as we promote anti-smoking activities in the future. As mentioned in the section regarding anti-smoking, smoking is legal, and decision concerning smoking is up to the smoker himself/herself. Since accurate information is needed for accurate decision making, information on the effect smoking has on the psychological aspect must also be well provided besides scientific information.

#### Conclusion

NRT is now more easily conducted in Japan, and management of nicotine dependency, which is one of the areas that had hindered smoking cessation, has become much easier than before. However, in order to reduce the smoking rate, we must not only provide anti-smoking education, but also figure out how to help smokers themselves to come to the decision of relinquishing their smoking habits. For this purpose, it is essential to spread scientifically accurate information on the effects of smoking on health and psychological effects. Unless smokers gain interest in cessation based on such information, and make the right decision for themselves, various anti-smoking methods and NRT will not prove to be effective. Future anti-smoking education should be developed not only from the perspective of how to help smokers who wish to quit smoking succeed in cessation, but also from the perspective of how to help many smokers move toward the implementation phase of cessation.

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## Tobacco Control Measures and Their Evaluation

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Abstract: Tobacco control measures were reviewed in general and comprehensively classified into four groups, i.e. self help method, clinic based method, group based method, and community wide method, in terms of their major objectives and prominent methodological characteristics. Each method was further divided into several sub-categories and was briefly described in terms of its prominent features and the essential environmental factors necessary to yield good results. Of these, the Five A's method, which is easily applicable in various daily clinic settings, is characterized as being one of the best methods available since it is highly costeffective in terms of both cost-per-quit and cost-per-year-of-life-saved. In terms of recent global trends, this article emphasizes the fact that increasing attention is being focused on the community wide method, including national and international approaches. Moreover, the significance of active and comprehensive support for tobacco control measure by medical and co-medical professionals is highlighted in response to the Framework Convention on Tobacco Control sponsored by WHO. Methods for evaluating each tobacco control method were briefly reviewed.

Self-help method; Smoking control clinic;

Nicotine replacement method; "Five A's" method

#### Introduction

As a member of the Japan Medical Association in the field of public health, the present author considers it important to be aware of "tobacco controls" in a broad sense. Accordingly, this article offers a consolidated look at the relationships among the various guidelines and methods targeting tobacco control in the general sense (tobacco control measures), followed by a review of each of the tobacco control methods and concludes with a brief review of the methods of evaluating their effectiveness.

This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol. 127, No. 7, 2002, pages 1019–1023).

## The Position of Smoking Control **Methods in Tobacco Control Measures**

"No Smoking" is a caveat used to mean "Do not smoke" in the narrow sense of the word smoking cessation, however, the word "No Smoking" used in the national health promotion movement "Healthy Japan 21" advocated by the Ministry of Health, Labor and Welfare (Japan MHLW) means to quit smoking. One of the aims of "Healthy Japan 21" is the promotion of tobacco control in its broad sense, which is the combination of smoking cessation, and preventing the acquisition of a smoking habit, and to separate smoking/non-smoking areas. In a similar way, the objectives of the various tobacco control measures included in the World Health Organization (WHO) Framework Convention on Tobacco Control, which is progressing toward ratification in 2003, are smoking prevention, smoking cessation, and the promotion of smoke-free environments.1) These are all interrelated, thus it is important to consider tobacco control in its broad sense as well as tobacco control measures as a whole. The various measures are outlined in the table on the following page.<sup>2-4)</sup>

To a certain extent it is possible to categorize tobacco control measures according to their target<sup>2)</sup> or the behavioral scientific theory on which they are founded.<sup>3)</sup> However, since the 1980s when it became clear that a tobacco control method based on a single behavioral theory had only limited efficacy, the trend has shifted toward developing tobacco control methods based on several theories, and a number of theories and models that encompass the transtheoretical model,40 diffusion theory,40 and the PRECEDE-PROCEED5) model have been applied to the planning, implementation, and evaluation of the various tobacco control methods, and reports have been published documenting their effectiveness.

#### **Outline of Tobacco Control Measures**

## 1. Self-Help Method

This method represents individual efforts to quit smoking and comprises self-management techniques, i.e. self-care, self-control, and selfmonitoring that are grounded in social cognitive theory. Numerous smoking cessation manuals are available including the "I Quit Kit" or "Smart Move" from the American Cancer Society (ACS), and the "Helping Smokers Quit Kit" from the National Cancer Institute (NCI), which combine various techniques for smoking cessation such as smokeless tobacco, recording the number of cigarettes smoked, setting goals for smoking cessation, and so on.

This method requires the person who is attempting to stop smoking (ex-smoker candidate) to improve his/her own environment to support him/herself by no longer carrying cigarettes, keeping neither tobacco nor ashtrays at home. If a smoker succeeds in quitting using the self-help method, the sense of achievement may act as a reinforcement and contribute to sustaining the duration of smoking cessation. Human behavior tends to be easily influenced by individual circumstances or the social environment, hence many ex-smokers may start smoking again. It is often the case that the self-help method does not yield a high lifetime quit rate.

#### 2. Clinic-Based Method

In this method, an ex-smoker candidate attempts to quit smoking with the aid of another, and can access smoking cessation facilities or professionals for smoking cessation treatment.

## (1) Smoking cessation counseling method

Under this method a physician or a counselor offers guidance on self-help methods to an ex-smoker candidate through counseling at an ordinary clinic. This method is considered to be superior to the self-help method in terms of behavioral science, because the counselor can demonstrate warm or supportive concern to the client through the counseling process.

Table Outline of Tobacco Control Measures and Their Sub-Types

|                          |   |  | F (1)   |  |
|--------------------------|---|--|---|--|
| Type                     | Name  | Outline & Examples   | Essential<br>Environmental<br>Measures                                  | Main Objective   |
| Self-Help<br>Method      | Self-help smoking cessation method                | Self- management methods and various smoking cessation aids, e.g. smokeless tobacco, utilized by individuals who want to quit  • ACS: I Quit Kit, Smart Move  • NCI: Helping Smokers Quit Kit  • ALA: Freedom from Smoking   | Improvement<br>of home (own)<br>environment<br>for smoking<br>cessation |  |
|                          | Smoking cessation counseling method               | Self-help smoking cessation method applied to individuals by medical professionals, etc., in clinic settings   |   |  |
|                          | IT counseling method                              | Self-help smoking cessation method applied to individuals by physicians, etc., via telephone, internet, etc.   |   | Smoking cessation  |
| Clinic-Based<br>Method   | Smoking cessation clinic method                   | Self-help cessation method, nicotine replacement therapy, etc., applied to individuals by medical professionals, etc.  • ALA: Freedom from Smoking  • DHHS: 5A's (Five A's)  • AHCPR: Smoking Cessation Clinical Practice Guideline  |   |  |
|                          | Aversion therapy                                  | Rapid smoking methods, etc., applied to individuals by medical professionals, etc., at clinic  | Improvement of  |  |
|                          | Acupuncture therapy                               | Acupuncture of the auricle of the ear applied to individuals by  |   |  |
|                          | Hypnotic therapy                                  | Self-help smoking cessation methods and hypnotic techniques applied to individuals by trained specialists at clinic  | in workplace<br>and at clinics<br>for smoking<br>cessation              |  |
| Group-Based<br>Method    | Group-based<br>smoking cessation<br>method        | Self-help smoking cessation methods applied to groups by trained specialists, may be accompanied by mass hypnosis  • SDA: Five-day or Breath-Free Plan  • Smoke Enders: Identically named programs  • St. Joseph Mercy Hospital: Smokeless and Smoke Stoppers Program  • ACS: Fresh Start  | cessation   |  |
|                          | Workplace-based<br>smoking cessation<br>method    | Application of education-based methods, self-help smoking cessation methods with the cooperation of corporations, employees, medical professionals, etc.   |   | Smoking cessation, separation of smoking/non-smoking areas                         |
|                          | Tobacco prevention education at school            | Implementation of a smoking prevention education curriculum by students, teachers, medical professionals, etc., at classes and schools  • AHF: Know Your Body Program  | Smoke-free schools  |  |
| Community<br>Wide Method | Local community<br>tobacco control<br>method      | Application of lectures, anti-smoking campaigns, and self-help methods with the cooperation of local residents, the media, medical professionals, NPOs, etc.  • Osaka Center Prevention and Detection Center: Anti-smoking contest  • ACS: The Great American Smokeout  • WHO: World No Tobacco Day  • SHDPP: Stanford Five-City Project  • NCI: COMMIT  • NCI & ACS: ASSIST | Improvement<br>of local<br>environments<br>for smoking<br>cessation     | Smoking prevention, smoking cessation, and separation of smoking/non-smoking areas |
|                          | National and international tobacco control method | Implementation of official measures for smoking prevention, smoking cessation, and smoke-free areas by legislative and government organizations  • WHO: Framework Convention on Tobacco Control  | Smoke-free<br>social<br>environment                                     |  |

(Compiled from items 2, 3, and 4 in the references section)

ACS: American Cancer Society, NCI: National Cancer Institute, ALA: American Lung Association, DHHS: Department of Health and Human Service, AHCPR: Agency for Health Care Policy and Research, SDA: Seventh-day Adventist, AHF: American Health Foundation, WHO: World Health Organization, SHDPP: Stanford Heart Disease Prevention Program, COMMIT: Community Intervention Trial for Smoking Cessation, ASSIST: American Stop-Smoking Intervention Study

## (2) IT counseling method

This method provides an ex-smoker candidate with smoking cessation counseling via the telephone or the Internet. It may not always sufficiently motivate an ex-smoker candidate, but its merits lie in the convenience of not having to make clinic visits and in its modernity.

## (3) Smoking cessation clinic method

In this method, a physician or a co-medical professional provides an ex-smoker candidate with advice on self-help methods with some nicotine replacement therapy, e.g. nicotine gum, nicotine patches or other forms of pharmacotherapy at clinics. It has recently been stressed that the "Five A's" (Five A's method) should be used widely not only at smoking cessation clinics but also as part of everyday diagnosis and treatment in general healthcare settings. The Five A's are: Ask, "asking the patient if he/ she uses tobacco"; Advice, "advising the patient to quit tobacco use"; Assess, "assessing the patient's willingness to quit tobacco use"; Assist, "assisting the patient in his/her quit attempt" whilst providing explanations on the significance of setting a quit date, self-help methods, smoking cessation aids, nicotine replacement therapy, or readiness to offer patient support; and Arrange, "arranging follow-up contacts and relapse prevention".

#### (4) Other clinic-based methods

Aversion therapy is a method of smoking cessation that involves conditioning an exsmoker candidate to develop feelings of aversion to smoking through rapid smoking. Acupuncture of the auricle of the ear or the nose and hypnotic therapy combined with self-help method are also available.

It is essential for the environment of domestic, occupational or clinic settings to be smokefree in order to yield a high quit rate by clinicbased methods.

### 3. Group-Based Methods

## (1) Group-based smoking cessation method

This method includes those offered by the Seventh-day Adventist Church, named as the Five-day Plan introduced in 1960, or the Breath-Free Plan introduced in 1985, in which a group of ex-smoker candidates receives lecture on self-help methods. The Smokeless and Smoke Stoppers Program offered by St. Joseph Mercy Hospital teaches a group of ex-smoker candidates self-help methods and comprises four initial sessions followed by three sessions for reinforcement. These methods utilize the operant conditioning theory, e.g. with reinforcement using rewards.

## (2) Workplace-based smoking cessation method

Basically, this is a self-help method that is carried out with the cooperation of the corporation, employees, and medical professionals, and which is sometimes coupled with operant conditioning theory type reinforcement measures such as smoking cessation allowances, and so forth. For this method to be effective it is essential that improvements be made to the environment surrounding the employees and in the workplace itself, and that the objectives of smoking cessation be officially announced in the corporation.

