

# Disease Management Reporter in Japan

August 2004 No.2

Asthma is a disease in which symptoms can be controlled, and hospitalization or emergency room visits can be avoided in many cases, by monitoring symptoms using a peak flow meter and taking appropriate medicines daily, mainly inhaled steroids. Many patients with asthma experience daily pain and suffering due to their symptoms. Thus, they are particularly well-suited for voluntary daily self-management of symptoms through education and guidance by physicians and nurses, as compared to patients that suffer from chronic diseases marked by fewer routine symptoms.

Accordingly, in the U.S., asthma is one of the main targets for disease management since improvements such as QOL (quality of life) and reduced medical care costs can be obtained in a relatively short period of time simply by promoting appropriate self-management by patients.

In Japan, there have been pilot projects in which disease management of asthma has been addressed for the same reasons with positive results. In this issue, we will describe one program conducted by payers for their insured members, and another conducted by providers, in this case a group of hospital outpatient clinics.

## DM Systems Inc. Asthma Management Program

DM Systems Inc. (hereinafter referred to as "DMS Inc.") conducted an experimental disease management program (hereinafter referred to as the "management program") among patients with chronic bronchial asthma through the collaboration of two health insurance organizations in eastern and western Japan during the period from February 1 to July 31, 2003. This management program was conducted by the insurers for the purpose of improving QOL (quality of life) of patients, optimizing medical exam processes, and to streamline medical care costs by supporting the patients' daily disease self-management.

DMS Inc. outlined and announced results of the management program trial in a report titled "Health Management Of The Ill – A Trial Insurance Program And Its Assessment For Patients With Chronic Bronchial Asthma" in November, 2003 and reported improvement in peak expiratory flow rates of patients and optimization of medical care costs. Based on the content of this report, as well as an interview with DMS Inc. management, we will describe the DMS Inc. management program.

## Management Program In Patients With Chronic Bronchial Asthma

### 1. Target Patients And Identification Methods

Participants for the management program were recruited from 28,000 insured persons covered by a health insurance organization in eastern Japan (hereinafter referred to as "Health

Insurer A") and 12,000 insured persons of another health insurance organization in western Japan (hereinafter referred to as "Health Insurer B"). The recruiting method was a public announcement to all insured persons of Health Insurer A, whereas a letter of invitation was sent to patients identified through claims review at Health Insurer B. The difference in recruiting methods between the two insurers was due to a difference in the way the insurers defined "equal opportunity" for participation in the selection of the target patients.

Initially, 56 patients with chronic bronchial asthma responded affirmatively (7 patients from Health Insurer A and 49 patients from Health Insurer B), but 4 patients withdrew from the program in the early stages, leaving 52 participants total. Participation was open to all who applied, and all who responded were accepted into the program.

The background of the participating patients was as follows:

Table 1: Patient Background

Mean age: 26.9 years old (standard deviation: 20.7 years old)
28 pediatric patients (18 years old or younger) and 24 adult patients
31 males and 21 females
18 primary insured and 34 covered dependents
Number of encounters potentially for the treatment of asthma (monthly mean number) 0.96 visits (standard deviation: 0.86 visits )

(Source) Prepared by the editorial office based on "Health Management Of The Ill-A Trial Insurance Program And Its Assessment For Patients With Chronic Bronchial Asthma" (2003) by Asthma Health Support Program Office.

## Contents

DM Systems Inc. Asthma Management Program ..... 1

Teijin Pharma Limited Telemedicine System ..... 4

## 2. Disease Management Methods

The management program was established so that patients could evaluate severity and exacerbation factors of asthma themselves by learning zone management practices, mainly the use of a peak flow diary. Two physicians specializing in the fields of adult and pediatric respiratory medicine (university hospital faculty) were asked to oversee the overall management process in patients. Both of these physicians felt that keeping a peak flow diary makes up about half of necessary asthma care.

