Establishment of Blood Glucose Monitoring System Using the Internet

HYUK-SANG KWON, MD[1]
JAE-HYOUNG CHO, MD[1]
HEE-SOO KIM, MD[1]
BOK-RE SONG, RN[2]
SEUNG-HYUN KO, MD, PHD[1]
JUNG-MIN LEE, MD[1]
SUNG-RAE KIM, MD, PHD[1]
SANG-AH CHANG, MD, PHD[1]
HEE-SEUNG KIM, RN, PHD[2]
BONG-YUN CHA, MD, PHD[1]
KWANG-WOO LEE, MD, PHD[1]
HO-YOUNG SON, MD, PHD[1]
JIN-HEE LEE, MS[3]
WON-CHUL LEE, MD, PHD[3]
KUN-HO YOON, MD, PHD[1]

OBJECTIVE — The Internet is used worldwide as a communication tool. To improve the quality of diabetes control, we investigated the effectiveness of an Internet-based blood glucose monitoring system (IBGMS) on controlling the changes in HbA_{1c} levels.

RESEARCH DESIGN AND METHODS — We conducted a randomized clinical trial involving 110 patients who visited the outpatient clinic at the Kangnam St. Mary's Hospital for 3 months. The study subjects were treated with IBGMS for 12 weeks, and the control group received the usual outpatient management over the same period. HbA_{1c} and other laboratory tests were performed twice, once at the beginning of the study and again at the end of the study.

RESULTS — The test results from the beginning of the study established that there were no significant differences between the two groups with respect to age, sex, diabetes duration, BMI, blood pressure, HbA_{1c}, and other laboratory data. On follow-up examination 12 weeks later, HbA_{1c} levels were significantly decreased from 7.59 to 6.94% within the intervention group ($P < 0.001$). At the end of the study, HbA_{1c} levels in the intervention group were significantly lower than in the control group after adjusting the baseline HbA_{1c} (6.94 vs. 7.62%; $P < 0.001$, respectively). Among patients with baseline HbA_{1c} <7.0%, the patients in the intervention group had lower HbA_{1c} than those in the control group (6.38 vs. 6.99%; $P < 0.05$). Among the patients with a baseline HbA_{1c} ≥7.0%, the difference between the two groups appeared more obvious: HbA_{1c} levels at the end of the study were 8.12%.

CONCLUSIONS — This new IBGMS resulted in a significant reduction of HbA_{1c} during the study period. We propose that this IBGMS be used as a method for improving diabetes control.

Diabetes Care 27:478–483, 2004

The importance of tight blood glucose control for the subsequent prevention of diabetes complication is well established (1,2). In addition, improving glucose control will also reduce the enormous economic burden associated with the disease (3,4). Therefore, various strategies for diabetes management have been designed to improve the quality and efficiency of care for patients with diabetes. To promote adherence for patients and providers to follow practical guidelines, studies have been carried out to establish educational programs for patients and health care workers. Other studies, including giving feedback to the providers as well as programs that remind providers and their patients of these guidelines, have been experimented with (5–8). Recently, a small number of computer-based or electronic management systems have been reported to improve diabetes care (9–11). However, many barriers are recognized in providing this care system into the community health care system (12,13). Diabetes care means managing vulnerable patients with chronic disease consistently in the outpatient setting. Chin et al. (13) reported that providers in health care centers indicated a need to enhance behavioral changes in diabetic patients to improve the health care delivery system. Reforms improving the affordability, accessibility, and efficiency of care are also required.

Therefore, a new patient communication system that can facilitate the patient's behavioral change and allow accessible, efficient, and continued medical advice and prescriptions is needed. The Internet has established itself as a worldwide communication system that allows a person to contact other people anywhere and anytime and exchange information directly online. To develop a more efficient delivery system for diabetes care, we designed a new diabetes management model using the Internet. By applying this new method, a diabetic patient can contact physicians online, provide information to physicians, and receive suitable recommendations from the physicians unhindered by location or time.

In this study, we compared diabetic patients who used the Internet-based blood glucose monitoring system (IBGMS) for 12 weeks and patients who used the conventional outpatient management system over the same period.

