Five-Year Blood Pressure Control and Mortality Following Health Education for Hypertensive Patients

DONALD E. MORISKY, SCD, MSPH, DAVID M. LEVINE, MD, MPH, LAWRENCE W. GREEN, DRPH, SAM SHAPIRO, BS, R. PATTERSON RUSSELL, MD, AND CRAIG R. SMITH, MD

Abstract: Three health education interventions for urban poor hypertensive patients were introduced sequentially in a randomized factorial design: 1) an exit interview to increase understanding of and compliance with the prescribed regimen; 2) a home visit to encourage a family member to provide support for the patient's regimen; and 3) invitations to small group sessions to increase the patient's confidence and ability to manage his/her problem. Previous evaluation of the initial two-year experience demonstrated a positive effect of the educational program on compliance with the medical treatment and blood pressure control. Data accumulated over an additional three years, including mortality analysis, are now presented. The study group consisted of the same cohort of 400

Introduction

Health education has come under harsh criticism for its failure to document "notable success",¹ to alter behavior meaningfully,² and its heavy emphasis on short-term cognitive and affective changes rather than long-term behavioral and medical changes.^{3,4} Reviews of the literature reveal that only a few studies report long-term maintenance of behavior and few studies until recently employed a randomized experimental-control design.^{5,6}

In order to examine the long-term effects of a health education program on weight control, appointment-keeping behavior, blood pressure (BP) control and mortality, a cohort of 400 hypertensive patients from various randomized educational experiences was followed for five years.

Materials and Methods

Study Subjects

The sampling unit consisted of diagnosed hypertensive outpatients attending the Hamman-Baker Internal Medical

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ambulatory hypertensive outpatients in the eight experimental and control groups. The five-year analysis shows a continuing positive effect on appointment keeping, weight control, and blood pressure control. All-cause life table mortality rate was 57.3 per cent less for the experimental group compared to the control group (12.9/100 vs 30.2/100, p < .05), while the hypertension-related mortality rate was 53.2 per cent less (8.9/100 vs 19.0/100, p < .01). The results from this longitudinal study provide evidence to encourage health practitioners to utilize such educational programs in the long-term management and control of high blood pressure. (*Am J Public Health* 1983; 73:153–162.)

Clinic (68 per cent) or the Adult Hypertension Clinic (32 per cent) of the Johns Hopkins Hospital during January through March 1975. The clinics were treated as two separate strata within which sampling procedures were applied. To be eligible for participation, patients had to have been receiving care at the Hospital at least six months prior to selection. A total of 400 patients were selected, 91 per cent Black, and 70 per cent female; they had a median age of 54 years, a median income of \$4,250, and a median of eight years of formal education. Patients had been receiving care at the Johns Hopkins Hospital for an average of six years.

Needs Assessment

Data from a previous survey of 305 prior patients in the same clinics showed high levels of knowledge about hypertension, its treatment, and the possible consequences of nontreatment, as well as positive beliefs in the benefits of treatment for BP control. Moreover, whatever variance existed was not correlated significantly with compliance or with blood pressure control. Patients did indicate, however, confusion regarding their own specific therapy and difficulty incorporating it into their daily schedule. Seventy per cent expressed a need for members of their family to learn more about hypertension; many others indicated family attitude was negative; still others reported discouragement and lack of confidence in their ability to manage their BP.

These and related problems identified in the diagnosticbaseline survey posited the need to clarify individual regimens, to engender family and social support, and to build patients' self-confidence. A three-phased educational program, consisting of an exit interview (E_1) , a family support

From the Johns Hopkins Medical Institutions, Health Services Research and Development Center, and the Division of Health Education, School of Hygiene and Public Health. Dr. Morisky is now at the UCLA School of Public Health. Address reprint requests to Lawrence W. Green, Center for Health Promotion Research and Development, University of Texas Health Science Center, P.O. Box 20708, Houston, TX 77025. This paper, submitted to the Journal August 14, 1981, was revised and accepted for publication September 2, 1982.