## 4. Community Wide Method

This methods target local community groups made up of large numbers of people as opposed to a group of employees or the like who know each other. Methods targeting students at schools fall into this category, since they are intrinsically related to their guardians and their environment outside of the school.

#### (1) Tobacco prevention education at schools

The "Know Your Body Program" of the American Health Foundation is famous and is used in Japan, though other forms of tobacco prevention education are also being attempted. It includes a self-help method but it targets all aspects of smoking prevention, smoking cessation, and promotion of smoke-free environments. In order to increase its effectiveness, schools must, at least, be made into smoke-free areas, as pointed out in cognitive dissonance theory.

## (2) Community wide tobacco control methods

This method of tobacco control targets an unspecified and large number of community residents. In Japan, aside from the anti-smoking contest sponsored by the Osaka Cancer Prevention and Detection Center, and the Smoke-Free Environment Poster Competition sponsored by the council to promote the "Smoke-Free Environments for Kids" campaign, there are various tobacco control activities being undertaken by, for example, the Japan Anti-Smoking Benefit Society, the Aichi Prefecture Lung Cancer Action Association, and the Nosecho district in Osaka.7) Globally, there is the World No Tobacco Day sponsored by WHO, plus the Stanford Five-City Project run by the National Institute of Health (NIH), and the Community Intervention Trial for Smoking Cessation (COMMIT) sponsored by NCI, which are examples of large-scale community wide tobacco control measures.4)

## (3) National and international tobacco control methods

The focus of tobacco control measures is currently shifting towards community wide methods,3) and measures are increasingly being implemented at the national and international level. WHO is endeavoring to promote smoking prevention, smoking cessation, and promotion of smoke-free environments at the global level via the "Framework Convention on Tobacco Control".1) The convention includes regulating vending machines, raising taxes on tobacco, making health warnings obligatory, regulating tobacco advertising, publicity events, promoting smoke-free public spaces, and smoking prevention education.

## **Evaluation of Tobacco Control Methods**

Green defines evaluation as "the comparison of an object of interest against a standard of acceptability",5) however, the evaluation of tobacco control measures is carried out from both a scientific perspective and in terms of public health policy.

## 1. Scientific evaluation of tobacco control methods

Although there are numerous perspectives, the most important aspect is the effectiveness of a tobacco control method in terms of both its internal and external validity. The former perspective means the effectiveness of a certain study designed to examine the effectiveness of a particular smoking control method in terms of epidemiological internal validity. The latter perspective explores the universal effectiveness observed in a certain study of a tobacco control method, in its application to other populations.

There are multiple research designs available for examining internal validity, including randomized controlled trials (RCT), nonrandomized controlled trials, and well controlled cohort studies,8) which are listed in order of the reliability or authenticity of the results, and the study results obtained by these research methods are adopted as proof of authenticity. The NCI-sponsored COMMIT program was examined using a RCT method, and the NIH-sponsored Stanford Five-City Project was evaluated using a non-RCT method. However, little research has been conducted on the efficacy evaluation of tobacco control methods using such highly authentic epidemiological research methods. A report on twelve smoking cessation counseling methods conducted by physicians in the US and Canada indicates that the median quit rate one year after the implementation of counseling was 6 percent.3) Furthermore, few reports have been published on the external validity of tobacco control methods.

## 2. Evaluation of tobacco control methods from the point of public health policy

Program evaluation from the perspective of public health policy includes cost-effectiveness, the acceptability of clients or ex-smoker candidates undergoing treatment or programs, and the resulting side effects. Among tobacco control methods, clinic-based methods of tobacco control are regarded as being cost-effective, although quit rates are low. Since the majority of smokers will seek medical attention, including at ordinary clinics, for one reason or another and the smoking cessation clinic methods, e.g. counseling or the Five A's are easy to implement in terms of time, effort and the costs involved, it is hoped that the use of these methods will become increasingly widespread. <sup>4,6)</sup>

#### Conclusion

Tobacco Control Measures were reviewed in the broad sense of smoking control, indicating that their focus has shifted to community wide approaches on a national and international level. This review also mentioned that clinicbased methods such as the Five A's method have been regarded as easily applicable and cost-effective to a large number of smoking patients who visit clinics for any number of reasons, and that they are expected to become more popular in the future. The Japan Medical Association has also established the JMA Antismoking Promotion Project Committee, and finally in accordance with Dubos' statement, "Think globally, act locally", 9) the present author would like to emphasize that medical and co-medical professionals are expected to support the planning and implementation of tobacco control measures in workplaces, educational institutions, healthcare institutions, and local communities. 10)

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## **Tobacco-Related Occupational Diseases and Smoking Management at the Workplace**

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Abstract: A high percentage of workers smoke and whilst the incidence of occupational diseases is decreasing, lifestyle-related diseases caused by daily living habits including smoking are currently the biggest issue for workers. Smoking is said to be the most significant health issue at the workplace. The following are some of the known occupational diseases related to smoking: (1) since chemical substances at the workplace enter the body through the respiratory tract, the stimulation and inflammation in the airway caused by smoking heightens the absorption of such substances and enhances the risk of poisoning; (2) smoking promotes and exacerbates work-related chronic non-specific pulmonary diseases; (3) smoking promotes and exacerbates pneumoconiosis; (4) smoking enhances the risk of occupational asthma; (5) smoking accelerates the morbidity rate of lung cancer accompanying pulmonary asbestosis and pneumoconiosis; (6) smoking promotes the incidence of vibration disorder (white finger disease); (7) smoking promotes the incidence of numerous occupational diseases. The Ministry of Health, Labor and Welfare has issued policy guidelines on management to address smoking at the workplace and is recommending the separation of smoking and nonsmoking areas as a basic means of fostering mutual respect between smokers and non-smokers, in addition to efforts to tackle smoking management at the organizational level.

Key words: Tobacco-related occupational diseases;

Smoking management at the workplace:

Work-related chronic non-specific pulmonary diseases:

Occupational cancer

## Introduction—Smoking is the most significant health issue at the workplace.

It has long been indicated that the rate of

smoking amongst workers is high, and the rate is particularly high for the stratum dubbed blue-collar workers. The smoking rate is taken as a socioeconomic index for workers and it is

This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol. 127, No. 7, 2002, pages 1035-1039). demonstrated that damage to health and the morbidity rate of cancer are high in those brackets that include a high percentage of smokers. In recent years, various factors at the workplace have led to a decrease in the incidence rate of occupational diseases, however, this has been replaced by increases in workrelated diseases that are related to smoking and other living habits. Smokers do not just damage their own health, they also perpetrate damage on non-smokers via exposure to secondary smoke (passive smoking) (Fig. 1); moreover, it has been pointed out that this leads

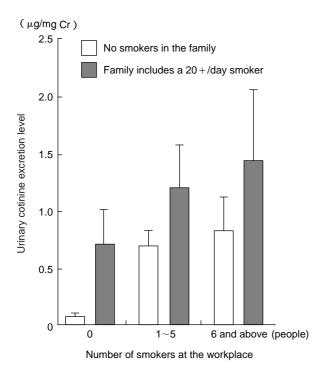


Fig. 1 Additive effects of passive smoking at the workplace and the home on the urinary cotinine excretion levels of non-smoking adult workers<sup>1)</sup>

to diminished productivity and to a drop in morale at the workplace due to conflict between smokers and non-smokers.

World No Tobacco Day (WNTD) has called attention to the need for smoking management at the workplace by adopting slogans such as "Tobacco or health: choose health" for the first WNTD in 1988, and "Smoke-free workplaces: safer and healthier" for the fifth WNTD (1992).

Among Japanese workers, the percentages of smokers who are employed in the service/sales industry, both male and female, are high (Table 1). The smoking rate for physicians is 10–20% lower than that for the general population.<sup>2)</sup>

# Tobacco-Related Occupational Diseases

Occupational diseases, particularly exposure to various chemical substances, are caused by respiratory inhalation, however, smoking reduces the capacity to excrete chemical substances from the respiratory tract, and increases respiratory inflammation and hypersensitivity. In addition, since smoking facilitates systemic absorption of chemical substances, it is known to exacerbate occupational respiratory diseases and to promote systemic poisoning; smoking has an adverse impact on virtually all occupational diseases.

# 1. Work-related chronic non-specific pulmonary diseases<sup>3)</sup>

Chronic Obstructive Pulmonary Disease (COPD) is a disease caused by smoking that is

| Table 1 Pe | rcentage of | Smokers | in Japan | by Occu | ipational Field | (1992) |
|------------|-------------|---------|----------|---------|-----------------|--------|
|------------|-------------|---------|----------|---------|-----------------|--------|

|        | Sales/<br>service<br>industry | Laborers | Commerce/<br>self-employed | Administrative/<br>technical | Managerial/<br>freelance | Agriculture,<br>forestry<br>and fishery | Unemployed | Nationwide |
|--------|-------------------------------|----------|----------------------------|------------------------------|--------------------------|---|------------|------------|
| Male   | 74.9                          | 69.0     | 64.5                       | 57.8                         | 55.7                     | 54.8                                    | 46.5       | 60.5       |
| Female | 26.5                          | 21.5     | 19.6                       | 13.8                         | _                        | 3.7                                     | 11.5       | 14.3       |

(Japan Tobacco Inc. survey)

Table 2 Workplaces Affected by Work-related Chronic Non-specific Pulmonary Diseases

#### 1. Mineral dust work

Coal mining, Other types of mining, Pit work (gold mining, etc.), Coal dust work, Metal refining (Iron, etc.)

2. Organic dust work

Raw cotton, Linum, Wheat, Tea, Other agricultural workers

3. Other types of work

Refractory metal, Isocyanate, Brick work, Construction industry, Pulp industry, Rubber/Wool/Polyvinyl chloride/Detergent industries

4. Work inducing occupational asthma

Formalin, Isocyanate, Platinum refining, Other work that induces occupational asthma

Table 3 Dust Workers and Lung Cancer (Compiled by the author)

1. Cohort study of the risk (Standardized Mortality Rate: SMR) of lung cancer for smokers and non-smokers

| Reported by (year)     | SMR for non-smokers | SMR for former smokers | SMR for current smokers |
|------------------------|---------------------|------------------------|-------------------------|
| Dong et al. (1995)     | 1.26                | _                      | 1.58*                   |
| Winter et al. (1990)   | 0                   | 0.3*                   | 1.9*                    |
| Amandus et al. (1991~) | 1.7                 | Included in smokers    | 3.4*                    |
| Partanen et al. (1994) | 0.44                | 1.89*                  | 6.67*                   |

<sup>\*</sup> There is a significant increase. No significant increase was observed in the incidence of lung cancer among non-smokers.

#### 2. Smoking history among fatal lung cancer patients

| Reported by (year)     | Survey numbers (persons) | Ratio with proven smoking history | Smokers    | Non-smokers | Unknown |
|------------------------|--------------------------|-----------------------------------|------------|-------------|---------|
| Costello et al. (1998) | 118                      | 81 (68.6%)                        | 81 ( 100%) | 0           |         |
| Merlo (Putoni) (1991)  | With silicosis 6         | 6 (100%)                          | 3 ( 50%)   | 2           | 1       |
|                        | Without silicosis 5      | 5 ( 100%)                         | 3 ( 60%)   | 1           | 1       |
| Winter et al. (1990)   | 60                       | 60 ( 100%)                        | 60 ( 100%) | 0           |         |
| Cherry et al. (1995)   | 88                       | 56 ( 64%)                         | 56 ( 100%) | 0           |         |
| Partanen et al. (1994) | 41                       | 41 ( 100%)                        | 40 (97.6%) | 1           |         |

The majority of fatal cases of lung cancer were smokers.

commonly seen in the general population, nonetheless, it is also a work-related disease at numerous workplaces with a central focus on dust work, in other words a disease that is prevalent in the general population but also extremely promoted by work. Furthermore, since the onset/exacerbation of COPD is seemingly promoted by working in such industries, measures to fight COPD as a representative work-related disease are being implemented in Europe and the United States (Table 2). In Japan, COPD has been concealed behind pneumoconiosis and has attracted little attention; however, it will be necessary to prioritize the disease in the future.