RESERCH DESIGN AND METHODS

Study population

Men and women diagnosed with type 2 diabetes for ≥1 year were recruited from the outpatient clinic of Kangnam St. Mary's Hospital Diabetes Center between May and August 200l. All enrolled participants in this study had Internet access in

From the [1]Department of Internal Medicine, The Catholic University of Korea, Seoul, Korea; the [2]College of Nursing, The Catholic University of Korea, Seoul, Korea; and the [3]Department of Preventive Medicine, The Catholic University of Korea, Seoul, Korea.

Address correspondence and reprint requests to Kun-Ho Yoon, MD, Division of Endocrinology and Metabolism, Department of Internal Medicine, The Catholic University of Korea, Kangnam St. Mary's Hospital, 505 Banpo-Dong, Seocho-Ku Seoul, Korea, 137-701. E-mail: yoonk@catholic.ac.kr.

Received for publication 4 April 2003 and accepted in revised form 25 September 2003.

Abbreviations: IBGMS, Internet-based blood glucose monitoring system.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

their homes for this specialized web-based diabetes management system and were ≥30 years of age. Patients were excluded if they had any significant diseases that were likely to affect the outcome and compliance of this study. Such diseases or conditions included heart failure, hepatic dysfunction, renal insufficiency with a creatinine level >1.5 mg/dl, and use of insulin pumps. Patients who had any history of participating in other programs that provided any information or education for diabetes management from specific websites other than ours were also excluded. Among the 180 patients asked to participate in the study, 110 patients agreed and were randomly divided into the intervention and control groups, each with 55 patients. Fifty-one patients in the intervention group and 50 patients in the control group completed the protocol over a 12-week period. Written informed consent was obtained from each participant.

Randomization and study design

Upon enrollment, each participant was assigned to either the intervention or control group using adaptive randomization (14) after receiving the written informed consent. Ethics committee approval was obtained from our institution and the review board of Korea Institution for Social and Health Affairs. Patients in the intervention group visited Kangnam St. Mary's Hospital Diabetes Center in September 2001. At the initial interview, weight, height, and blood pressures were checked. Laboratory tests including HbA_{1c}, which was measured by high-performance liquid chromatography (Variant II HbA_{1c} analyzer; Bio-Rad, Montreal, Quebec, Canada), fasting plasma glucose, serum cholesterol, triglyceride, HDL, blood urea nitrogen, and creatinine levels were performed. Patients in the intervention group were taught how to use the Internet-based system and used the IBGMS for 12 weeks without outpatient management visits. After 12 weeks, in December 2001, subjects revisited the diabetes center, and the same laboratory tests were carried out. Patients in the control group were unaware of any knowledge regarding the new diabetes management system. They visited the diabetes center monthly and received their usual outpatient treatment from their physicians during the study period.

The Internet-based system

Patients in the intervention group contacted our website (www.biodang.com) and logged on whenever it was convenient for them. Participants in our study could contact our website at any place where Internet access was possible, but most participants accessed the website in their own homes. The patients sent information about their self-monitored blood glucose levels before and after eating (fasting and postprandial) and drug information including the types and dosages of insulin and oral antidiabetic medication used for diabetes control. In addition, when necessary, changes in their blood pressure or weight and any questions or detailed information the patient may have (for example, diet, exercise, hypoglycemic event, or other factors that can cause changes in the glucose level) were also recorded.

Figure 1 shows the screen viewed by the patients and the physicians. Patients were able to see the recommendations from their physicians as well as the laboratory data. Physicians, meanwhile, were able to inspect the information for each of their patients, including the blood glucose levels, medication, and other details provided by the patients. In addition, physicians could also review basic personal data, including past history, family history, smoking habits, anthropometry, BMI, blood pressure, and baseline laboratory data. After integrating the above given facts, the physicians sent optimal recommendations back to each patient.