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TABLE	1—Size c	of Stud	dy Groups	Ac	cord	ling to	Ran	dom A	\ssign-
	ment	and	Exposure	to	the	Comp	lete	Educ	ational
	Interv	entior	ns in the C	com	nbina	ation À	ssig	ned	

Combinations	Number of Patients Randomly Assigned	Number of Patients Completing the Ful Combination*		
 C1C2C3	50	50		
E ₁ C ₂ C ₃	50	50		
C ₁ E ₂ C ₃	50	40		
C ₁ C ₂ E ₃	50	28		
E ₁ E ₂ C ₃	50	24		
E ₁ C ₂ E ₃	50	15		
C ₁ E ₂ E ₃	50	19		
$E_1E_2E_3$	50	13		

*C = Control; E₁ = Exit Interview; E₂ = Family Support; E₃ = Small Groups. Each combination indicates the interventions introduced sequentially in a randomized factorial procedure. For example, E₁E₂E₃ includes the patients who were randomly assigned to the exit interview in Phase I; E₂ the patients with an exit interview assigned to family support in Phase II; and E₃, the patients with both an exit interview and family support assigned to small groups in Phase III.

approach (E₂), and a small group process (E₃), was designed to address each of these treatment problems in sequence. The interventions were sequentially introduced approximately six months apart beginning in January 1975 with the least complicated and least expensive and ending with the most complicated.^{7.8}

Educational Program Content

The exit interview, conducted immediately following the patient's encounter with his or her medical provider, was an individualized 5–10 minute counseling session explaining and reinforcing the instructions of the practitioner whom the patient had just seen, and adapting the regimen to the patient's individual schedule, cueing behaviors (e.g., medication taking) to daily activities (e.g., toothbrushing).⁹ All 200 patients randomly assigned to this intervention received it.

The second intervention consisted of an instructional session with an adult whom the patient identified as having the most frequent contact at home, usually a spouse. The education in this encounter discussed how the household member could help the patient adhere to the regimen and follow-up care.¹⁰ A total of 160 of the 200 patients randomly assigned to this intervention were interviewed.

The third intervention was a series of three, one-hour group sessions led by a social worker which patients were invited to attend. The purpose was to provide group support, to strengthen the self-confidence of patients through discussions centering on hypertension management and compliance. The sessions used a broad range of action-related procedures (e.g., role-playing, behavioral rehearsal, problem clarification, cognitive restructuring). A total of 96 of the 200 patients randomly assigned to the small group intervention attended at least one session.¹¹

Randomization Procedures

A randomized factorial design distributed the patients into experimental and control groups at each of the three phases of the educational program. On alternate weeks, patients seen in the two clinics were allocated to various intervention and control groups through simple random sampling procedures. Fifty per cent of those patients who had been experimentals in Phase I (Exit Interview) remained experimentals for Phase II (Family Support) and 50 per cent became controls. This accumulated sampling procedure also

TABLE 2—Comparison of 1975 Baseline Characteristics by Study Group

				Study	Group				
Variable	$C_1C_2C_3$	E ₁ C ₂ C ₃	$C_1E_2C_3$	C ₁ C ₂ E ₃	E ₁ E ₂ C ₃	E ₁ C ₂ E ₃	C ₁ E ₂ E ₃	E ₁ E ₂ E ₃	Sig.
Mean age	54.1	51.6	56.2	51.4	53.2	53.7	55.7	54.1	N.S.
Per cent female	66	72	66	76	66	76	76	62	N.S.
Per cent Black	90	96	92	86	94	94	96	94	N.S.
Mean years of diagnosed hypertension at time of									
entry to study	6.5	6.2	6.7	6.1	6.6	6.5	6.7	6.3	N.S.
Per cent high risk*	62	66	60	56	62	64	62	66	N.S.
Previous stroke or									
myocardial infarction	10	12	8	8	10	10	8	10	N.S.
History of angina or									
congestive heart failure	10	10	10	8	10	12	12	12	N.S.
Arteriosclerotic									
cardiovascular disease	10	10	10	10	8	12	10	12	N.S.
Kidney disease	2	2		_	2		2	2	N.S.
Diabetes mellitus	2	4	4	2	4	2	2	2	N.S.
Previous hospitalization									
for hypertension	6	6	4	4	6	6	6	8	N.S.
Black males < 50	6	4	6	6	4	6	6	2	N.S.
Combination of above risk									
factors	16	18	18	16	18	16	16	18	N.S.

*High risk = previous stroke or myocardial infarction, end organ damage, previously hospitalized for hypertension, or Black male less than 50 years of age.

Variable	Total Cohort (N = 400)	Patients Remaining in Treatment (N = 290)	Patients Discontinuing Medical Care (N = 64)	Patients Who Died during the Study (N = 46)
Mean age	54.1	54.4	51.8	55.3
Per cent female	75.5	75	79	74
Per cent Black	91.6	92	91	90
Median years of schooling Median 1974 household	8.2	8	9	8
income	\$4250	\$4250	\$4210	\$4280
Mean years of diagnosed hypertension at time	¢.200	\$,200	<i>Q</i> I Z I O	\$ 1200
of entry to study	6.1	6.1	5.9	6.3
Per cent high risk Previous stroke or	62	62	66	71
myocardial infarction History of angina or	10	9	12	11
congestive heart failure Arteriosclerotic	11	10	12	13
cardiovascular disease	10	9	10	11
Kidnev disease	2	3	1	2
Diabetes mellitus Previous hospitalization	3	3	4	4
for hypertension	6	6	5	7
Black males < 50 Combination of above	5	5	6	4
risk factors	17	17	16	19