#### 2. Pneumoconiosis

Smoking is related to pneumoconiosis in a number of ways: (1) it promotes pneumoconiosis, (2) it aggravates the symptoms of pneumoconiosis, (3) it creates a margin for error when interpreting chest X-rays for pneumoconiosis (it is especially difficult to distinguish I-type shadows), and (4) it increases the incidence of pneumoconiosis lung cancer (Table 3).

#### 3. Occupational asthma

Although there are virtually no reports detailing the extent to which smoking is related to occupational asthma, smoking is reported to enhance the risk for occupational diseases that involve IgE (Fig. 2).<sup>4)</sup>

# 4. Lung cancer among patients with pulmonary asbestosis

Asbestos is a designated human carcinogen (carcinogenic substance), and smoking report-

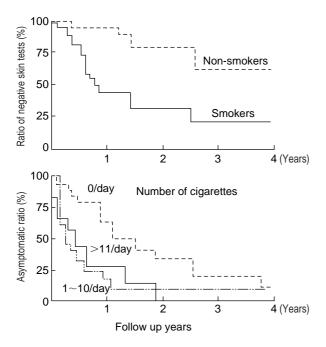


Fig. 2 Ratio of allergy sensitization among smokers and non-smokers in the platinum refining industry (follow-up survey on 91 people)<sup>4)</sup>

edly increases the morbidity rate of lung cancer, however it does not adversely affect the incidence of mesothelioma tumors caused by asbestos among workers with pulmonary asbestosis (Table 4).<sup>5)</sup>

## 5. Vibration disorder (white finger disease)

In addition to cold, smoking is heavily involved in the incidence of local vibration disorder caused by using chainsaws and so forth. Smoking is strongly related to vascular constriction and decreases skin temperature in distal regions such as the fingers.

### 6. Various types of respiratory tract poisoning

Damage to the respiratory tract among workers who handle various chemical substances including lead is known to promote the absorption of and to intensify poisoning by such substances. In particular, if tobacco is smoked while such chemicals remain on the hands the absorption rate is remarkably increased because the chemicals adhere to the tobacco and are then converted to fumes at high temperatures. Meticulous precautions are necessary such as the washing of hands, gargling, and prohibiting workers from bringing tobacco into the workplace.

### 7. Occupational cancer

Among the various occupational cancers those that are consistent with tobacco-related cancers include lung cancer, bladder cancer, and pharyngeal cancer. Smoking is considered

| Table 4 Effects of Smoking on Asbestos (Pr | Pulmonary Asbestosis) Lung Cancer <sup>5)</sup> |
|--|---|
|--|---|

| Smoking habit           | Observed     | Mortality/1,000 person-years |                      |                         |  |
|-------------------------|--------------|------------------------------|----------------------|-------------------------|--|
| Smoking naon            | person-years | Lung cancer                  | Pleural mesothelioma | Peritoneal mesothelioma |  |
| Have smoked tobacco     | 81,316       | 3.50                         | 0.38                 | 0.73                    |  |
| Have not smoked tobacco | 17,909       | 0.33                         | 0.39                 | 0.83                    |  |
| Have never smoked       | 12,756       | 0.31                         | 0.16                 | 0.71                    |  |
| Pipe/cigars             | 5,153        | 0.39                         | 0.97                 | 1.16                    |  |
| Unknown                 | 51,750       | 2.62                         | 0.25                 | 0.37                    |  |

<sup>\*</sup>Although smoking has no impact on mesotheliomas, it has synergic effects on lung cancer.

Subject Hours Scope Effects of smoking on workers 1. Outline of the effects on health of passive smoking at the workplace 0.5 2. Smoking management and cost effects 3. Current status of smoking management at the workplace Advancing smoking management 1. Guidelines on smoking management for the workplace 1.0 at the workplace (1) Aims, basic concepts (2) Roles to be assigned to executive managers, managers and workers (3) Planning and structuring the promotion of smoking management (4) Facilities, equipment (5) Air quality at the workplace (6) Education on smoking (7) Evaluating smoking management (8) Other points to consider in promoting smoking management 2. Outline of equipment for smoking management Types, features, selection and maintenance of equipment for smoking management Announcement of example offices and exchange of 1.5 Announcement of example smoking management and exchanges of opinions opinions among participants Total 3.0

Table 5 Educational Curriculum to Promote Smoking Management at the Workplace

(Ministry of Health, Labor and Welfare, 2000)

to increase the morbidity rate of such occupational cancer.

Actually documented cases include lung cancers in pulmonary asbestosis and in pneumoconiosis as cited above, as well as radon lung cancer, 6) and smoking is reported to have synergistic action on and to increase the risk for such cancers by 25-100%.

## **Smoking Management at** the Workplace

In 1992, the Ministry of Health, Labor and Welfare issued "Policies on management for the mandatory creation of comfortable work environments by employers (Public Notice 59)", which was followed by "Educational methods for those responsible for promoting smoking management at the workplace" in 2000, as specific indications on smoking management for workers and to reduce passive smoking via the creation of comfortable workplaces (Table 5).

## 1. Guidelines on smoking management at the workplace

An outline of the guidelines is given in Table 6. The basis for the guidelines is the separation of smoking and non-smoking areas. The "Explanation of the guidelines for smoking management at the workplace" (Ministry of Labor, Safety and Health Division, Environmental Improvements Section edition) by the Japan Industrial Safety and Health Association, and "The Science of Smoking – A textbook on separating smoking and non-smoking areas at the workplace" (Roudou Chousakai) by the University of Occupational and Environmental Health, Institute of Industrial Ecological Sciences, provide commentary and guidance on these guidelines. It is hoped that these guidelines will be referenced when implementing smoking management.

In addition, small and medium-sized companies that have their comfortable workplace promotion plans approved by the Prefectural

Table 6 Guidelines for Smoking Management at the Workplace

| Item   | Content   |
|--|---|
| Basic concepts   | <ul> <li>Smoking management should aim to promote respect among smokers and non-smokers of their mutual viewpoints</li> <li>Smoking management at the workplace should be addressed at the organizational level as part of occupational health administration, and should be reliably promoted with the participation of all employees</li> <li>Promoting the separation of smoking and non-smoking areas is an appropriate method of introducing smoking management</li> </ul>   |
| Roles to be assigned<br>to executive managers,<br>managers and workers | Executive managers, managers and workers should cooperate in tackling smoking management whilst endeavoring to perform the roles outlined below.  • Executive managers should initiate activities to bring about the smooth promotion of smoking management  • Managers should actively tackle smoking management, and should provide appropriate guidance to staff members who do not adhere to the mandated smoking activity standards for smokers, etc.  • Workers should be aware of the importance of their role in promoting smoking management and should actively volunteer opinions on the management  |
| Planning the promotion of smoking management                           | The health committee, etc. should explore plans for the promotion of smoking management in order to determine plans for immediate implementation and medium to long-term plans  |
| Organizing the promotion of smoking management                         | The smoking issue is an interpersonal problem involving both smokers and non-smokers and entrusting its resolution to the workers has the potential to result in difficulties by inviting the deterioration in the relationships between the two groups and so forth.  In consequence, employers are answerable for formulating the following management.  • A smoking management committee should be set up under the supervision of the health committee, etc., to explore consensus-building methods for promoting specific smoking management, tangible ways of addressing smoking management, and to study standards for smoking behavior.   |
|  | • Departments and sections, together with key personnel, should be determined in order to be responsible for mandating overall smoking policy operations including the operation of the smoking management committee, related discussions, smoking management, and so forth.  |
| Management for facilities and equipment                                | <ul> <li>Offices and meeting rooms Where it is not possible to formulate management for equipment/facilities in all rooms, smoking should be restricted to smoking rooms, etc.</li> <li>Reception rooms Install effective smoking management equipment to render smoking in reception rooms possible. Visitors should be requested to not smoke if this is difficult to achieve.</li> <li>Eating facilities Where it is not possible to formulate management for equipment/facilities in all rooms, dining facilities should be designated as non-smoking areas during meal times.</li> <li>Recreation and refreshment rooms Where it is not possible to formulate management for equipment/facilities in all rooms, smoking should be restricted to smoking rooms, etc.</li> <li>Corridors, elevator hallways Should be designated non-smoking areas.</li> </ul> |
| Air quality at the workplace   | Air quality at the workplace should be maintained so that the concentration of suspended dust particles does not exceed $0.15\text{mg/m}^3$ and that of carbon monoxide does not exceed $10\text{ppm}$ . In order to ascertain the effectiveness of smoking management, measurement of air quality at the workplace should be undertaken both before and after such management are implemented and at periodic intervals in order that such effects are maintained.   |
| Smoking-related education, etc.  | Education and discussions should be held on the subject of the impact on health of passive smoking, the content of smoking management, standards for smoking behavior, and so forth.  |
| Evaluating smoking management  | Smoking management should be evaluated at regular intervals to assess the status of progress and their effectiveness and, where necessary, improvements should be made on the basis of the results of such evaluations.   |
| Other points to consider   | <ul> <li>Promoting understanding of the respective viewpoints of smokers and non-smokers</li> <li>Putting specific considerations in place for pregnant workers and those with respiratory diseases</li> <li>Making announcements, putting up posters and so on in smoking areas in order to disseminate information on smoking management</li> <li>Gathering information on examples of smoking management and providing it to related parties</li> </ul>  |

Labor Standards Bureau are eligible to receive subsidies on purchases of air purifying manufacturing devices and equipment for use in implementing smoking management.

#### Conclusion

This paper represents a summary of the tobacco-related occupational diseases that have been reported to date, the risks attributable to smoking and smoking management for the workplace. Occupational physicians have an obligation to offer firm guidance from the dual perspective of the creation of comfortable workplaces and the protection of the health of workers.

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## **Bronchial Asthma: Psychosomatic aspect**

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Abstract: Bronchial asthma is a stress disease that may be induced by various stressors. Psychosocial stressors, working through the central nervous system as an inducing factor, cause disorders in the autonomous nervous system, the endocrine system, and the immune system, and affect the onset and process of asthma. The disease tends to become serious and difficult to cure unless stressors are properly dealt with. The involvement, or lack of, psychosocial stressors, and the psychological state of the patients, are mainly diagnosed from interviews with them and observation of their behavior. With the premise that somatic medical treatments are fully carried out, the patients are encouraged to become aware by themselves of the relationship between stressors and asthma. If depression or anxiety is observed, the patients are treated with an antidepressant or an antianxiety agent. If asthma is not relieved by the continued practice of ordinary psychosomatic medicine, or if it is desired to reduce the levels of anti-asthmatics or to stop the medication, then other therapies can also be utilized. These include autogenic training, bio-feedback therapy based on respiratory resistance value, and fasting therapy.

Key words: Bronchial asthma; Psychosomatic medicine;

Psychological approach; Psychotropic drug

## Introduction

When we are exposed to various stressors, we try to respond or to adapt ourselves to the stress. As a living body, we try to maintain homeostasis through the endocrine system, the immune system, and the autonomic nervous system. If, however, we cannot sufficiently

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respond, homeostasis of our body will fail, and we will develop stress-related diseases.

Various stressors are involved in the onset and process of bronchial asthma. It is one of the representative psychosomatic diseases of the respiratory system which is reported to be related to psychosocial stressors. Therefore, we need to take a comprehensive psychosomatic approach to the physical and psychosocial aspects. A survey by Miyaoka et al.1) revealed some cases in which doctors treating outpatients realized that the patients had some psychological problems. These patients were found to represent 56% of all the patients with bronchial asthma. A questionnaire survey of the asthmatic patients conducted by the Niigata Asthma Treatment Study Group showed that about 10% of the respondents answered that "Asthmatic attacks have a relationship with stress."