Additionally, DMS Inc. established the "Asthma Health Support Program Office" (hereinafter referred to as the "Office") as the contact to which patients submitted their peak flow diaries and addressed their inquiries, with DMS Inc. providing administrative support services.

## 3. Disease Management Tools

### (1) Peak Flow Meter, Peak Flow Diary

Patients were asked to measure peak expiratory flow rate every day, record it in their diaries and then submit the diaries to the Office once a week by fax.

### (2) Peak Flow Graph

The peak expiratory flow rates and presence or absence of attacks, etc. submitted by patients were monitored by the Office and a peak flow graph prepared in which asthma management zones was set under the guidance of the specialist physicians. The peak flow graph was sent to the patient usually once every 2 months, or as needed if a matter required immediate attention.

### (3) Educational Literature

An educational pamphlet was issued once a month to boost the patients' knowledge about asthma.

### (4) Monthly Guidance

Individualized patient guidance, based on review of the peak flow graphs by the specialist physicians, was sent to each patient once a month together with the educational pamphlet.

### (5) Patient Survey

A survey was conducted among participants of the management program at the start, middle and completion of the management program, which helped to gauge and confirm patients' knowledge about the disease and changes in symptoms, in addition to measuring patient satisfaction with the management program.

## 4. Communication With Patients

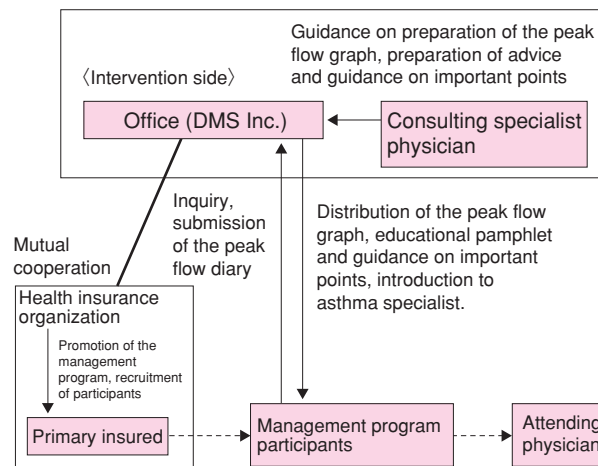
Though feedback to patients was usually conducted by mail, communication by fax was employed for urgent messages. Consideration was made to keep communications paper-based for documentation purposes, whereas phone calls, which were not documented, remained merely a supplementary means for communication.

## 5. Guidance On Receiving Medical Care / Introduction Of Specialist Physicians

In the management program, 3 management zones (green: safe, yellow: caution, red: alert), set based on peak expiratory flow rates and represented on each patient's peak flow graph, were used to prompt both the patient's daily self-management, as well as smooth communication between patient and their primary care physicians. Patients whose peak expiratory flow rates reached the yellow zone received guidance to either seek

immediate medical attention or use specific drugs prescribed by their attending physicians. An asthma specialist was introduced upon request by the patient. The specialists introduced to patients were those using peak flow management among their patients, though DMS Inc. speculates that these physicians are currently few in number in Japan.

Fig. 1: Structure Of The Management Program



(Source) Prepared by the editorial office based on "Health Management Of The Ill-Evaluation Of Insurance Business In Patients With Chronic Bronchial Asthma" (2003) by Asthma Health Support Program Office.

## Results

### 1. Improvement In Peak Expiratory Flow Rates

Changes in peak expiratory flow rates were observed in 12 of 52 participants during the period of continued management from the start of the program. As a result, peak expiratory flow rates gradually increased about 3 months after the program's start and higher peak expiratory flow rates persisted thereafter. The increases observed in the first month after the start of the management program may also be due to improvement in peak flow meter use by previously inexperienced users. But since the rates continued to increase thereafter, DMS Inc. believes that these improvements were primarily due to favorable symptom control attributed to the increased awareness of peak flow and self-management among patients who participated in the program.