TABLE 3—Comparison of the 1975 Baseline Characteristics for the Total Cohort, Patients Remaining in Treatment, Patients Discontinuing Medical Care, and Patients Who Died during the Five-Year Period

was used for those who were controls in Phase I. Randomization was further stratified for Phase III (Small Group) using the same procedures as in Phase II. The eight possible educational treatment combinations and the completion of all interventions in each combination are displayed in Table 1.

The compliance, weight control, appointment record, BP control, and mortality of patients randomly assigned to various combinations of the three interventions were included in experimental group results even when some patients did not complete interventions assigned to them. Not all patients necessarily received all components of the interventions to which they were randomized (Table 1). Comparative analyses of the assigned vs received intervention groups indicate no significant differences with respect to any of the outcome variables being investigated. Patients who were randomly assigned but opted not to participate at all in the third intervention had better BP control than those not randomized and those who did participate but attended only one of the three sessions.¹¹

Measurement

The patient's medical record was reviewed three times during the course of the study. Information collected con-

Study Group		Method 1		Method 2			
	% in Control	N	Rank	% in Control	N	Rank	
$C_1C_2C_3$	36	50	8	30	50	7.5	
E ₁ C ₂ C ₃	52	50	6	38	50	6	
$C_1 E_2 C_3$	68	50	4	54	50	4	
C ₁ C ₂ E ₃	44	50	7	30	50	7.5	
E ₁ C ₂ E ₃	46	50	5	40	50	5	
	76	50	1.5	60	50	2	
E ₁ E ₂ C ₃	74	50	3	58	50	3	
E ₁ E ₂ E ₃	76	50	1.5	66	50	1	

TABLE 4—Blood Pressure Control Status at Time of Dropout by Study Group for Individuals Who Discontinued Care during the Study Period by Method*

*Method 1: Assumes all dropouts continue their last BP control status as measured prior to dropout. Method 2: Assumes all dropouts are out of control (worst-case analysis)

	Base	line	2 Ye	ars	5 Years		
Study Group	Index	N‡	Index	N‡	Index	N‡	
$C_1C_2C_3$	19.3	50	27.2	36	26.0	30	
$E_1C_2C_3$	25.6	50	23.6	41	10.0	35	
$C_1E_2C_3$	12.2	50	14.7	35	10.2	36	
C ₁ C ₂ E ₃	11.3	50	15.7	40	16.5	32	
$E_1E_2C_3$	18.6	50	17.2	45	17.5	43	
E ₁ C ₂ E ₃	19.8	50	9.6†	37	5.6†	36	
	17.0	50	23.5	35	19.5	36	
$E_1E_2E_3$	11.1	50	4.3††	38	1.5††	42	
TOTAĽ	15.6*	400	17.0**	307	14.4***	290	

 TABLE 5—Deviation (in lbs) from Ideal Weight (Obesity Index) by Study Group for Baseline, 2

 Years and 5 Years

*F_{7,392} = 1.3; p = .36

**F_{7,299} = 1.8; p = .09

***F_{7,282} = 2.1; p = .04

†Significantly different from $C_1C_2C_3$ at p < .05

††Significantly different from $C_1C_2C_3$ at p < .01

The Ns represent the numbers of individual patients according to study group who had a recorded weight during the final 6 months of the respective observation period.

sisted of average systolic and diastolic BP, weight, appointment-keeping behavior, presence of cardiovascular-related risk factors,* and date of any terminal event (mortality or withdrawal from the study). Medical record abstractors were not aware of the treatment status of the patients.

Comparison of an individual's actual weight with a standard weight for height and age is used as the criterion of leanness or fatness.^{12,13} It was obtained at entry, between 18 and 24 months, and between 54 and 60 months.

Appointment-keeping behavior is measured by dividing the total number of appointments kept during a given time period by the total number of appointments scheduled. The baseline appointment-keeping period is six months preceding entry into the study. Two-year and three-year follow-up periods constitute the subsequent time intervals. Patients included in this analysis consist of those individuals who were in active care during the respective time period (i.e., had visited their doctor about their high BP during the last six months of the time period under consideration).