## **Diagnosis and Treatment of Bronchial Asthma**

For the diagnosis of bronchial asthma, there is "A guideline for the prevention and treatment of asthma",2) which serves as a guide to the clinical diagnosis of the disease. However, when we diagnose bronchial asthma as a stressrelated disease, it is important to realize that psychosocial stressors<sup>3)</sup> are involved in its onset and process. In this report, we define bronchial asthma as a stress-related disease, and describe its diagnosis and treatment from the viewpoint of psychosomatic medicine. Refer to existing textbooks for the somatic diagnosis and treatment of bronchial asthma.

## **Diagnosis and Treatment of Bronchial** Asthma as a Psychosomatic Disease

Chronic inflammation of the respiratory tract is maintained by atopy, in which hypersensitivity of the respiratory tract has been determined innately, by the ability to produce IgE, and by the immune reaction. When the

acquired attack-inducing factors are added, bronchial asthma occurs.4) Psychosocial stressors serve as the attack-inducing factors. They pass through the central nervous system, cause disorders in the autonomic nervous system, the endocrine system, and the immune system, and affect the onset and process of asthma. From the perspective of psychosomatic medicine, asthma is described in the above-mentioned guideline<sup>2)</sup> as quoted: "When we look in detail into the onset and process of asthma from both the mental and physical aspects, it becomes clear that, in many cases, the patients have undergone more physical changes caused by various psychosomatic factors than before the onset of the disease."

## 1. Practice of psychosomatic diagnosis

## (1) Cases of asthmatic attacks

Prompt treatment of attacks should have priority over all other things.

#### (2) Cases of no attack

Bronchial asthma is diagnosed physically. At the same time, the onset and process are also reviewed from the psychosomatic aspect. Patients are examined to see if there is a possibility of an involvement of the following psychosocial stressors:

- (a) Physical stressors: Changes in temperature, humidity, and atmospheric pressure, and especially the influence of air conditioning and chills.
- (b) Chemical stressors: Smoking, exhaust gas, alcohol, and drugs.
- (c) Biological stressors: Microbes (bacteria, viruses, etc.), pollen, and foods.
- (d) Psychological stressors: Anxiety, fear, anger, hatred, inferiority complex, guilt, and the psychological stimuli that cause these emotions.
- (e) Social stressors: School entrance examinations, employment, reassignment, promotion, retirement, marriage, divorce, housing loan, and legal problems.

Care should be taken when we try to understand the psychosocial stressors because sometimes we simply consider these stressors as "problems of mental attitude," without evaluating them correctly. The expression "problems of mental attitude" may have an implication that reduces the value of patients as human beings. When we conduct diagnostic interviews with the patients having ordinary adult onset bronchial asthma, we consider the following points:

- (a) Actual living environment: Presence or lack of noise, exhaust gas, fungi, etc.
- (b) Situations in the workplace: Working hours, workload, excessive training or lack of sufficient training, etc.
- (c) Changes in family life and, if there are some changes, how family members respond to the changes.
- (d) How to treat asthmatic attacks, and how the family responds to the attacks.
- (e) Decreased appetite, sleep disorder, depression such as decreased motivation, symptoms caused by anxiety, etc.
- (f) Record of visits to medical institutions, patients' distrust of medical institutions, etc.
- (g) Parent-child relationship in their infanthood. We obtain these pieces of information from our interviews with the patients.<sup>5)</sup> Such information is very private, and is obtained for the first time when a good rapport has been established between a doctor and a patient. Thus, it is important to make sure that the patients are free to choose not to tell their doctor what they do not want to tell.

We check the patients for the existence, or lack, of psychosocial stress, and evaluate the psychological aspect of the disease, mainly through interviews and the observations of the patient's behavior. But, if the patient agrees, we can utilize a psychological test as an aid. There are such questionnaires as the Comprehensive Asthma Inventory (CAI),<sup>6)</sup> the Self-Rating Questionnaire for Depression (SRQ-D), and the State-Trait Anxiety Inventory (STAI). We also make use of the Somatosensory Amplification Scale (SSAS)<sup>7)</sup> for near-fatal asthmatic patients.

## 2. Practice of psychosomatic medical treatment

The following treatments are given on the premise that somatic medical treatments are also fully carried out.

# (1) Psychosomatic treatment for outpatients

It is important to have the patients make regular visits to the offices of their attending physicians, and to build a good relationship between the patients and the medical institutions. For this purpose, we need to explain to them at their first visit that bronchial asthma is a curable disease, that they should visit the hospital on a regular basis, that they should understand what is being prescribed for their disease and, by giving them an actual goal for the treatment, that they should not make any uninformed judgment of their own.<sup>8)</sup>

After the need for regular visits to the hospital has been established, we take the detailed clinical histories of patients and work out what we can do for them, starting with those problems that can be easily recognized by the patients. For better understanding of the psychosomatic relationships, we as physicians do not point out the problems to the patients, but we help them to think by themselves and to become aware of those problems. Then, treatment will become effective when we address not only the bodily symptoms but also the asthmatic journals and the changes in peak flow value.

#### (2) Psychosomatic medical approach

As a psychological approach, there is a stepby-step treatment proposed by Ago. 9) We follow this approach to continue with the treatment. If asthma is not relieved by the continued practice of ordinary psychosomatic medicine, or if it is desired to reduce the levels of anti-asthmatics or to stop the medication, then other therapies can also be utilized, including autogenic training, bio-feedback therapy based on the respiratory resistance value, and fasting therapy.

- (3) Drug treatment
- a) **Anti-depressants**: If the process of bronchial asthma is affected by depression, some-

times the disease conditions become complicated and we have difficulty in giving treatment to the patients. Therefore, if any depressive conditions are observed, it is necessary to treat them with an anti-depressant. But anti-depressants are known to have an anti-cholinergic action and, because of this action, patients may find it difficult to cough up sputa. Thus, it is better to start with an anti-depressant that is less anti-cholinergic, such as those drugs that inhibit the selective reuptake of serotonin, while paying full attention to the adverse effects.

b) Anti-anxiety agents: Anti-anxiety agents may be used in those cases where the patients are emotionally unstable and hyperventilation is observed, or where the patients have severe complaints and tend to be seized by panic in spite of slight attacks, as evidenced by physiotherapeutic findings and the results of blood gas analysis. However, anti-anxiety drugs have a respiratory depression and a muscle-relaxing action, and it is better not to use them in cases of severe attacks and when symptoms are complicated. If it is necessary to use one, an anti-anxiety drug of the non-benzodiazepine type can be safely used, as this type of agent has less musclerelaxing and respiration-restricting action.

## In Closing

Serious conditions and intractable asthma are often observed when stress is not properly dealt with. In the treatment of asthma, it is important to approach it not only from a physical aspect but also from a psychosocial aspect.

If involvement of psychosocial factors has become clear during the process of diagnosis in the early stage of onset in individual cases, then we need to take adequate measures against the relevant factors.

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## **Genetically Modified Foods and Health Problems**

JMAJ 46(5): 208-216, 2003

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Abstract: Genetically modified (GM) foods and their related health problems are receiving great concern in Japan. Regarding the criteria of safety assessment of GM foods, the Japanese government and consumer organizations still have conflicting opinions, and there are still many problems and points that need clarifying. We should deal with them with a broad outlook and pay adequate attention to the situation abroad as well. Further examination and compliance with the labeling obligation is also needed to allow consumers to choose for themselves and to ensure their right of choice.

**Key words**: GM (genetically modified) foods; Health problems;

Labeling obligation; Safety

## What are Genetically Modified Foods?

Genetically modified (GM) crops are the novel crops that are developed by transferring gene(s) from other species to the traditional crops in order to make them more readily cultivable. Foods thereof are called GM foods. 1,2) According to the announcement of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, the foods and the food additives that are produced by applying recombinant DNA techniques are called GM foods.<sup>3)</sup> The recombinant DNA techniques are those preparation techniques by which a recombinant DNA

molecule is prepared by connecting DNA through scission and recombination using an enzyme, transferring it into a living cell, and allowing it to proliferate. (Article 2 (Definition), Ministry of Health, Labour and Welfare Announcement No. 233, "Procedures of Application for Safety Assessment of Foods and Food Additives Produced by recombinant DNA Technology")

#### What Kinds of GM Foods are There?

Typical GM foods include soybean, corn, rapeseed, potato, and cotton. GM foods in Japanese markets are mostly imported from

This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol. 126, No. 6, 2001, pages 779-786). foreign countries. They have various properties, the most common being the herbicide resistance (71% of all) followed by an insecticidal property (28%).2)

The GM foods that have passed the safety assessment procedure by the Ministry of Health, Labour and Welfare (March 30, 2001) are 2 kinds of potatoes, 2 kinds of soybeans, 1 kind of beet, 10 kinds of corn, 14 kinds of rapeseed, and 6 kinds of cotton.3)

## The Health Problems (Safety) of GM Foods—Including the Past Cases

Are GM foods bad for the health? - There are various opinions as for the answer to this question:

- 1) Safety has not been confirmed;
- 2) Safety of eating them over a prolonged period has not been examined;
- 3) Allergenicity has not been properly tested;
- 4) We cannot consume foods whose safety has not been confirmed.<sup>2)</sup>

The L-tryptophan case refers to cases of food poisoning that occurred from 1988 to 1999. Showa Denko produced L-tryptophan, an essential amino acid, as food supplement by using GM bacteria. Among those who took this product predominantly in the U.S.A., 1543 people had complications and 38 people died.

This health impairment is called EMS (Eosinophilia-myalgia Syndrome) that remarkably increases the number of eosinophils, type of leukocytes, and causes myalgia of the entire body. The GM bacteria, used by Showa Denko, for producing the tryptophan, apparently caused this syndrome. The bacteria had unexpectedly produced 2 kinds of proteins, which contaminated the product.

Thus there is no clear understanding of the behavioral process of bacteria after genetic modification, and the possibility that unexpected substances may be produced cannot be denied.2)

The StarLink case occurred by using the GM

corn "Starlink" which has been developed by Aventis, a giant French biotechnology company. StarLink contains an insecticidal protein that keeps pests away but may cause allergic reactions in people if consumed. StarLink was approved for cultivation as animal feed in the U.S.A., however, traces of StarLink turned up in tortillas (shells for tacos) used in Mexican dishes in September 2000. In Japan where StarLink was not approved even for animal feed, it was investigated and found that some foods made from the U.S. corn were contaminated with StarLink. In December 2000, an expert panel of United States Environmental Protection Agency (EPA) confirmed the Star-Link case had caused allergic reactions in humans, and the danger of StarLink again acquired a great deal of attention.

The past cases are as follows.

## "A case in which an allergen was produced by GM foods"

A company introduced the DNA of Brazil nuts into a soybean strain in order to improve its nutritive value. This soybean produced allergic reactions, and its further development was abandoned. Since it was already known that some people were allergic to Brazil nuts, the allergenic nature of the soybean could have been predicted from the very beginning. However, the fact that the allergenic nature of that particular strain of soybean was confirmed, and its commercialization cancelled, demonstrates that the safety assessment system worked effectively.

## "Report of impaired rat immune system by **GM** potatoes"

On a British TV program on Monday, August 10, 1998, Dr. Arpad Pusztai of Rowett Research Institute in the U.K. announced that potatoes produced by recombinant DNA techniques impaired the rat immune system.

Lectin producing genes that exist in jackbeans or snowdrops were transferred to the potatoes used for this research. Lectin is a protein for physiological activity, and it protects plants from aphids and nematodes. Especially, lectin isolated from jackbeans is reportedly toxic to immune cells.