### 2. Sustained Use Of The Peak Flow Diary

Table 2 shows the rate at which the peak flow diary was kept for periods of 12 and 24 weeks. DMS Inc. noted the relative difficulty among pediatric patients in maintaining management program discipline, as compared to adults.

Table 2: Peak Flow Diary Use Rates In Pediatric Patients And Adult Patients

	12 weeks	24 weeks
Pediatric patients	63.6%	27.3%
Adult patients	75.0%	56.3%

(Source) Prepared by the editorial office based on "Health Management Of The Ill-A Trial Insurance Program And Its Assessment For Patients With Chronic Bronchial Asthma" (2003) by Asthma Health Support Program Office.

### 3. Improvement In Medical Care Costs

The target encounters chosen to measure changes in medical care costs under the management program were identified by those claims which included: receipt of guidance, such as specialized disease nursing guidance or asthma therapy management, administration of drugs with an indication of “bronchial asthma” for 14 days or more, and those claims including any drug administered by nebulizer as treatment. While excluding medical care costs apparently unrelated to asthma, the target medical care costs were obtained by adding up medical treatment and pharmacy claims. Of the participants in the management program, 24 patients who were skilled in peak flow monitoring (patients who submitted the diary for 4 weeks or longer) were assigned to the management group, and 62 asthma patients who are on record as having received asthma drug prescriptions or treatment during the selection process were randomly assigned to the control group.

Mean medical care costs in February and in the period from March to June were compared between the management and control groups. Assigning medical care costs in February the value of 100, medical care costs in the period from March to June decreased to 67 in the management group, while that in the control group increased to 115. However, the difference was not statistically significant in either group ( $r = 0.05$ ). DMS Inc. intends to run a comparison between the management group and control group using a larger sample size and longer observation period, and to continue to observe changes in medical care costs.

Under the management program, DMS Inc. called for medical examination in the early stages of exacerbation and inferred that this resulted in decreased frequency of future medical examinations and greater optimization of medical care costs.

### 4. Patient Satisfaction

Based on the result of an interim questionnaire related to patient satisfaction (answered by 19 of 52 patients), 94% of the patients said the program was “very useful” or “moderately useful”.

DMS Inc. believes it is noteworthy that 84% of patients answered “able to grasp own physical condition” by participation in the management program. Moreover, even though no “medical treatment” was conducted in the program and the objective was only to teach self-management, not improve physical condition, 26% of patients answered that their “physical condition improved” by participating.

## Issues Raised By The Trial

### 1. Continuation Rate In Patients

DMS Inc. pointed out that about half of the patients who expressed their intention to participate in the management program did not continue. Among those who suspended their measurement of peak expiratory flow rates, there were many who stopped once their symptoms grew stable. Conversely, patients who could not measure peak expiratory flow rates due to poor symptoms initially, but began to measure peak expiratory flow rates as symptoms improved, were also observed.

DMS Inc. feels it is necessary to develop a system that can remove the patient’s sense of burden and easily be started again any time by patients who may have suspended the program for a period.

### 2. Management Of Pediatric Patients

While many family members of pediatric patients in the program said that measurement of peak expiratory flow rates cannot be initiated because of the natural reluctance in children, DMS Inc. is developing a new pediatric patient-focused management program. As a part of this, DMS Inc. plans to devise and conduct a new monitoring test for pediatric patients for introduction in July this year.

### 3. Other Issues

DMS Inc. points out the following issues for improvement based on the initial results reported herein:

- Improvement of management technique and elaboration of process management in the program
- Improvement in participation and enrollment rates in the management program
- Grouping of patients by good/bad control and ideas for promoting increased participation

## Direction Of Future Business Deployment

The above trial was conducted using the specified tools for a period of 6 months with all costs underwritten by DMS Inc.