For this program, our staff consisted of three endocrinology specialists (one professor and two fellows), three nurses, two dietitians, and four programmers. For the intervention group, two endocrinology fellows checked in with the system daily. They analyzed all uploaded blood glucose data or questions regarding medication and hypoglycemic episodes and sent recommendations to the patients in the intervention group according to the diabetes management guidelines based on "Korean Staged Diabetes Management Guidelines." But, we did not adopt any automated algorithm in this whole process of our study. If there was any need to change the patient's medication or dosage, the two endocrinology fellows referred the case to the professor. Three nurses mainly commented upon lifestyle modification, including exercise, and the two dietitians supplied individually modified medical nutrition therapy. All of the responses from the nurses and dietitians were also monitored by medical staff. The medical staff (two fellows and one professor) had meetings regularly to develop the appropriate individual recommendations.

If the patient in the intervention group did not forward a blood glucose level for >1 week, a warning message was sent. If individuals continued to not record their glucose levels for >3 consecutive weeks despite such warning messages, the patients were withdrawn from the intervention group. The telephone was not used for follow-up, and our participants were only contacted via the Internet through their own individual electronic chart system.

Participants in the control group met the professor two or three times during the 12 weeks. As customary in our outpatient clinic for diabetic patients, when the patients in the control group visited our center, they were provided recommendations about medication, medication dosage, lifestyle modification, and so on from the endocrinology specialist (professor, not fellows). When the doctor chose to consult for special education or if the patient wished, the dietitian or nurse came to aid with a more individualized and detailed information for lifestyle modification.

Analysis and statistics

The sample size was sufficient to provide a power of 80% to detect a 10% (absolute value 0.75%, estimated SD 1.0) change in HbA_{1c} at the 5% level of significance, based on our previously unpublished data. We assumed a dropout rate of 10% from this study. Statistical analysis was performed using SAS (version 8.12). All results were expressed as means ± SD. To assess the significant changes of the variables observed within each cohort between the baseline and follow-up, we used the paired sample Student's *t* test. Comparison between the patients who were treated with the new management system using the Internet and those who had routine outpatient diabetes care delivered by physicians in the diabetes clinic was based on the independent Student's *t* test. HbA_{1c} was treated as the major outcome variable. The significance of difference between the intervention and control groups was evaluated by ANCOVA that tested changes between the two groups from the preintervention to