According to Dr. Pusztai's announcement, five rats fed for 110 days (corresponding to 10 years in humans) on the potatoes to which the jackbean gene had been transferred grew slightly less and suffered immune damage, however no effects were observed in the rats fed on potatoes to which the snowdrop gene had been transferred. These potatoes were produced only experimentally.

According to the press release on August 12, 1998, these research results had been announced during the research without complete evaluation of the data. Therefore, it was necessary to reexamine and evaluate the results. Dr. Arpad Pusztai who made this announcement prematurely was suspended from the said institute.

October 22, 1998, Dr. Pusztai submitted a report at the request of the Rowett Research Institute. The Audit Committee that had been appointed in the institute in August 1998 examined the report.

The committee announced, "Dr. Pusztai conducted long-term (110 days) feeding experiments using 2 kinds of potatoes and concluded that the rats grew less and suffered immune damage. But, this conclusion was based on inappropriate data." The committee particularly stressed, "potatoes used for the experiments were much different from the parent potatoes in composition and the experiment was not worth evaluating." Regarding the report that differences were observed in the weight of guts between the rats kept on the GM potato diet and those on a non-GM potato diet, the committee pointed out, "this data was acquired in the experiment conducted solely on peculiar guts, and only the quality and weight of guts were determined. Therefore, the change in the weight of gut per rat's weight was not reported. Furthermore, no significant difference was observed in the growth rate between the rats fed on potatoes to which the lectin gene was transferred and the rats fed on lectin itself.

Since the examination of the immune system was not sufficient, biologically significant differences cannot be discussed."3)

After that, the British medical journal Lancet (October 16, 1999) issued Dr. Pusztai's report on the lectin GM potato having resistance to insects and nematodes under the condition that the experiments were insufficient in many aspects of design and analysis.

In the experiment, the diets were prepared by using GM potatoes, non-GM potatoes, and non-GM potatoes with lectin, both raw and boiled, and the effects of these 6 kinds of diets were compared by feeding the rats on them. It was pointed out that the gut and immune system of some rats were influenced by the GM potato diets. However, the journal reported that these effects might have been produced by the stress of low protein diet or by the low digestibility of the potato strain in the diet, so that the fore-mentioned conclusion cannot be drawn.

The editor of *Lancet* said that the purpose of publishing the article was to activate the debate among scientists, media, and general public regarding GM foods.

## "Report that pest-resistant Bt-corn pollen killed insects which were not the targeted pests"

Dr. John. E. Losey et al., scientists of Cornell University in the U.S.A., reported their research results that pest-resistant corn to which Btprotein was transferred might have a harmful effect on butterflies (British Science Journal, Nature, May 20, 1999).

In this research 44% of the butterfly (monarch) caterpillars that were fed milkweed, a family of Asclepiadaceae, whose leaves were dusted with pollen from a Bt-corn, died within 4 days, and the surviving caterpillars did not grow sufficiently.

Since this is the environmental effect of the crop, the Ministry of Agriculture, Forestry and Fisheries (MAFF) investigated this problem and declared, "This experiment was conducted under dense corn pollen dusting onto milkweed in the GM cornfield. In the natural environment, beyond the cornfield, the density of GM corn pollen decreases as it goes further away from the field. Moreover, the corn pollen scatters over a very short period of 7 to 10 days. Therefore, it is inappropriate to conclude that GM corn affects the insect fauna on the basis of this research result." However, the MAFF noted, "if there is a habitat of butterflies close to a large cornfield, fears may be expressed in the papers. Therefore, we need to investigate the effects on such living things around the cornfield."3)

In the case that crops with Bt-protein in their pollen is employed to confirm the safety assessment in order to cultivate them in Japan, then in order to protect the living things around and to arrive at a conclusion, the MAFF plans to prepare for the framing of new parameters and the criteria for the assessment at the science committee for environmental safety assessment of the GMO subcommittee for environmental safety assessment of GM plants. Furthermore, unless new parameters and the criteria for the assessment are established, GM crops such as GM corn with Bt-protein in their pollen will not be cultivated in Japan because of the safety assessment. (Science committee for environmental safety assessment of the GMO subcommittee for environmental safety assessment of GM plants, the MAFF)

## "History of the L-tryptophan case and the progress thereafter"

In this case impurities produced during the processing of foods containing L-tryptophan appeared to be the cause of health impairment. "The investigating team on health impairment by products such as essential amino acids" in the Ministry of Health, Labour and Welfare declared that there was no direct relation between these impurities and the recombinant DNA techniques.<sup>3)</sup> Furthermore, the Ministry reported that although the mechanism of health impairment has been investigated by specifying the impurities in the said foods, and 2 kinds of impurities have been determined, it is necessary to investigate and conduct more research on the relation between these impurities and health impairment.

## **Long-Term Problems Associated with** Intake of GM Foods

The consensus conference to discuss GM crops (18 panelists from the general public), established by MAFF in order to answer consumers' questions and deal with their anxieties concerning GM foods through dialogue, has made a proposal entitled Opinions and Proposals of the General Public and announced it. Since September 2000, 18 panelists have discussed 4 times 9 provisions, such as the effects on health and environment, labeling, and they have listened to what experts have said in favor and against.

In the proposal, they expected the benefit of recombinant DNA techniques to help in the food and environmental problems in the 21st century, although they regarded it necessary to continue discussing about the risks. Moreover, they reported, "They cannot judge from the present situation" the effects of long-term consumption of GM foods, and asked for a longterm follow-up investigation. They claimed that insufficient information was provided by the government regarding GM crops, and demanded that various media, taking into consideration the weak terms of information, should provide comprehensible information. (The full text of the "Opinions and Proposals of the General Public" proposed by the consensus committee is available on the MAFF website at http://www. s.affrc.go.jp//docs/sentan/intro/press1104.htm under the "Announcement of the consensus committee discussion on GM crops, November 4, 2000").

"It is necessary to secure a high degree of safety for the GM foods used for everyday dishes. What is the reason for not conducting long-term toxicity tests?"

The Department of Food Safety of the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare's response to this question was, according to the criteria for safety assessment, toxicity test is not always necessary for the safety assessment of foods produced by recombinant DNA techniques (GM foods) but chronic toxicity test should be conducted when required.

Regarding, the criteria for the safety assessment, a series of toxicity test data (on acute toxicity, subacute toxicity, chronic toxicity, effects on reproduction, mutagenicity, carcinogenicity, and data from other necessary tests, such as intestinal toxicity) are required when necessary. However, the data judged scientifically irrelevant can be omitted. In fact, of the nearly 30 kinds of foods produced by recombinant DNA techniques that have been examined for the safety assessment so far, some of them have been applied to the acute toxicity test, but the chronic toxicity test was judged as being unnecessary for them all.

At the safety assessment, it is first of all confirmed by the submitted data that no harmful substances, such as known allergens and toxic substances to human health, are produced. In case there is no ground for showing clear safety of added substances produced by recombinant DNA techniques, toxicological tests, such as the acute toxicity test, are to be conducted when necessary. If added substances are inherent substances of the human body, or exist as known foods, or are those which promptly decompose and metabolize to inherent substances, it is prescribed that the safety of the parent substances can be assessed from the result of the acute toxicity test.3)

## Response to GM Foods in **Foreign Countries**

The following is some of the news as reported in the newspapers of various countries.<sup>5)</sup>

## 1. The British accept GM foods more than before (summary)

Dr. William Rolleston, the chairman of the

New Zealand Life Sciences Network, said that GM foods have become more acceptable to the British than before according to an investigation done in the U.K. by a famous nonprofit organization, which was different from the assertion of the Green Party, Greenpeace, and the organic cultivation industry.

Mr. Rolleston pointed out, "according to the investigation, the number of the British who answered that they consumed GM foods without inhibition was almost half of all the respondents, which was more than that of the year before. On the other hand, the number of consumers who considered GM foods unsafe dropped to 20 percent, from 30 percent the year before. Two out of three people did not feel they had sufficient knowledge of GM foods."

It is said that there is no demand for GM foods in the U.K. and that the opposition movement is strong. However, the fact is that 48 percent of the British consume GM foods well aware of what they are consuming. Those who do not consume GM foods constitute 44 percent of the respondents.

The chairman, Mr. Rolleston, said, "farmers in New Zealand have to be careful not to be deceived by the anti-GM foods campaign asserting that there is a demand for GM foods in the U.K." (New Zealand Spinner, April 4, 2001)

## 2. Increasing numbers of American consumers expect benefit from

biotechnology (summary)

The fifth food biotechnology survey conducted by the International Food Information Council (IFIC) suggested that American consumers paid attention to the biotechnology issue. Is this really true?

In a recent survey conducted between January 19 and 21, 2001, we investigated how the effect of the news concerning the recall of foods made from GM corn (StarLink) on consumers' knowledge and behavior towards GM foods. Greater number of consumers knew correctly that GM corn is sold in supermarkets and was made using biotechnology. However, the overall awareness of the presence of GM foods in grocery stores has actually declined since May 2000.

When the consumers were asked if they had heard about the recall of the biotech crops, only one fourth answered, "Yes." When the name "StarLink" was mentioned, almost half answered, "Yes, I know." Furthermore, 95 percent of the respondents stated that they have not taken any action in the past few months regarding the anxiety and apprehensions about GM foods.

Consumers have complex feelings on the labeling issue of GM foods. When asked unaided, what information should be added to the current one on food labels, 74 percent of the respondents said, "Nothing," and only 2 percent mentioned "GM foods." Furthermore, when presented with the current U.S. Food and Drug Administration (FDA) policy on the labeling of GM foods, 70 percent of the consumers expressed their support. As for a substitute source of information, 75 percent of the consumers were of the opinion that information regarding GM foods should be provided through toll-free numbers, brochures, and websites.

Although most consumers still respond affirmatively to the expected benefits of food biotechnology, more consumers are likely to buy a variety of foods modified by biotechnology to taste better or fresher (58% in the 2001 survey, 54% in the 2000 survey), and to reduce saturated fatty acids (46% in the 2001 survey, 40% in the 2000 survey). However, 33 percent answered that this benefit would have no effect on their purchase decision. Public acceptance of the crops modified by biotechnology and requiring less pesticide still shows a high percentage of 70 percent. This is the first time that the number of American consumers expecting benefits from GM foods has increased since IFIC started a series of this survey. Details of this survey are available on the website at http://ific.org under "IFIC Background, February 2001."

## 3. A GMA survey showed that Americans are learning more about biotechnology; and food consumption patterns remain unchanged.

A survey by the Grocery Manufacturers of America (GMA) showed that American consumers have become increasingly aware of agricultural biotechnology. However, their food consumption behavior remains unchanged, despite the publicity over the recall of taco shells (tortillas) allegedly containing unapproved GM corn. In addition, the survey showed that biotechnology is still acceptable to the majority of American consumers as a means to improve farming practices and food quality.

More than half (53%) of all consumers interviewed had personally read or heard recent news about the recall of food products by their manufacturers. General awareness of agricultural biotechnology has also risen, with over three quarters of those interviewed reporting that they had heard or read about this topic. This survey was designed and analyzed by Thomas J. Hoban, Ph.D., Professor of Sociology and Food Science, North Carolina State University, who concluded, "Biotechnology is simply not an issue for the vast majority of American consumers."

Survey results demonstrated that recognition of the use of biotechnology has not affected food consumption. One third of all consumers interviewed reported that they had not avoided or reduced consumption of any foods over the past few months. No one interviewed mentioned avoiding any foods with GM ingredients.

In fact, American consumers remain positive over the benefits of agricultural biotechnology. Two-thirds (67%) are likely to buy products, such as potatoes or tomatoes, modified through recombinant DNA techniques that require fewer pesticides. Just as many (66%) would buy such a product if it were modified to contain more vitamins and nutrients. "Basically this is the same response we have seen over the past five years to the same question on other national polls," Hoban said.