Overall adherence to the prescribed drug regimen was measured at two-years by a self-reported measure (low, medium, and high), which is a score totaled from patient's responses to four questions concerning their usual patterns of medication taking. Prior work had indicated this measure to be reliable (Cronbach alpha = 0.61), easily implemented, and to demonstrate predictive validity in regard to BP control.⁸

Baseline BP levels were determined by averaging systolic and diastolic measures found in the medical records over a six-month period (July–December 1974) prior to entry into the study. The median number of visits during this period was two. Using an age-adjusted measure of control that had been agreed on by physicians in the same clinic,¹⁴⁻¹⁶ only 40 per cent of the patients met the criteria for blood pressure control at the start of the study.**

If either the systolic or diastolic reading exceeded the limit set for controlled BP, the BP was considered elevated. Similar averaging was done for the two-year and five-year follow-up. Individuals measuring and abstracting the BP were not aware of the treatment status of the patients.

Of the original sample, 290 patients were alive and still being followed in their respective clinics, while 110 patients did not have a clinic appointment during the last six months of the five-year follow-up. Maryland State vital registrations identified 46 of these as deaths (11.5 per cent of the original

 TABLE 6—Appointment-Keeping Ratio by Study Group for Year

 2 and Year 5

	2 Ye	ars	5 Ye	ars			
Study Group	Ratio	N	Ratio	N	Change	EI	
C ₁ C ₂ C ₃	.63	40	.83	30	.20	54	
E ₁ C ₂ C ₃	.70†	46	.81	35	.11	37	
C ₁ E ₂ C ₃	.78††	42	.92†	36	.14	64	
C ₁ C ₂ E ₃	.66	44	.80	32	.14	41	
E ₁ C ₂ E ₃	.74††	47	.83	43	.09	35	
$C_1E_2E_3$.66	43	.95††	36	.29	85	
E ₁ E ₂ C ₃	.75††	44	.93††	36	.18	72	
E ₁ E ₂ E ₃	.68	44	.95††	42	.27	84	
TOTAL	.70*	350	.86**	290	.16	53	

 $*F_{7,342} = 1.67; p = .11$

**F_{7,282} = 7.032; p < .001

†Significantly different from $C_1C_2C_3$ at p < .05

††Significantly different from $C_1 C_2 C_3$ at p < .01

^{*}High-risk = history of target organ damage (heart, brain, kidney) previously hospitalized for hypertension, or being a Black male under 50 years of age.

^{**}The criteria were as follows: for patients under 40 years of age, greater than 140/90 mm Hg was considered elevated BP; age 40-59 years, greater than 150/95 mm Hg was considered elevated BP; and for those age 60 years or older, greater than 160/100 mm Hg was considered elevated BP.

		Percentage with BP in Control								
Baseline		Year 2		Year 5						
%	N	%	N	%	N	El†	p‡			
41	50	42	40	50	30	15.3	.73			
40	50	41	46	54	35	23.3	.61			
37	50	48	42	75**	36	60.3	.01			
34	50	52	44	46	32	18.1	.87			
40	50	53	47	47	43	11.6	.78			
41	50	54*	43	83**	36	71.2	.02			
45	50	55*	44	81**	36	65.4	.02			
38	50	66**	44	79**	42	66.1	.03			
40	350	52*	310	66*	260	43.3	.02			
	Bas % 41 40 37 34 40 41 45 38 40	Baseline % N 41 50 40 50 37 50 34 50 40 50 41 50 34 50 45 50 38 50 40 350	Baseline Yea % N % 41 50 42 40 50 41 37 50 48 34 50 52 40 50 53 41 50 54* 45 50 55* 38 50 66** 40 350 52*	Baseline Year 2 % N % N 41 50 42 40 40 50 41 46 37 50 48 42 34 50 52 44 40 50 53 47 41 50 54* 43 45 50 55* 44 38 50 66** 44 40 350 52* 310	Baseline Year 2 Year % N % N % 41 50 42 40 50 40 50 41 46 54 37 50 48 42 75** 34 50 52 44 46 40 50 53 47 47 41 50 54* 43 83** 45 50 55* 44 81** 38 50 66** 44 79** 40 350 52* 310 66*	Percentage with BP in Cont Baseline Year 2 Year 5 % N % N 41 50 42 40 50 30 40 50 41 46 54 35 37 50 48 42 75** 36 34 50 52 44 46 32 40 50 53 47 47 43 41 50 54* 43 83** 36 45 50 55* 44 81** 36 38 50 66** 44 79** 42 40 350 52* 310 66* 260	Percentage with BP in Control Baseline Year 2 Year 5 % N % N % N EI† 41 50 42 40 50 30 15.3 40 50 41 46 54 35 23.3 37 50 48 42 75** 36 60.3 34 50 52 44 46 32 18.1 40 50 53 47 47 43 11.6 41 50 54* 43 83** 36 71.2 45 50 55* 44 81** 36 65.4 38 50 66** 44 79** 42 66.1 40 350 52* 310 66* 260 43.3			