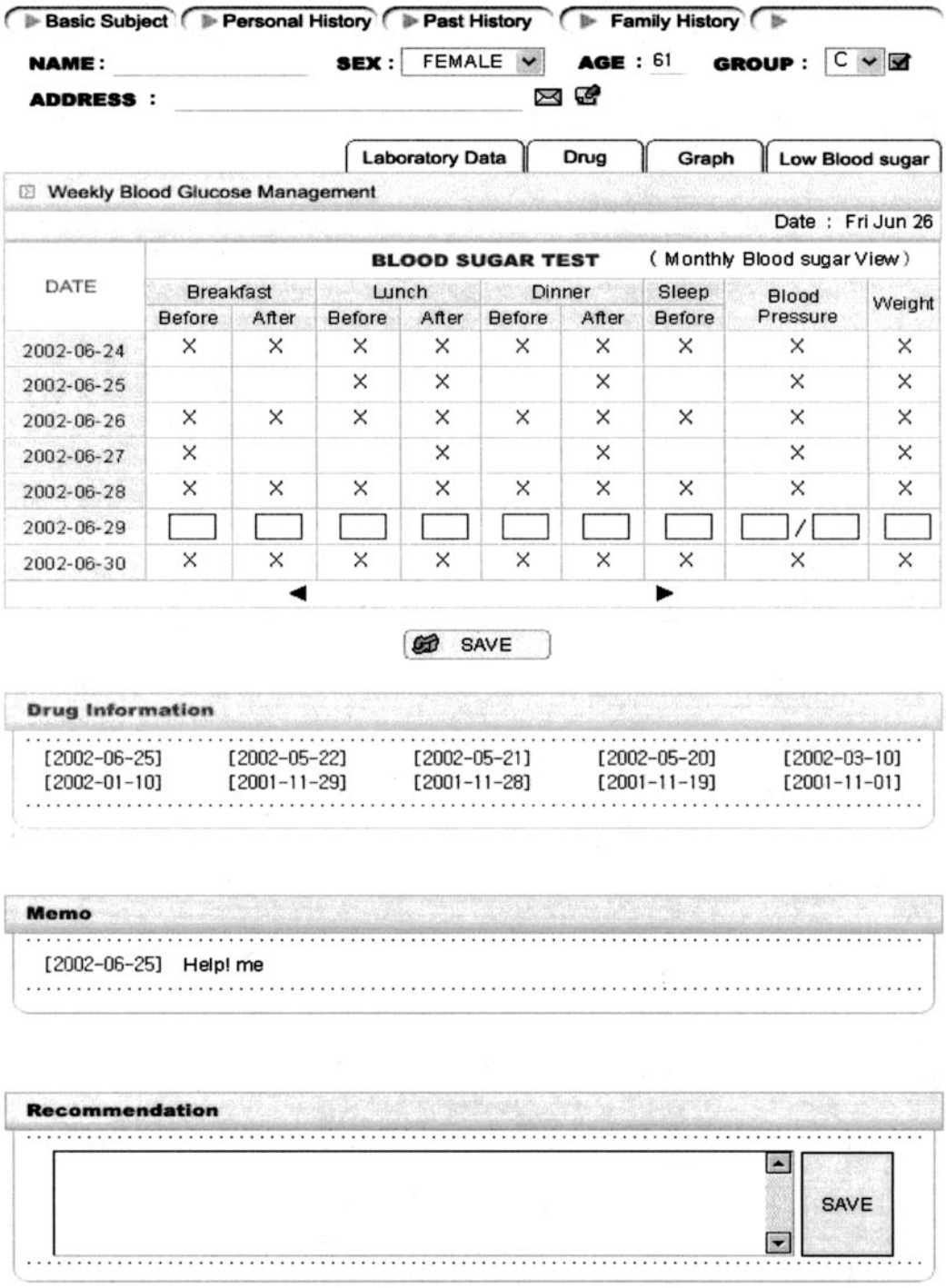

Figure 1—*Screen viewed by patients and physicians on the website (www.biodang.com) for diabetes management. Basic profile, past history, family history, and laboratory data are shown on the* top. *Self-monitored blood glucose levels are shown* (middle)*, which are recorded as fasting or postprandial (breakfast, lunch, and dinner). Drug information, notes from the patients, and recommendations from the physicians are shown at the* bottom.

postintervention period while controlling the different baseline values on the outcomes of interest. A P value <0.05 was considered to be statistically significant.

RESULTS — In this study, we recruited participants who were able to access the Internet in their homes for this specialized web-based diabetes management system all from our outpatient clinic of Kangnam St. Mary's hospital through the hospital bulletin board. Among 180 patients who expressed their intention to

Table 1—*Clinical characteristics and baseline laboratory data of the control and intervention groups*

Characteristics	Control group	Intervention group	*P*
n	55	55	
Age (years)	54.7 ± 9.4	53.5 ± 8.8	0.507
Sex (M/F)	32/18	35/16	0.623
BMI (kg/m^2)	23.9 ± 3.1	24.4 ± 3.4	0.493
Diabetes duration (years)	6.6 ± 5.7	7.0 ± 6.3	0.751
Diagnosis of hypertension (*n*)	13	17	0.420
Systolic blood pressure (mmHg)	128.5 ± 17.0	124.7 ± 15.8	0.999
Diastolic blood pressure (mmHg)	77.0 ± 9.7	77.5 ± 8.7	0.254
HbA_{1c} (%)	7.19 ± 1.17	7.59 ± 1.43	0.133
Fasting plasma glucose (mg/dl)	136.4 ± 32.3	136.0 ± 35.0	0.826
Total cholesterol (mg/dl)	180.9 ± 28.9	188.8 ± 30.10	0.231
Triglyceride (mg/dl)	136.8 ± 94.0	154.7 ± 98.1	0.358
HDL (mg/dl)	47.9 ± 13.2	47.7 ± 11.0	0.925
Blood urea nitrogen (mg/dl)	16.2 ± 5.2	15.2 ± 3.8	0.393
Creatinine (mg/dl)	0.9 ± 0.3	0.9 ± 0.2	0.498

Data are means ± SD.

participate in our study, 70 patients were excluded due to several reasons. Seventeen patients were excluded due to significant diseases that could affect the study outcome, and 25 patients were excluded due to history of participation in other web-based management programs. Twenty-eight patients refused to participate in our study after learning that our program includes frequent access to our homepage and randomization into the intervention and control group.