Under the current business model, DMS Inc. provides a fixed content program for a specific contract period to health insurers and receives monthly per patient fees of several thousand yen from the insurers. DMS Inc. believes that due to the small participant number, this is not presently a profitable business endeavor. However, the company’s first priority rests with confirmation of whether the program works smoothly or not, followed by whether the program can find wide application.

DMS Inc. intends to provide this management program flexibly depending on health insurers’ future needs. As one example, DMS Inc. is studying a system in which intensive management is conducted for 3 months after the start of the program as a “core period”, with patient participation voluntary thereafter. This is based on the view that if self-management is firmly established in the first 3 months, sustained management should become easier. However, periodic follow-up is likely to be needed, even after completion of the management program, to reinforce self-management habits, since some patients are apt to abandon them once the program is completed.

In addition to a set monthly fee per patient pricing model, others, such as one determined by the resources actually used by the patient, are also under consideration. For some health insurers, a model in which part of the price is borne by the participating patient may also be introduced.

In terms of target diseases for the management program, though asthma was employed because results can be obtained rapidly, DMS Inc. is preparing the introduction of additional management programs for diabetes mellitus and hypertension in the future. These will also be based on medical guidelines, and approaches will likely differ from that for asthma.

DMS Inc. points out that challenges in commercialization, include how the company, which operates the management program but does not conduct “medical treatment”, can maintain the appropriate distance from medical institutions, and also what kinds of incentives can be devised to improve continued compliance rates among patients.

## Teijin Pharma Limited Telemedicine System

Teijin Pharma Limited (hereinafter referred to as “Teijin Pharma”) devised an “asthma telemedicine system”. This system is a remote medical care system for the purpose of supporting patient self-management, optimizing therapy by continuous individual instruction to patients with a nurse via phone based on accurate assessment of the daily pulmonary function of asthma patients at home, and the prevention of attacks.

Since 1996 Teijin Pharma has conducted clinical studies to examine the utility of this system and has reported such effects as decreases in hospitalization, utilization of overtime emergency outpatient units, and risk factors for asthma-related death. Decreases in hospitalization and utilization of after hours emergency outpatient units may lead to lower medical costs for asthma therapy.

The following describes the effort by Teijin Pharma based on 3 published articles concerning the clinical study results, combined with information obtained through an interview with Teijin Pharma.<sup>1</sup>

### Asthma Telemedicine System

The asthma telemedicine system targets patients with potentially high risk of serious asthma attacks requiring hospitalization. It is composed of: an electronic peak flow meter (PFM) capable of recording and transmitting data for monitoring daily pulmonary function, a central patient database, and a nurse who provides individual instruction to patients (hereinafter referred to as the telemedicine nurse). The telemedicine nurse provides over-the-phone guidance based on the physician's instruction while referring to the central patient database.

#### 1. AirWatch

The electronic peak flow meter “AirWatch” enabling measurement of peak expiratory flow rate (PEF) and forced expiratory volume in one second (FEV<sub>1.0</sub>), is capable of recording data of up to 500 readings (max.) and transmits data to the central patient database via modem connected to a standard phone line. By registering the highest PEF value of patients, “AirWatch” also displays the measured PEF in a graph distinguished by 3 colored zones of green, yellow and red for zone control described later.

#### 2. Central Patient Database

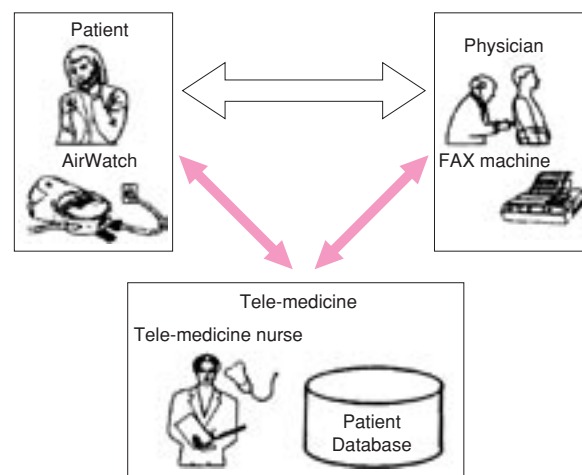
The data transmitted through AirWatch is accumulated in the central patient database and analyzed. Data sent by the patient is automatically registered and a report containing a graph demonstrating PEF for 1 month, FEV<sub>1.0</sub> and the diurnal variation rate of PEF is periodically sent to a physician by fax. Physicians can access the data of their patients at any time over the phone using an automatic response function.