TABLE 7-Blood Pressure Control Status by Study Group for Year 2 and Year 5

*Significantly different from $C_1C_2C_3$ at p < .05

**Significantly different from $C_1C_2C_3$ at p < .01

†EI between baseline (P₁) and year 5 (P₂) where EI = $\frac{P_2 - P_1}{100 - P_1} \times 100$

tp-level between baseline (pre-program) and 5-year follow-up

cohort). An exhaustive follow-up through telephone interviews and state public assistance records revealed 47 of the remaining 64 patients to be alive in 1980. Vital status was not determined on 17 patients (4.2 per cent) who had discontinued their medical care at the Hospital and could not be located through any of the above follow-up procedures. There was no significant difference between these 17 individuals and the rest of the sample with respect to age, race, sex, weight control, complications from high BP or other cardiovascular risk factors (history of target organ damage, a previous hospitalization for hypertension), or BP control status at baseline and at two-year follow-up. Moreover, they were equally distributed among the intervention groups.

Date of death and all entries in the cause of death section were abstracted from each of the 46 death certificates, and the information was given to two cardiologists who independently judged whether the deaths were hypertension-related on the basis of: epidemiological evidence that high BP represented a significant risk factor (cerebrovascular, cardiovascular, and renal disease); high BP being considered an exacerbating factor; or malignant high BP being mentioned as the underlying cause of death. The concordance between the two clinicians was 100 per cent. The categorization of each cause of death is contained in Appendix A.

The issue of change in each of the dependent variables is handled by direct comparison of the variable across study group at T_1 (time 1) and T_2 (time 2). The degree of change was measured both within each study group over time, as well as by comparative analyses of experimental and control groups at similar points in time. An effectiveness index (EI), similar to the epidemiological measure of attributable risk, assesses the degree of change adjusted according to the groups' potential change.***17

Results

At baseline (1974), no significant differences were observed between any of the study groups with respect to such factors as race, sex, mean years of diagnosed hypertension, complications from high BP, or other related comorbidity (Table 2).

Based on initial two-year findings of a positive effect of the educational program on patient behaviors and blood pressure control,¹⁸ components of the family support intervention and exit interview were integrated into the routine care processes of the Adult Hypertension Clinic at that time, but not into the Internal Medical Clinic. Consequently, differentials between the experimental and usual care group were hypothesized to be smaller in the Adult Hypertension Clinic than in the Internal Medical Clinic by the end of the five-year period.

Table 3 compares the baseline characteristics of the 290 patients who were still in active care with those of the original sample, as well as with the 64 patients who discontinued care and the 46 patients who died during the five-year period. No significant differences were found.

The problem of differential dropout according to study groups was addressed by two methods: method 1 assumes that all dropouts continue their last recorded BP control status as measured prior to dropout; method 2 assumes that all dropouts would be out of control (worst case analysis). Both methods project the BP control rates to five years using the reconstituted study groups. Analyses indicated no change in ranking of groups by blood pressure control status (Table 4). $E_1E_2E_3$, and $C_1E_2E_3$, and $E_1E_2C_3$ rank first, second, and third, respectively, single interventions rank intermediate, and the usual care $C_1C_2C_3$ group ranks last in each method.

Weight Control

Two-thirds of the patients were told to lose weight and referred to a nutritionist in the hospital for dietary instruc-

^{***}EI = $P_2 - P_1/100 - P_1 \times 100$, where the numerator represents actual change between T_1 and T_2 and the denominator represents potential change at T_1 .



FIGURE 1—Blood Pressure Control Status for $C_1C_2C_3$ ("usual care") Group at Baseline, Two Years, and Five Years by Clinical Site of Treatment, Adult Hypertension Clinic (AHC) and Internal Medical Clinic (IMC)

tions. No differences in this proportion were noted between study groups. Analysis of variance using a factorial design with equal cell frequencies at baseline also indicated no significant differences in weight control between the eight study groups ($F_{7,392} = 1.3$; p = .36) (Table 5). Follow-up analyses at two and five years indicated a reduction in the obesity index for most of the groups assigned to any intervention, and an overall reduction of 1.5 lbs significant at p =.04, but an increase in this index for the usual care ($C_1C_2C_3$) group (19.3 lbs to 26.0 lbs).