No direct consumer action is evident from the recent news stories. Only 5 percent of respondents reported that they had "actually done something or taken some action due to concern about GM foods."

"These results show that consumers continue to have confidence in the regulatory structure provided by the government agencies like the U.S. Food and Drug Administration (FDA) and the expert panel of the United States Environmental Protection Agency (EPA)," said GMA President and CEO C. Manly Molpus. "In addition, swift action taken by responsible food manufacturers and retailers, prior to the need for government intervention, has reinforced the strong and well-founded confidence of consumers in the U.S. food supply."

The survey found that only 10 percent of the consumers were considerably worried that a great deal of the foods consumed by them might not be safe. Almost two-thirds had little or no such concern. Consumers' main concerns remain those related to food that is not fresh or not handled appropriately. Their attention is focused on spoilage or bacterial contamination that can have immediate health impacts.

Interviews were conducted with 500 American adults between October 6 and 8, 2000 by KRC Research. The margin of error in the results is 4.4 percent. The GMA said it would continue monitoring consumers to determine whether the most recent recall of taco shells had any impact on food safety concerns.

The GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than \$460 billion, GMA members employ more than 2.5 million workers in all 50 states. (Washington, DC, News Release, October 12, 2000)

## 4. Most consumers support biotechnology even after the "StarLink problem": a GMA survey (summary)

A consumer survey conducted on the GMA's

commission recently showed that most of the consumers support biotechnology, despite the problem of the GM-corn "StarLink." This survey was conducted by Thomas J. Hoban, Ph.D., Professor of Sociology and Food Science, North Carolina State University.

The survey concretely showed that a lot of American consumers had heard of the "StarLink" problem concerning the recall of taco shells (tortillias) by the manufacturers, and that the general awareness of biotechnology had risen, but the use of biotechnology has not affected food consumption. In addition, American consumers remain positive over the benefits of biotechnology. Two-thirds are likely to buy biotechnologically modified foods to reduce the amount of required pesticides. And just as many (two-thirds) are likely to buy foods modified to increase the content of vitamins and nutrients. (Washington, DC, GMA News Release, October 12, 2000)

## Obligation of Labeling

The Federation of Housewives submitted a demand in February 1997 to Mr. Junichiro Koizumi, the Minister of Health and Welfare, Mr. Takao Fujimoto, the Minister of Agriculture, Forestry and Fisheries, and Mr. Yasuchika Negoro, the Chairman of the Fair Trade Commission. The text of the demand was as follows, "We, consumers, are greatly worried that GM foods might be brought to the market and we might consume them. We certainly cannot accept the state of consuming GM foods without our knowledge. We strongly demand that the concerned ministries should promptly oblige consumers by labeling all GM foods including those used as raw materials on the basis of the Food Hygiene Law, so that consumers with anxiety and apprehensions about GM foods can exercise their own judgement in choosing them."6)

The National Liaison Committee of Consumers' Organizations in their public comments also requested the labeling GM foods in order to secure the consumers' right of choice.<sup>7)</sup>

The following requests have been made since 1999.

- 1. Labeling based on the How to label GM foods should be put in force as soon as possible, knowing that GM foods are actually marketed.
- 2. The number of designated items requiring labels should be increased.
- 3. Regarding voluntary labeling, as *GM crops* are not used as raw materials, surprise inspections should be conducted in order to improve the labeling reliability.
- 4. The following measures should be undertaken to increase the number of designated items requiring labels and to reinforce the inspection of the voluntary labeling.
  - (i) Further research and development regarding the inspection methods and consolidating the inspection system should be carried out.
  - (ii) The identity preserved handling system should be consolidated.
  - (iii) The traceability system for inspection and its results for imported agricultural products should be consolidated.
- 5. When distributing GM foods in Japanese markets, their conformity to the "Safety Assessment Policy" of the Ministry of Health, Labour and Welfare should be established.
- 6. Appeal at the Codex Alimentarius Commission should be increased and strengthened so that the labeling of GM foods can be standardized following the international standards.

In the report of the Special Panel of the Food Safety Investigation Council, the Ministry of Health, Labour and Welfare, about the obligation to label GM foods, the labeling on the following have been temporarily designated as obligatory since April 2001:80 "the foods from among the GM crops and processed foods." However, regarding "those in which recombinant DNA and the resulting protein thereof has been removed or decomposed" such as soy sauce, soy oil, corn oil, cornflakes, and mashed potatoes, and "those made from GM foods but not as main ingredients" (It is not realistic to label products, if only a small amount of GM food is present. Therefore, some limits are required. At present, the ingredients that are ranked within the top three constituents in terms of weight ratio, and the weight ratios of which account for five percent or more of the total should be labelled in the same way as JAS.) The report states, "obligatory labeling will not be fixed for the moment, but voluntary labeling is not prohibited." Thus, "obligatory" labeling is not "necessarily" compulsive.

We must discuss the problem of the labeling obligation, including the category of the obligation, so that consumers with anxiety and apprehensions about GM foods can exercise their own judgement in shopping, and so that their right of choice can be ensured.

## **Summary**

As for GM foods and their related health problems, there have been some cases in the past in Europe and the U.S.A. Moreover, regarding the criteria for the safety assessment of GM foods in Japan, the Japanese government and consumer organizations still have varying opinions. And many problems, as well as unclear points, remain even today concerning the problems related to the long-term consumption of such foods.

In many foreign countries, consumers expect much more from food biotechnology and tend to accept it. While the mass media and lobbying organizations respond harshly, there are still various persisting problems that need clearing up.

We must deal with these problems carefully and with a broad outlook paying close attention to the situation overseas as well. Regarding the labeling obligation, it will require further discussion so that anxious and apprehensive consumers can make informed choices on their own and to ensure their right of choice.

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## **Diagnosis and Treatment of Acute Appendicitis**

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**Abstract**: The diagnosis and treatment of acute appendicitis are described with emphasis on the significance of ultrasonography, computed tomography (CT), and laparoscopic appendectomy. The diagnosis of acute appendicitis has traditionally been made by physical examination and blood tests. However, use of ultrasonography and CT as well as these conventional methods makes more precise diagnosis possible. These imaging modalities are useful for determining whether surgery is necessary. Ultrasonography is easy to perform and minimally invasive, making it essential for diagnosis. This examination can visualize hypertrophy, disturbance, and disruption of the layered structure of the appendiceal wall, accumulation of purulent fluid, and the presence of a fecolith in the appendix. In catarrhal appendicitis, the wall of the appendix consists of three layers. In phlegmonous appendicitis, these layers become unclear, and in gangrenous appendicitis, the layered structure is lost. CT is superior to ultrasonography in objectivity, but is unable to depict the layers of the appendiceal wall. It is useful for demonstrating periappendiceal fat, ascites, and abscess formation, and for determining whether an operation is necessary based on these findings. Laparoscopic appendectomy is one of the choices for obese patients, young women, and patients in whom a condition other than acute appendicitis is suspected.

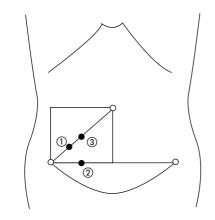
**Key words**: Acute appendicitis; Imaging diagnosis;

Abdominal ultrasonography; Laparoscopic appendectomy

#### Introduction

Acute appendicitis is one of the most common conditions treated by emergency operation. Physicians from a wide range of medical specialties including internal medicine and pediatrics, as well as surgeons, encounter patients with this condition in their daily practice. When it presents with typical symptoms, it is relatively easy to diagnose and treat. In young children, elderly persons, and those presenting with various atypical symptoms, however, the diagnosis

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① McBurney's point ② Lanz's point ③ Munro's point

Fig. 1 Points at which tenderness can be elicited in acute appendicitis

may be delayed and treatment may become difficult.

The diagnosis and treatment of acute appendicitis, particularly the diagnostic role of imaging modalities such as ultrasonography and computed tomography (CT), and the therapeutic role of laparoscopic appendectomy (a new surgical procedure for this disease) are described in the following article.

## Pathology of Acute Appendicitis

The cause of appendicitis is considered to be obstruction of the appendiceal lumen and the subsequent onset of bacterial infection. Luminal obstruction can be produced by various mechanisms and it results in the retention of mucus. If bacterial infection supervenes, the intraluminal pressure increases, leading to interruption of lymphatic flow and the development of appendiceal edema. This process leads to acute appedicitis characterized by distension of the appendix and vascular congestion, which is designated as catarrhal appendicitis. If this condition progresses further, appendiceal edema and vascular congestion become pronounced with the formation of multiple abscesses in the wall and purulent fluid on the serosal surface. This condition is designated as phlegmonous appendicitis. If it progresses further and causes local circulatory dysfunction, this will result in infarction opposite the junction between the mesoappendix and appendix, where the blood supply is inadequate. As a result, the appendix becomes congested dark red with black necrotic areas, a condition that is designated as gangrenous appendicitis. If perforation of the necrotic wall occurs, appendicitis becomes complicated by perforative peritonitis. Usually, peritonitis is localized, being confined to the ileocecal region. In young children, however, the omentum is not fully developed, so the clinical course is often complicated by diffuse peritonitis.

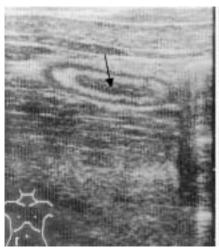
## **Diagnosis of Acute Appendicitis**

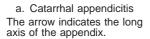
## 1. Clinical manifestations

Abdominal pain, fever, and anorexia are classical symptoms. Pain occurs in the upper abdomen at first. It then moves slowly and localizes to the right lower quadrant. In many cases, a fever of around 38°C is present.

#### 2. Findings on physical examination

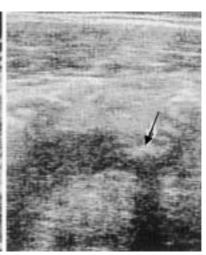
Physical examination is the most useful method for diagnosing appendicitis and for determining whether an operation is necessary. Tenderness can be elicited at various points in the right lower quadrant of the abdomen, including McBurney's, Lanz's, and Munro's points (Fig. 1). Among the indications for surgical treatment, the presence of peritoneal irritation is critical. Operation is indicated when Blumberg's sign is positive (the pain elicited by steadily increasing pressure at the site of tenderness increases on abrupt release of the pressure), and when Rosenstein's sign is elicited (tenderness in the right lower quadrant increases when the patient moves from the supine position to a recumbent posture on the left side). As a matter of course, the detection of abdominal muscular guarding and tenderness on rectal examination are among the surgical indications.







b. Phlegmonous appendicitis The arrow indicates an indistinct lavered structure.



c. Gangrenous appendicitis The arrow indicates a fecalith.

Ultrasonographic features of each type of appendicitis<sup>1)</sup>

### 3. Laboratory tests

The white blood cell count (WBC) and CRP are of diagnostic value. The WBC usually exceeds 10,000/mm<sup>3</sup>. In severe cases associated with diffuse peritonitis, however, the WBC may be decreased rather than increased, so care must be taken. Although the CRP rises in appendicitis, the increase is not necessarily associated with the severity of inflammation.

### 4. Imaging diagnosis

Plain abdominal radiographs show no particular evidence of appendicitis. If an air-fluid level is seen in the lower abdomen, however, localized peritonitis should be suspected. Ultrasonography and CT scanning are of diagnostic value, and provide useful information for determining whether or not appendectomy is necessary.