Of 110 patients who participated in this study, 101 (91.8%) completed the final clinical examination. The dropout rates were very similar between the intervention and control group. Of the 55 patients randomly selected to belong to the intervention group, two patients were withdrawn for not following the study protocol. Two more patients were also withdrawn from the study because they did not revisit the diabetes center after 12 weeks. Five patients in the control group were excluded for not revisiting the diabetes center. Therefore, we report data from the 51 patients in the intervention group and 50 patients in the control group who remained to complete the study protocol.

The clinical characteristics and baseline laboratory data are shown in Table 1. There were no significant differences between the two groups with respect to age, BMI, diabetes duration, and glucose control methods or in terms of laboratory data, including baseline HbA_{1c}, fasting plasma glucose, total cholesterol, triglyceride, HDL, blood urea nitrogen, and creatinine. There were, respectively, 13 and 17 patients with a diagnosis of hypertension in the control group and intervention group.

Before starting this program, we recommended our patients in both groups to check their blood glucose ≥3 days a week (one to three times a day) including postprandial level according to the level of glycemic control. We also provided the same number of glucose test strips to both groups. During the study period, patients in the intervention group recorded their glucose level one to three times per day for an average of 20 days a month, whereas the patients in the control group visited the diabetes center two or three times in 12 weeks. The average frequency of blood glucose monitoring during study period in intervention group was 71.5 ± 36.2 and 38.1 ± 24.8 in control group.

The mean number of logon times per each patient during the study period was 42.3 ± 32.2/patient in the intervention group. Only participants in the intervention group mailed their questions to their health care providers and received a reply. The mean number of questions posted by patients was 13.5 ± 14.7/patient during

Table 2—*Detailed list of questions asked via the Internet homepage by the patients in the intervention group to their health care providers*

Category	Number of questions	Percentage in total questions*
Nutritional		
Total	18	10.8
Exercise		
Total	6	3.6
Diabetic complications		
Total	12	7.2
Neuropathy	5	
Coronary artery disease	4	
Retinopathy	1	
Cerebrovascular disease	1	
Erectile dysfunction	1	
Hypoglycemia		
Total	7	4.2
Others		
Total	18	10.8
Hyperglycemia	4	
Side effects from medication	3	
Home glucose monitoring	3	
Oral antidiabetics	2	
Glucose analyzer	2	
Insulin injection	1	
Osteoporosis	1	
Postmenopausal symptom	1	
Glycated hemoglobin	1	

*Total number of questions was 167.

Table 3—*Changes in the laboratory data from the baseline at the 12-week follow-up examination*

	Control group data Δ from baseline	Intervention group data Δ from baseline
n	50	51
HbA_{1c} (%)	+0.33	−0.54*
Fasting blood glucose (mg/dl)	+9.34	+7.29
Total cholesterol (mg/dl)	+7.30	−3.33
Triglyceride (mg/dl)	+13.5	−19.5
HDL cholesterol (mg/dl)	+2.70*	+2.91
LDL cholesterol (mg/dl)	+1.88	−1.93

*Significant difference from the baseline values ($P < 0.05$).

the study period. A detailed list of questions posted by patients to their doctors is summarized in Table 2. According to the study protocol, participants in the intervention group sent their blood glucose monitoring data at least once a week. Among the participants in the intervention group, 23 patients got warning messages from their providers via e-mail. A final warning message notifying withdrawal from our program was sent out to two patients when 3 weeks passed by without any further blood glucose data feedback; their participation in the study was discontinued.