Appointment-Keeping and Medication Compliance

No significant differences with respect to the ratio of appointments kept to appointments scheduled were noted between any of the eight study groups at baseline. The ratio for all study groups increased from 54 per cent to 70 per cent (p < .005) at the two-year period (Table 6). The educational program continued to demonstrate a positive impact on appointment-keeping behavior over the next three years, with a group mean of 86 per cent. The greatest improvement in the appointment-keeping ratio was found in the study groups assigned to the full combination of educational experiences and the study group assigned to the family member support and group discussion interventions.

The proportion of individuals reporting high compliance (score of 4 on the 4-item scale) with their antihypertensive drug regimen at baseline was 40 per cent, with no significant differences between any of the eight study groups. At the two-year follow-up period, all intervention groups (either singly or in combination) demonstrated some improvement over the control group. However, the combination of the exit interview and the family support intervention ($E_1E_2C_3$) demonstrated the strongest impact with 53 per cent reporting high compliance vs 40 per cent in the control group. The family support intervention alone ($C_1E_2C_3$) also achieved approximately the same effects.¹⁷

Blood Pressure Control Status

Table 7 presents blood pressure control status at baseline, and two and five-year follow-up. The McNemar procedure was used to test the significance of change between baseline ("before") and at the five-year period ("after") within each study group.¹⁹ A test of proportions was used to determine the level of statistical significance between each study group and the usual care group at the five-year period.²⁰

Study patients assigned to any of the experimental groups displayed a statistically significant 30 per cent increase in BP control at the two-year follow-up, and a statistically significant 65 per cent increase in BP control over the five-year period. Patients who initially received standard care $(C_1C_2C_3)$ displayed a nonsignificant 22 per cent increase in BP control over the five-year period. A comparison of the BP control status at year five between the group with no interventions and the experimental group also revealed a significant difference.

As displayed in Table 7, the proportion of individual patients having their BP under control in the groups assigned to the family support intervention in combination with the

	Contro	Control for Interventions 1 Through 3				Educational Interventions 1 Through 3				
	Baseline		Year 5		Baseline		Year 5			
Diastolic Pressure, mm Hg	%	N	%	N	%	N	%	N		
<90	32	16	47	14	37	129	70	181		
91 9 5	22	11	7	2	13	44	14	36		
96-105	28	14	40	12	30	105	9	23		
≥106	81	9*	6	2†	20	72 ‡	7	20§		
TOTAL	100	50	100	30	100	350	100	260		

TABLE 8—Change in Diastolic Blood Pressure (DBP)

*Includes one patient, representing 2.0% of the total with a DBP >120 mm Hg.

†Includes one patient, representing 3.3% of the total with a DBP >120 mm Hg.

†Includes nine patients, representing 2.6% of the total with a DBP >120 mm Hg.

§No patient with DBP >120 mm Hg.

 TABLE 9—Pearson Correlation Coefficients between Outcome

 Variables

		1	2	3	4
1.	Medication Compliance		rx		
2.	Appointment Keeping	.14*			
З.	Weight Control	.02	.17**		
4.	Blood Pressure Control	.22**	.26**	.04	

*p value <0.05 and >.01

**p value <0.01

exit interview or small group intervention or both was found to be significantly different from the usual care $(C_1C_2C_3)$ group at year two. This difference persisted at year five. This combination of interventions also demonstrated strong statistically significant gains in the proportion of individuals coming under control between year two and year five. These positive effects were noted both for patients in the Internal Medical Clinic (IMC) and the Adult Hypertension Clinic (AHC). A positive increase in the effectiveness index was noted for each study group's BP control level over the fiveyear period.

The usual care group $(C_1C_2C_3)$ displayed an average increase in BP control of 22 per cent over the five-year period (42 per cent to 50 per cent). Analysis according to clinic status, however, indicated that the entire increase in the proportion under control in the usual care group is accounted for by patients in the AHC, as shown in Figure 1, and the only period during which the increase in BP control in the usual care group was noted was between years two and five, after the positive aspects of the educational program had been introduced into routine procedures of the AHC, but not the IMC.

Additional analyses were carried out examining the change in diastolic BP between baseline and at five years (Table 8) for the usual care group and the experimental groups combined. Both groups were equivalent at baseline with 32 per cent and 37 per cent of the usual care and experimental groups, respectively, having diastolic BP less than or equal to 90 mm Hg. Preintervention and five-year follow-up comparisons demonstrated little change in the usual care group, with slight increases in the proportion in the 90 mm Hg or less group (15 percentage points), but similar increases in the 96-105 mm Hg group (12 percentage points). The combined experimental groups, however, demonstrated strong improvements of diastolic BP, with proportional shifting from higher to lower categories. While 50 per cent of patients in the experimental group had moderate or severe diastolic hypertension (96 mm Hg or greater) before intervention, only 16 per cent had such hypertension at five years. In contrast, the usual care group had slightly smaller percentages in these categories before intervention (46 per cent) but exhibited little change at five years.