## (1) Abdominal ultrasonography

Because this minimally invasive examination is easy to perform and can be repeated, it is essential for diagnosing acute appendicitis. A normal appendix is usually not imaged by ultrasonography. When it is involved by inflammation and enlarges, however, it can be visualized. The features of appendicitis include hypertrophy of the appendiceal wall, disturbance of the normal layered structure, destruction of the wall, and purulent fluid or fecaliths within the appendiceal lumen.<sup>1)</sup> In catarrhal appendicitis, the wall of the appendix shows three layers, while this layered structure becomes unclear in phlegmonous appendicitis. No layered structure is depicted in the more advanced gangrenous appendicitis (Fig. 2). The periappendiceal accumulation of fluid suggests abscess formation secondary to perforation. A high periappendiceal echo suggests the aggregation of the omentum and other tissues that have been affected by inflammation. If some of these findings are recognized, an operation is indicated.

Kojima et al. divided appendicitis into three types depending on the ultrasonographic findings.2) The classification depended on the features of the high echo bands representing the submucosal layer, as described by Yuasa et al., 3) as well as the presence or absence of a visualized appendix and the length of the shorter diameter of the appendix (Table 1). The ultrasonographic pattern was type I in 76% of patients with catarrhal appendicitis, while it was type II in 82% of patients with phlegmonous appendicitis and type III in 94% of patients with gan-

|          | Pathological diagnosis | Layer structure of the appendiceal wall | Submucosal layer           |
|----------|------------------------|---|----------------------------|
| Type I   | Catarrhal              | Clear                                   | No hypertrophy             |
| Type II  | Phlegmonous            | Indistinct                              | Hypertrophied              |
| Type III | Gangrenous             | Disrupted                               | Indistinct and partly lost |

Table 1 Classification of Acute Appendicitis According to Ultrasonographic Findings

grenous appendicitis. They concluded that, the severity of appendicitis could be assessed by preoperative ultrasonography, so that unnecessary appendectomy could be avoided.

As described above, ultrasonography is an indispensable modality because it can be used to both diagnose appendicitis and assess its severity.

### (2) Abdominal CT

CT is superior to ultrasonography in some respects, because its findings are more objective and it is not affected by the presence of intestinal gas. The diagnosis of appendicitis by CT depends on hypertrophy of the appendiceal wall, enlargement of the appendix, periappendiceal abscess formation, the presence of a fecalith, increased density of periappendiceal adipose tissue, and/or the presence of ascites in the pouch of Douglas.<sup>1)</sup> CT can depict an enlarged appendix, but cannot visualize the structure of the wall unlike ultrasonography.

Thus, ultrasonography is superior to CT for assessing the severity of appendicitis depending on the mural changes.

## **Management of Acute Appendicitis**

#### 1. Medical therapy

Catarrhal appendicitis should be treated conservatively. It is diagnosed by physical examination, blood tests, ultrasonography, and CT, or is characterized by tenderness without peritoneal irritation. On ultrasonography, the appendix cannot be visualized or is not enlarged if it is detected. Patients with catarrhal appendicitis should generally be hospitalized for treatment with antibiotics, bed rest, intravenous fluids,

and nil orally. For outpatient management, antibiotics are administered and the course is followed closely.

#### 2. Surgical therapy

Phlegmonous or more advanced appendicitis should be treated surgically. Ultrasonographic findings are the most important factor for deciding whether surgery is necessary. In addition to the symptoms of phlegmonous appendicitis described above in the section on diagnosis, the presence of ascites or an abscess indicates the necessity for surgery. Among the abdominal findings on physical examination, the presence of peritoneal irritation is critical. If this is positive, an operation is indicated.

In the field of surgery for acute appendicitis, laparoscopic appendectomy is attracting much attention (Fig. 3). This procedure has become established in Japan and other countries. Although its usefulness has been gradually accepted, whether it is superior to conventional open appendectomy remains controversial, so it is not yet considered to be a standard therapy for acute appendicitis. The advantages and drawbacks of this procedure are described next. For the technical details that are not described in this article, see the relevant text-books and reports.

For the patient, the advantages of laparoscopic appendectomy are reported to include decreased postoperative pain, faster recovery of muscle tone, earlier return to normal activities, minimal scarring, a low risk of wound infection, no ventral hernia, and a reduced risk of postoperative adhesions.<sup>4)</sup> On the other hand, conventional open appendectomy seldom causes

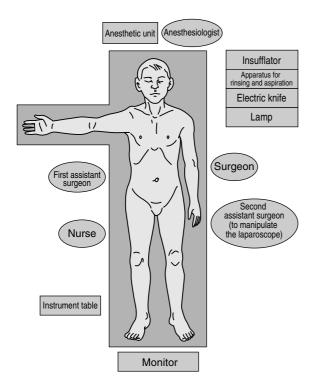


Illustration of the arrangement of personnel and apparatus for laparoscopic appendectomy

problematic postoperative pain, scarring, or ventral hernia. In other words, the laparoscopic and open procedures may only be different in their degree of difficulty.

From the standpoint of the surgeon, laparoscopy is useful to rule out appendicitis in patients with confusing symptoms. Also, if a diagnosis of appendicitis is established, wideranging examination of the peritoneal cavity becomes possible. Furthermore, intraperitoneal cleansing of the site can be done under vision on the monitor. It has even been reported that a drain could be inserted and placed appropriately under laparoscopic vision.<sup>4)</sup>

Drawbacks of laparoscopic appendectomy include the necessity for general anesthesia, the need for special apparatus including an insufflator to create pneumoperitonium, the need for more staff including surgeons and anesthesiologists, and the risk of complications due to special procedures for laparoscopic surgery such as peritoneal insufflation and insertion of trocars.

The greatest merit of laparoscopic appendectomy is being "minimally invasive." Because conventional open appendectomy is already relatively simple and not so invasive, however, this merit itself is not highly attractive. In particular cases, such as obese patients, young female patients seeking a better cosmetic outcome, and patients with suspected appendicitis who may have other conditions, it would seem that laparoscopic appendectomy may be useful.

#### Conclusion

The diagnosis and management of acute appendicitis have been described with a focus on some current issues. For diagnosis, findings on ultrasonography and CT are important. For management, laparoscopic appendectomy should be considered as a possible choice if there are indications for this procedure.

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## **General Practitioners in** the Twenty-First Century

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**Abstract**: The health care of the twentieth century was characterized by its key concept, cure, i.e., curing disease with medical technology. As a result, specialists, i.e., physicians trained for cure, were highly valued, while general practitioners, i.e., physicians trained for care, were neglected. This tendency was especially notable in Japan. In contrast to Western countries, general practice is not recognized in Japan as a specialty. However, as the technology for cure has advanced, the following problems have emerged: 1) medical technology is still limited, 2) new medical technology is inefficient, 3) medical technology increases the number of patients, and 4) medical technology increases economic inequality. Since these problems have shown that it is impossible, both technically and financially, to solve all of the problems of disease by cure-based health care alone, it is necessary to acknowledge that care-based health care was the basis of health care for thousands of years, and to recognize general practice as an essential part of health care.

**Key words**: General practice; Cure; Care; Specialty; Medical technology

#### Introduction

To have a prospect of the health care in the twenty-first century, one must review the twentieth century health care, and general practitioners' broad perspective is essential. This article first presents general practitioners' views and perspectives. It then describes the characteristics and problems of twentieth century health care based on them. Finally, it concludes that the role of the general practitioners, which was neglected in Japan throughout the twentieth century, should be properly appreciated in twenty-first century health care.

## **General Practitioners as Specialists**

## 1. Wisdom in ignorance

Statements such as "general practitioners are specialists" and "this is a normal abnormality"

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are perplexing, because they are contradictory. However, being contradictory is one thing, and being wrong is another.

For example, we are familiar with the phrase "wisdom in ignorance", which means that true wisdom lies in acknowledging one's lack of wisdom. Socrates persuaded his dialogue partner that parading one's knowledge was vain, and demonstrated that he possessed true wisdom because he frankly confessed that he was ignorant.

This story provides a lesson: while a phrase such as "wisdom in ignorance" is outwardly contradictory, it makes sense when examined from a different viewpoint.

"Normal abnormalities" is a phrase invented by the British general practitioner John Fry, who claimed that some of his patients presented symptoms that he would call "normal abnormalities". He insisted on simply observing them instead of trying some treatment. For example, a fever is an abnormality, yet recent studies have revealed that it is a very important biological defensive reaction. Endogenous pyrogens have been found to be identical to interleukin-1, the information-relaying substance related to immune reactions. Thus, a fever and immune reactions are the "two sides of the same coin" in biological defensive reactions. Another example is pain. Pain can be interpreted as a defensive reaction to prevent further damage to injured parts. Fever and pain are indeed abnormalities, but when looked at from different viewpoints, they are sound reactions directed at the recovery of health.

## 2. General practitioners as specialists

Then what about the statement, "General practitioners are specialists"?

This statement is unwarranted in Japan, because general practice is not recognized as a specialty here. Some other countries, however, officially recognize general practitioners as specialists. In the U.K., for example, the Todd report recognized general practice as a specialty in 1968. In other words, general practitioners are recognized as specialists in the U.K. In Germany, too, Allgemenärzte were recognized as specialists in the same year, and one can no longer be a health-insurance physician there without this qualification.

If general practitioners are to be recognized as specialists whose role cannot be assumed by members of other fields, then health care in Japan must be in dire straits. For example, if a lack of specialists in a particular field, e.g., dermatology, forces specialists in other fields, e.g., internists, surgeons or pediatricians, to serve in dermatology, such a health care system cannot be called first-class.

The statement "general practitioners are specialists" is apparently contradictory. Nevertheless, as in the case of "wisdom in ignorance" and "normal abnormality", we cannot reject it as erroneous. Instead, we need to consider why Europeans countries have accepted it.

### 3. The whole is not simply the sum of its parts

The difference between general practitioners and specialists is that while specialists deal with particular parts of health care, general practitioners cover the whole field. What then is the relationship between the "whole" and the "parts"? The Iwanami Dictionary of Philosophy defines the "whole" as follows:

Antonym of "parts". The whole consists of parts, and parts are the elements that make up the whole. (1) When the whole is considered to be just the sum of the parts, then the whole does not have any meaning of its own. (2) When the parts which make up the whole are combined in correlative or interdependent relationships, then the whole is more than just the sum of its parts, and each of the parts loses its meaning if separated from the whole.

The phrase "the whole is more than just the sum of its parts" in this definition is notable. This concept seems to provide grounds for thinking that general practitioners have a unique role and are specialists. Here we are reminded of Gestalt psychology. "Gestalt" means significant totality made up of components or elements.

The meaning of "whole" varies according to how we view it and how we think of it. There are things that can only be understood by examining them from several viewpoints, and by unifying the observations. Unified views, obtained in this manner, are more than just the sum of their components. Thus, general practitioners' broad perspective is helpful to observe things from different viewpoints, and to think flexibly. In other words, they are good at accepting concepts such as "wisdom in ignorance" and "normal abnormality". In order to cover the whole field of health care, as general practitioners are expected to do, we should look into our inner world, i.e., our total image of health care, as well as examine the systems outside.

### The Gestalt of Care

#### 1. Limitations of knowledge and technology

When Tetsujiro Ihara entered the medical department of a British university, he was full of ambition. However, he was shocked by the speech of the dean of the medical department given at the orientation for new students:

The mortality of human beings is one hundred per cent, i.e., death occurs universally, and our medical knowledge is limited. The most important thing that medical students should learn in the medical department is how limited his or his colleagues' medical knowledge is, and how to behave and speak as health care experts.

Upon hearing this, Ihara became angry. Yet, in the course of his first two years in the medical department, many sessions were held on this issue, and in the end he came to support the dean's view. He stated in retrospect "when I entered the college, I did not understand how important the idea of 'wisdom in ignorance' was".

The dean's speech was characterized by observation of health care from a viewpoint, different from the traditional Japanese viewpoint. His attitude is comparable to that of appreciating "wisdom in ignorance". If so, what

behavior and way of speaking are suitable for health care experts who are aware of the limitations of medical knowledge and technology?