On the 12-week follow-up examination, HbA_{1c} levels were significantly decreased from 7.59 to 6.94% within the intervention group ($P < 0.001$). Within the control group, HDL cholesterol changed from 47.9 to 50.6 mg/dl ($P < 0.05$). There were no significant changes in other variables, such as fasting blood glucose, total cholesterol, triglyceride, and LDL cholesterol within the groups (Table 3). At the end of this study, HbA_{1c} levels in the intervention group were significantly lower than in the control group after adjusting the baseline HbA_{1c}. The level was 7.59 and 6.94% in the control and intervention groups, respectively. To assess whether the effect of the intervention varied according to the degree of HbA_{1c} at baseline, the subjects were then separated into two groups by baseline HbA_{1c}. The cutoff point was 7%, which is the diabetic patient's treatment target. Among the patients with baseline HbA_{1c} <7.0%, the patients in the intervention group had lower HbA_{1c} than those in the control group ($P < 0.05$). Interestingly, among the patients with a baseline HbA_{1c} ≥7.0%, the difference between two groups appeared more noticeably. HbA_{1c} levels were 7.38 and 8.12% ($P < 0.001$) in the intervention and control groups, respectively, which showed that the control of HbA_{1c} was enhanced in the intervention group (Table 4).

CONCLUSIONS — In this study, a new delivery system of diabetic control using the Internet has revealed great efficacy in glucose control. The intervention group showed a marked decrease in HbA_{1c} levels after 12 weeks of follow-up versus the baseline levels, whereas the control group showed slightly increased HbA_{1c} levels after the same period. This result has important clinical implications because the medical service for diabetic patients provided via the Internet is now increasing, whereas the efficacy of the Internet service for glucose control has not been evaluated extensively (15–18).

Many reasons exist for the improved glucose control in the intervention group. First, the patients have more frequent contact with the physicians than those in the control group. In addition, the patients in the intervention group received medical advice according to their most recent data, confirming their current state. These factors may have stimulated and motivated the patients to control glucose levels more enthusiastically. There have been some suggestions that the Internet may be a useful method for encouraging patients before (19,20). We also confirmed that patients with a baseline HbA_{1c} <7.0% in the intervention group maintained good control, whereas those in the control group showed significant HbA_{1c} aggravation. Therefore, the IBGMS not only allowed for the patients to maintain steady levels of glucose but improved the degree of their glucose control as well.

Internet-based disease management for chronic diseases are becoming popular universally. Numerous online education, exercise, and nutrition programs are used by the diabetic patients and their family. Most of the Internet disease management programs for diabetes evolved from focusing on emotional support to providing more information to engage the patients and allow self-management and counseling (21–23). No study has been made to test the direct efficacy of the Internet systems on controlling glucose control. However, our study results show evidence that online services are as effective as face-to-face guidance and treatment in managing diabetes.

The IBGMS introduced here has further potential for development to more advanced networking systems, which would allow close communication between the network center (the physician) and the personal computer (the patients). For example, the mobile phones or camera phones of the patients could allow the physicians to send messages immediately after the test results come out. In addition,

Table 4—*Comparison of HbA_{1c} between intervention and control groups*

Patients	*n*	HbA_{1c} (%)	*P**
Total			<0.001
Control	50	7.62 ± 0.13	
Intervention	51	6.94 ± 0.13	
HbA_{1c} <7% at baseline			0.046
Control	26	6.99 ± 0.18	
Intervention	18	6.38 ± 0.22	
HbA_{1c} ≥7% at baseline			<0.001
Control	24	8.12 ± 0.19	
Intervention	33	7.38 ± 0.16	

Data are means ± SE. Means were adjusted according to HbA_{1c} at baseline. **P* for control vs. intervention.

the system would allow the networked feedback of patient information, such as details of a hypoglycemic accident or images of a diabetic ulcer to the networks center.

Although we have demonstrated that this new Internet-based system can reduce HbA_{1c} levels remarkably during a short-term study period of 12 weeks, the long-term effectiveness remains to be determined. To further the development, more trials and studies are needed.

Finally, we would like to comment that the Internet technology makes it possible to transcend the traditional face-to-face treatment for diabetes management. We expect this IBGMS will become generalized around the world because of the ease with which both the physician and patient can use the system. Furthermore, the advantages of continued Internet penetration into the general population, as well as the development of more advanced information technology will help the distribution of this new system in daily clinical practice.

Acknowledgments— This work was supported by the 2001 Korea Health Promotion Research Program and the Korea Health 21 R&D Project, Ministry of Health and Welfare of Republic of Korea Grant 02-PJ1-PG3-21906-0004.

We thank John D. Piette for valuable comments and advice.

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