Other analyses of the two-year data have demonstrated that the positive effect on BP control was not a function of the number of patient contacts, but rather the content of the interaction, and that the contact provided by the medical care system needed to be supplemented by support outside

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TABLE 10—Mortality from All Causes by Study Group during Five-Year Follow-up, Patient Hypertension Education Project

Study Group	Sample Size	Deaths	Life Table Death Rate per 100 (SE)*
C1C2C3	50	11	30.2 (8.3)
E ₁ C ₂ C ₃	50	4	11.9 (6.1)
C ₁ E ₂ C ₃	50	8	16.5 (5.3)
	50	6	17.6 (7.1)
E ₁ C ₂ E ₃	50	2	6.6 (4.8)
C ₁ E ₂ E ₃	50	3	9.5 (5.8)
E ₁ E ₂ C ₃	50	8	22.0 (6.8)
E,E,E,	50	4	8.6 (4.1)
All Experimental			
Groups	350	35	12.9 (2.2)*

*Standard error of cumulative proportion surviving; 95% confidence limits for differences in Experimental Groups vs $C_1C_2C_3 = 1.53 - 32.13$; p < .05. Per cent reduction in mortality for Experimental Group vs $C_1C_2C_3$ Group = Experimental rate – Control rate/Control rate \times 100.

the system. Only 7 per cent of the variance in BP control explained by the educational program was attributable to contact alone, the remainder being attributable to content and an interactive combination of contact and content.^{9,21}

Relationship between Dependent Variables

A review of Tables 5 through 8 indicates that patients who were assigned to the various educational interventions generally improved their weight-control and appointmentkeeping behaviors and blood pressure control levels from baseline. Table 9 presents the relationship between the various dependent variables being analyzed in this study. As noted in this Table, there are significant positive relationships between medication taking and appointment keeping. as well as appointment keeping and weight control. The strongest correlations are between BP control and medication compliance and BP control and appointment keeping. Continuity of care, as measured by appointment keeping is positively related to medication compliance, weight control, and BP control. Thus, individuals who improved on one dependent variable tended to improve on others, in particular, those who achieved BP control.

General and Hypertension-Related Mortality

The computation of the survival function is based on the actuarial method described by Berkson and Gage.²³ The cumulative survival rate for the entire cohort at the end of the five-year period was 88.7 ± 2.2 . Numbers of deaths and five-year life table death rates for the "usual care" and experimental groups are given in Table 10. The five-year all cause mortality rate for the usual care group was 30.2 ± 8.3 compared to 12.9 ± 2.2 for the combined experimental groups, which represents a 57.3 per cent reduction in mortality (p < .05) when various combinations of health education interventions are added to usual care for hypertensive patients of the kind in this study. Furthermore, each study group demonstrated a reduction in mortality compared to the usual care group.

		Us	sual Care			P-Level-Usual			
Year	Number	Deaths	Lost to Follow-up	Cumulative Mortality	Number	Deaths	Lost to Follow-up	Cumulative Mortality	Experimental Group*
1	50	3	1	.07	350	13	6	.04	.79
2	46	3	0	.14	331	7	4	.06	.17
3	43	3	1	.21	320	6	3	.08	.03
4	39	0	0	.21	311	4	2	.10	.05
5	39	2	0	.30	304	5	0	.13	.02

TABLE 11—Five-Year All Cause Annual Life Tables for Usual Care and Experimental Groups

*Mantel N, Haenszel W: Statistical Aspects of the Analysis of Data from Retrospective Studies of Disease. J Nat'l Cancer Inst. 1959; 22:719–748.

Table 11 presents annual cumulative life table mortality rates for the usual care and the experimental groups and indicates that the rate is lower in the experimental group in each year of the study, with statistically significant lower rates for years 3-5 compared to the rates for the usual care group.

The five-year life table hypertension-related survival rate for the entire study population was 89.7 ± 1.9 . Hypertension-related deaths comprised 67 per cent of all deaths. As demonstrated in Table 12, the hypertension-related mortality rate varied significantly between the experimental and usual care groups with the proportion of hypertension-related deaths being 2.4 times greater in the latter group. The life table analysis indicated a 53 per cent reduction in hypertension-related mortality between experimental and usual care groups. As was the case with all-cause mortality, each individual study group demonstrated a reduction in mortality compared to the usual care group.