#### 3. Telemedicine Nurse

The telemedicine nurse has professional knowledge about asthma based on guidelines and has received training for instruction of asthma patients. The telemedicine nurse responds to calls from patients on a round-the-clock basis in the

telemedicine center and conducts individual instruction to patients by phone, while referring to individual patient data recorded in the central patient database.

Fig. 2: The Asthma Telemedicine System



(Source) Adachi, M. et al. "Effect of Telemedicine System on Asthma Death Risk Factors" (The Allergy in Practice 22 (1) 2002)

### Operation Of The Asthma Telemedicine System

Management and medical treatment of asthma utilizing the asthma telemedicine system are based on a zone system. With this system, patient condition is classified into one of 3 zones: green (safe), yellow (caution) or red (alert) according to measured PEF based on the highest PEF value recorded. Self-management, such as appropriate daily medication use, as well as clinic medical treatment, are conducted in accordance with each zone.

System operations consist of: preparation of a plan for zone control at the time of introduction of the program, initial orientation of patients, therapy and instruction of patients based on monitoring of pulmonary function, and feedback and confirmation of the effectiveness of therapy and patient instructions. Through repeated monitoring, and feedback on therapy and patient instruction, the system tries to support optimization of therapy and patient self-management.

In the self-management portion, such as daily measurement of PEF and appropriate drug intake, it is important in the operation of this system to set appropriate (i.e. not too high) goals for each patient and for the telemedicine nurse to carefully conduct follow-up and provide feedback on results.

#### 1. Initiating the Program

The attending physician determines a patient's highest PEF value, prepares a plan for zone control and gives the telemedicine nurse direction on the education of patients. The telemedicine nurse then provides the patient with introductory training including an explanation of the asthma telemedicine system, instruction on how to use a metered dose inhaler (MDI), or powder inhaler, and the AirWatch system, and instruction on drugs, along with other supplemental instruction

as directed by the attending physician. A self-management regime is evaluated for each patient and an asthma nursing plan is prepared based on the evaluation of patients, the attending physician's directions for the patient's individual education, and the plan for zone control.

## 2. Self-management

Patients measure PEF (and FEV<sub>1.0</sub>) at least twice a day using AirWatch and transmit the data to the telemedicine center once a week. Patients also undertake self-management based on the plan for zone control by referring to a graph of PEF displaying green, yellow or red color on the AirWatch. If a patient is unsure about what to do, he/she can receive instruction from the telemedicine nurse by phone.

## 3. Patient Instruction

The telemedicine nurse provides patients with continuous instruction mainly by phone in accordance with the nursing plan based on patient data and providing patients with support on self-management activities. The telemedicine nurse gives instruction over the phone whenever data is transmitted or on the scheduled day of data transmission. Daily instruction is conducted, however, in patients whose PEF is in the yellow zone until it improves to the green zone. In the event that a problem is believed to exist in the procedure for inhalation by MDI or the powder inhaler, or in the method for use of the AirWatch, etc., more frequent assessment may be conducted as appropriate. The telemedicine nurse submits a monthly report to the attending physician.

## 4. Optimization Of Therapy

At the time of outpatient visits, the attending physician modifies therapy such as drug prescriptions, the zone control plan and highest PEF value based on the data transmitted from the patient. Analysis of these data and the report from the telemedicine nurse helps the physician to optimize therapy in the control plan. The telemedicine nurse then reviews and adjusts the nursing plan accordingly.