#### 2. Health care before modern medical science

Lewis Thomas is an American medical scientist and an essayist. In his essay "Medicine as a Very Old Profession", one of the four essays at the beginning of *The Cecil Textbook of Medicine*, he skilfully describes how health care changed over the course of the twentieth century. He described his father, a typical early-twentieth century physician in private practice. He said:

During all his years in general practice he possessed only small bits of science . . . .

Not to say that treatments for illness were not used by doctors, but these were more like gestures of reassurance, sometimes like incantations of amulets.... but neither my father nor other doctors of this time had any real faith in them [=drugs]....

I was taught at Harvard Medical School, as my father had been taught at Columbia, that treating disease would be the least of my future responsibilities. The doctor's job was to recognize the nature of disease with precision, and so that he could explain to the patient, and to the patient's family, what was happening to him and how it was most likely to turn out.

This task, the explaining of illness, was the most important part of what was then called the art of medicine. It still is. Indeed, it has been a central duty of medicine, justifying all those millennia of the profession's existence, dating all the way back to our origin in shamanism.

This description seems to be an example of the British dean's idea of "how to behave and speak as health care experts". Lewis Thomas also said, "I remember a short story from real life which illustrates an aspect of the responsibility of doctoring which does not find emphasis in many textbooks of medicine", and told the story. It is a concrete example of the idea that the British dean presented.

Lewis Thomas visited a medical society in a

remote rural area to give a lecture on antibiotics. The president of the society was a man in his forties. He had just been officially inducted into the office of president, and had his lecture ready for the occasion. However, when the meeting began, he was handed a note and went out to answer a phone call. He returned three hours later. He looked tired, worn out and disappointed to have missed what should have been his own professional triumph. When Thomas asked what had happened, the president answered that he received a phone call from the family of an elderly patient, informing him of the patient's death.

The president thought, in Thomas' words, "he ought to be there, to help the family, and to be useful. He simply had to be there".

Thomas concluded as follows:

This was about 30 years ago, but I've never been able to forget that doctor and his example of good doctoring that evening. It's not quite the same thing as open-heart surgery or curing meningitis, but if I were looking around for a role model for today's medical students to look at very closely, I'd pick that country doctor in the backwoods countryside of Mississippi, if I could find him.

#### 3. Cure and Care

John Fry pointed out that health care has two purposes, cure and care. He listed the following as keywords of cure: "science, clinical, biological, physical, disease, body and hospital", and contrasted them with the keywords of care: "art, pastoral, behavioral and social, emotional, person, soul and community". He also said that it was wrong to think of the former as first-class and the latter as second-class, and that neither must be provided either "too much" or "too little".

In summary, cure solves the problem by curing the disease, while care helps patients to accept their disease when physicians cannot cure or control it. The former corresponds to Lewis Thomas' example of open-heart surgery and curing meningitis, and the latter to the

president of the medical society in the remote rural area of Mississippi.

However, the term care is also used in a broader sense to mean health care in general, as in "primary care". Here, "primary" means "at the first stage", and "care" means "health care". Thus, the idea of cure can be included in a broader sense of care. In other words, "care (in a broader sense) = cure + care (in the narrower sense)".

#### 4. Revaluation of Care

By examining the history of health care with the keywords cure and care, we can summarize it as follows:

- (1) For thousands of years after the beginning of health care
  - health care characterized by care.
- (2) For several centuries after the birth of modern science
  - health care characterized by care (the preparatory period for cure).
- (3) The twentieth century (especially the second half)
  - health care characterized by cure.

Thus, the second half of the twentieth century was the first period of cure-based health care in history. In a historical sense, it can be called a very exceptional period.

Moreover, the period characterized by cure was a period when care-based health care was neglected. This tendency was especially notable in Japan. For example, are we teaching today's medical students the importance of the view that the British dean expounded in his speech and of the behavior shown by the president of a local medical society in Mississippi?

At the beginning of the twenty-first century, we are confronted by various problems in health care. Since many of these problems emerged as cure-based health care developed, we need to examine cure-based health care in comparison with care-based health care, in order to cope with them.

I think that we should begin with reviving the Gestalt of care in order to set twenty-first century health care on a good course.

## **Problems of Medical Technology**

### 1. Problems of medical technology

What we expect of health care is cure of disease with medical technology. However, we can point out the following problems with the medical technology:

- (1) Medical technology has its limitations.
- (2) New medical technology is inefficient.
- (3) Medical technology increases the number of patients.
- (4) Medical technology increases inequality.

## 2. Medical technology cannot solve the problems

Today it is generally held that we can cure many diseases with medical technology. For example, we can cure many infectious diseases with antibiotics.

However, most of the mild viral diseases that we see in our clinics are better described as healing naturally, rather than being cured by us. This part, "healing naturally", is something that medical technology cannot deal with, and that is outside physicians' control. In reality, however, this fact has been neglected with the excuse that treatment ends in a favorable condition.

For example, a mild injury of the fingertips will heal if we disinfect and bandage it. Yet, what heals the injury is the regenerative power of the skin, and not the disinfectant or the bandage. The regenerative power of the skin is quite magical, and physicians cannot control it easily. For example it is impossible to make an injury heal in a day or two that takes a week to heal by itself.

The sixteenth-century surgeon Anbroise Paré said, "I dress a wound, and God heals it". This phrase is still valid in the practical scene of health care today, and it will continue to be in the future. The extent to which medical technology can solve problems is limited. We need to revaluate an alternative solution, i.e., *care*.

### 3. New medical technology is inefficient

Scientifically justified and truly effective remedies have been invented over the past several centuries. Today, at the beginning of the twenty-first century, the areas where medical technology is effective have been exploited, and only technically difficult areas remain. As a result, in terms of the balance between cost and benefit, recent medical technology seems to be becoming increasingly inefficient. For example, examination of the following list of treatments, "improvement of living environment, vaccination, antibiotics, surgery and transplantation" reveals that as one proceeds down the list, the medical expense increases and the number of patients saved grows smaller. This tendency is expected to accelerate.

# 4. Medical technology increases the number of patients

Before there was any concept of blood pressure, people with high blood pressure were not thought to be a problem. Similarly, the phenomenon of elderly people becoming bent over was not recognized as an illness. Yet, as medical knowledge increased, these diseases came to be labelled "hypertension" and "osteoporosis", respectively. Thus, people who used to be classified as healthy are now regarded as ill. As the technology of genetic diagnosis advances, everyone will be found to have defective genes, and no one will ever be described as healthy any more.

John Fry said that health was a fantasy. According to him, "health is a rare subjective state of mind and even more rare objective physical state". Thanks to this fantasy, he claimed, expectations of health care would grow enormously, and medical expenditures would increase forever.

Fry summarized the problems of today's health care in the form of "insoluble equation of health care". He said:

.... our wants always will be greater than our needs, which always will be greater than our available resources.

If this insoluble equation is to be believed, then we should pursue efficient and fair management within a limited medical budget.

## 5. Medical technology increases inequality

As medical technology becomes more costly, access to health care depends on whether patients can afford it. This is an issue that cannot be neglected from an ethical standpoint. Thus, as medical technology developed enormously in the second half of the twentieth century, health insurance systems were introduced in various countries. At the same time, health care no longer remained a matter between physicians and patients, but an important political issue.

As medical technology advances, this issue will become more and more serious. Today's health care problems in Japan appear to lie in this context.

## **Health Care in the Twenty-First** Century

## 1. Basic ideas of twenty-first century health care

The second half of the twentieth century was a period when traditional care-based health care shifted to cure-based health care. A different style will be needed in the twenty-first century, and the basic concepts of the twenty-first century health care will be as follows:

- (1) Cure-based health care is reaching its limits, both technologically and financially.
- (2) Care-based health care has been the basis of health care over thousands of years of history.
- (3) Health care in Japan must be reorganized based on the care-based system.
- (4) General practitioners, i.e., specialists in care-based health care, are essential to twenty-first-century health care.

## 2. Measures to cope with the problems of cure-based health care

In cure-based health care, medical technology

is sought to treat patients. But, since inequality has increased with it, we must cope with this problem. In Japan, we have coped with it by means of Universal National Health Insurance.

Nevertheless, the development of medical technology has promoted the condition which John Fry called "the insoluble equation of health care". Accordingly, it has caused medical expenses to increase. As a result, it became difficult to keep health care services fair. This is the source of today's problems in medicine.

We are forced to design a system to provide health care services that is as fair as possible under the conditions of "the insoluble equation of health care". If we fail to cope with it, medical technology will not benefit us, but disappoint patients.

More specifically, we have to cope with the following issues:

- (1) Classifying the demands of patients.
- (2) Accepting a certain degree of inequality.
- (3) Establishing a health care system based on primary care by general practitioners.
- (4) Establishing a qualification system for specialists, including general practitioners.
- (5) Rejecting excessive expectations (or "fantasy") in regard to health care.
- (6) Reviving the concept of care (or "common sense") in health care.

### 3. Index of fair and unfair health care

## (1) Evidence-based medicine (EBM)

In concrete terms, the main issue in today's health care is how to keep health care services fair with limited medical expenditures.

This has been long discussed in the U.K., a leading country in the field of health insurance system. What has resulted in the discussion was the idea of the evidence-based medicine (EBM). As shown by the dean's speech quoted above, the U.K. has a tradition of acknowledging the limitations of medical technology, and viewing its effectiveness critically. This tendency became conspicuous because a new target, i.e., maintaining fair health care services within a limited medical budget, was newly added. For example, Archie Cochrane, famous for the "Cochrane Collaboration", defined his basic concept as follows: "because resources would always be limited, they should be used to provide equitably those forms of health care which had been shown in properly designed evaluations to be effective". In its basic concept, therefore, EBM accepts inequality in medical treatments whose effects have not been proved.

### (2) Numbers needed to treat (NNT)

EBM includes the concept of "number needed to treat" (NNT), i.e., how many patients physicians have to treat to save one. For example, not all hyperlipemia patients develop ischemic heart disease. The fewer patients develop the disease, the higher NNT is. The higher NNT is, the lower the risk that patients develop the disease.

We are at risk of traffic accidents and of various problems related to our life style. If the risk of a particular disease is less than these risks, we can exclude it from the list of the targets of fair health care services.

#### (3) Cost versus benefit

In terms of cost and benefit, we should give priority to inexpensive services as the target of fair health care services, rather than expensive services. The total medical budget decides the extent fair health care services can cover.

### Conclusion

Disease cannot be cured: this is the starting point of health care. Before the first half of the twentieth century, it was technically impossible to cure most disease, but in the second half of the twentieth century it became more or less possible to do it. In turn, financial problems have occurred in today's health care.

When technological aspects matter, the results of treatment depend on patients' luck. When financial aspects matter, however, they depend on patients' economic power. Moreover, while under the capitalistic, or free economy system, everyone has an equal chance

to earn. Since the results are not always equal, differences in income determine accessibility to health care. One might accept one's misfortune, if a matter of luck, but is it acceptable in the same manner if it is a matter of economic

Since developments in medical technology inevitably cause inequality in health care under the capitalistic system, we must design a health care system that will mitigate the inequality as much as possible. At the same time, we must acknowledge that we cannot cure all the diseases. Therefore, we need to revaluate the concept of care as a final solution in health care for some incurable diseases.

Today, the need for informed consent is emphasized as a means of allowing patients to choose remedies independently. However, as Lewis Thomas stated, the explanation to patients is a far more fundamental part of health care.

Accordingly, physicians must be familiar with the disease themselves to be able to explain it to their patients. They need not merely medical knowledge, but a view and perspective based on the concept of care. They must explain to their patients what is happening, and how it is most likely to turn out, with sympathy towards the patients' suffering. They also have to explain how limited medical knowledge and technology are.

Revaluation of general practitioners, i.e., specialists in care-based health care, is essential in the health care system of the twenty-first century.

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