## Research Results To Date

Based on results of remote medical care for asthma in the U.S., Teijin Pharma proposed that significant therapeutic effects through daily monitoring and individual instruction over the telephone could also be obtained in Japan, and introduced AirWatch from ENACT Co., Ltd. in U.S. in 1995. Research has been conducted from 1996 in the first group of 16 patients and the results of numerous clinical studies thereafter have been published in a series of articles.

### 1. Research Setting

The research was conducted mainly by Professor Mitsuru Adachi, First Department of Internal Medicine, Showa University, and by the physicians of various hospitals participating in the clinical studies. Teijin Pharma provided an AirWatch system for each patient and operated the central patient database and telemedicine center.

### 2. Research Results

In a study conducted for about 1 year from December 1996 to December 1997, with 6-month observation periods, patients

were identified who had a potentially high risk of hospitalization and who had frequently visited emergency outpatient units in the past one-year period at any of the 4 hospitals participating in the research, including Showa University, First Department of Internal Medicine. The study was conducted by a random, non-blinded, comparative control method in a total of 50 patients including 24 patients in the study group who received therapy by the asthma telemedicine system and 26 patients in the control group who received conventional outpatient therapy. Among the adult asthma patient candidates, those who were considered to have any factors interfering with the performance of the research, such as COPD complications or heart disease, were excluded. Written consent was obtained from patients participating in the research.

In this study, the two groups were compared and evaluated with regard to: the number of visits to emergency outpatient units, the number of hospitalizations, and improvement of activities of daily living (ADL). Patient behavior in monitoring their own pulmonary function, changes in PEF and factors behind improvements in PEF were evaluated only in the study group. The number of visits to emergency outpatient units significantly decreased in the study group when comparing the number of visits in the year prior to the study with the number of visits in the year following the study. For improvement of ADL, results of a 10-item ADL questionnaire revealed significant improvement among in the study group. The evaluations of patient self-monitoring of pulmonary function and changes in PEF revealed significant improvement in PEF among the study group patients along with favorable self-monitoring behavior.

Subsequently, another one-year study was conducted from August 1998 to August 1999, with a 6-month observation period, using a randomized, non-blinded comparative control method with a total of 75 patients, including 37 patients in the study group and 38 patients in the control group and a greater number of participating hospitals (i.e. 13). Subjects were adult asthma patients with a history of visiting after hours emergency outpatient units 3 or more times in the past one-year period despite receiving sufficient inhalation steroid therapy. Written consent was obtained from the patients.

This study also examined the compliance status of patients for activities such as peak flow meter measurement and drug intake within the study and control groups, in addition to the number of emergency outpatient unit visits, the number of hospitalizations and changes in PEF that were evaluated in the previous study. Quality of life (QOL) was also evaluated using a "QOL Questionnaire On Bronchial Asthma" prepared by a research group of the Ministry of Health, Labour and Welfare.

As the result of the intervention, the number of hospitalizations and number of emergency outpatient unit visits were significantly smaller in the study group. Moreover, PEF was significantly improved only in the study group. Peak flow meter use, too, was significantly higher in the study group. Significant improvement in QOL was observed only in the study group, while no significant difference was observed in drug intake between the two groups.

The study also discussed the economic effect of decreasing hospitalizations or emergency outpatient unit visits, and it was reported that the asthma telemedicine system saved 459,000 yen in direct costs (i.e. medical care costs) and 298,000 yen in indirect costs (i.e. loss of productivity by absenteeism at work) per patient annually.

With these past two research studies having shown the asthma telemedicine system to contribute to fewer hospitalizations and emergency outpatient unit visits, the effect of improving risk factors for asthma death was evaluated in another one-year study conducted from October 2000 to August 2001, with a 6-month observation period.

In this study, subjects were patients at high risk of asthma death, and with a history of hospitalizations or emergency outpatient unit visits due to asthma attacks in the past one-year period despite receiving sufficient inhalation steroid therapy. Written consent was obtained from the patients. Conventional therapy combined with the telemedicine system was conducted in all 21 patients and evaluation results scored for 8 items defined as risk factors for asthma death by the "Subcommittee on Asthma Death, the Japanese Society of Allergology," after which differences between the score before the start of the study and the score after completion of the study were compared.<sup>ii</sup>

Out of the 8 risk factors for asthma death, marked improvement was observed in the items: "lack of patients' recognition" and "lack of patient education by physician". The number of emergency outpatient unit visits at night significantly decreased in the item: "irregular and nighttime unit visits".

## Future Tasks And Deployment

### 1. Issues In The Operational Scheme Of The Asthma Telemedicine System

In the clinical studies, because certain professional knowledge and instructional skills are required by the telemedicine nurse who conducts instruction of patients, and consistent action on at least some level is required in interacting among all patients, operation of the telemedicine center, including training of nurses, has been conducted by Teijin Pharma. However, upon considering the scope of work that can practically be conducted by a private company, Teijin Pharma is examining a future business scheme in which they will conduct operation of only the central patient database and utilize nurses at each hospital to oversee instruction of patients.

### 2. Issues Regarding Medical Service Fees

Based on the results of the clinical studies, Teijin Pharma has demonstrated the utility of the asthma telemedicine system such as its clinical and economic efficacy (in terms of reduction of utilization of hospitalization and emergency outpatient visits, as well as improvements in productivity) in management and therapy of asthma. However, since Teijin Pharma's business model includes patients visiting medical institutions for care on their own, they recognize as a problem for future commercialization that medical service fees for management and therapy of patients utilizing the telemedicine system are not yet reimbursable to medical institutions by the public health insurance system.<sup>iii</sup>

Because the system's efficacy has been, to at least some degree, confirmed additional clinical studies have been suspended for the moment. However, some asthma patients who utilized the system in clinical studies have strongly requested continuation of the service. In a survey taken of patients after the clinical study, many answered that an acceptable co-payment for utilizing this system would be about 5,000 to 6,000 yen per month and Teijin Pharma thinks patient demand for this system would be large.

At present, Teijin Pharma is at the stage of examining new deployment of the system in medical practice so an evaluation of medical service fees can also be conducted.

- i: Adachi, M. et al. "Tele-medicine System for High-risk Asthmatic Patients" (Japanese Journal of Allergology 48 (7), 1999), Adachi, M. et al. "Hospitalization Reduction by Asthma Tele-medicine System" (Japanese Journal of Allergology 49 (1), 2000), Adachi, M. et al. "Effect of Telemedicine System on Asthma Death Risk Factors" (The Allergy in Practice 22 (1) 2002)
- ii: 8 items: "lack of patient recognition", "delay in receiving medical examination", "lack of patient education by physician", "inappropriate therapy by physician", "irregular and nighttime unit visits", "priority in works and study", "personality of patients" and "not observing inhalation or drug intake regime"
- iii: At present, in the case where a medical institution supplies patients with a PFM and a diary for peak flow measurement, etc. and conducts management of therapy based on the plan, the asthma therapy management fee paid to the institution by health insurance is calculated and paid monthly (750 yen in the first month and 250 yen in the second month and thereafter).

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#### Editorial Department of Disease Management Reporter in Japan

Attention: Mr. Naonori Yakura  
Mailing Address: Sompo Japan Research Institute Inc.  
1-26-1 Nishishinjuku, Shinjuku-ku, Tokyo, 160-8338, Japan  
E-mail: dmr@sj-ri.co.jp  
Tel: +81-3-3348-6147  
FAX: +81-3-3348-6146

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"Sompo Japan Research Institute Inc. [Disease Management Reporter in Japan No. 2] (August, 2004)"

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