Discussion

These results compare favorably with other programmatic efforts and, in particular, with the Hypertension Detection and Follow-Up Program (HDFP).²³ All cause mortality rates were 57.3 per cent lower in the experimental group than in the control group, as compared to a 17 per cent difference between the 6.4 and 7.7 mortality rates in the HDFP stepped care (SC) and referred care (RC) groups, respectively. Provisional data from the HDFP on causespecific mortality indicated the number of deaths from cerebrovascular disease was smaller by approximately 45 per cent for the SC group as compared to the RC group; for coronary heart disease, it was 15 per cent; and for those from hypertension, about 36 per cent.²⁴ Comparative data in the Hopkins study indicate the number of deaths from cerebrovascular disease was smaller by approximately 80 per cent for the experimental group, for ischemic heart disease it was 50 per cent, and for those from hypertension it was also 50 per cent.

In interpreting these comparisons, it is important to note that the patients sampled at Hopkins were at higher risk for complications of high BP than the HDFP sample. The Hopkins sample was older (median age 56 vs 51 in the

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HDFP); a larger proportion Black (91 per cent vs 44 per cent); and a higher distribution of BP complications (59 per cent vs 32 per cent). All-cause mortality was directly related to age in the HDFP, rising from 3.3 (age 30-49) to 12.7 (60-69 years) in the stepped care (SC) and 3.5 to 15.2 respectively in the referred care (RC). While the overall reduction in mortality between SC and RC was 17 per cent, it was only 5.7 per cent in the 30-49 age group; in the 50-59 year group, reduction was 25.3 per cent. Likewise, both Black males and females displayed higher death rates than White males. The Hopkins sample had almost threefold the proportion of Black females, the group experiencing the largest reduction in comparative mortality, as well as an older population. The variance that may have existed by community in the 14community HDFP study was not reported. Unlike the HDFP interventions, the specific interventions in the Hopkins study were based on behavioral theory and an educational diagnosis of the needs of this population. They were designed to be reinforcing over time in the patient's usual medical and home circumstances. All interventions were linked to daily life circumstances and sources of support. Each intervention was specific to a particular problem

TABLE 12—Hypertension-Related Mortality by Study Group during Five-Year Follow-up, Patient Hypertension Education Project

Study Group	Sample Size	Deaths	Life Table Death Rate Per 100 (SE)*
C ₁ C ₂ C ₂	50	8	19.0 (6.1)
E ₁ C ₂ C ₃	50	3	9.7 (5.9)
C ₁ E ₂ C ₃	50	5	10.6 (4.5)
C ₁ C ₂ E ₃	50	3	7.7 (4.3)
E ₁ C ₂ E ₃	50	2	6.6 (4.8)
C ₁ E ₂ E ₃	50	3	9.5 (5.8)
E ₁ E ₂ C ₃	50	4	11.9 (6.1)
E ₁ E ₂ E ₃	50	3	6.6 (3.7)
All Experimental			
Groups	350	23	8.9 (1.9)*

*Standard error of cumulative proportion surviving; 95% confidence limits for differences in Experimental Groups vs $C_1C_2C_3 = 6.1 - 18.8$; p < .01. Per cent reduction in mortality for Experimental Group vs $C_1C_2C_3$ Group = Experimental rate – Control rate/Control rate × 100.

identified during the baseline educational diagnosis. Such an approach minimizes decay of behavioral changes. It has been raised that, because the program was designed as a group experiment, the interventions were not individually tailored (e.g., family support was not necessarily offered to all experimental groups to whom it may have been important). This is true, but the experimental design was developed to test the separate and combined effects of the interventions on a randomized group of patients. Given the significant findings of the educational program, without tailoring, would therefore represent a minimal level of effectiveness. The positive effects of dietary, appointment keeping and drug compliance behaviors, as well as BP control appear to have occurred for a five-year period. Other studies have noted that such socially supportive and self-reinforcing interventions may have a broader effect in simultaneously inducing other cardiovascular risk behaviors, e.g., exercise, smoking cessation, and stress reduction.25,26 These relationships, however, cannot be examined within the context of this study.

Analysis of the individual experimental groups suggests that BP control was more likely to result by using a combination of interventions, but the type of intervention was also found to differentiate outcome levels. Such control was not related to the frequency of provider-patient interaction, but was strengthened most notably by the involvement of family members in the patient's care. All intervention groups demonstrated an improvement in survivorship compared to the control group.

Neither the effect on BP control or mortality reduction was related to differences in baseline characteristics between experimental and control groups. Notably, however, there was a differential effect on BP control within the nonintervention group between the control patients treated in the Adult Hypertension Clinic (AHC) compared to those treated in the Internal Medicine Clinic, but only after introduction of components of the educational program (i.e., the exit interview and family support) into the ongoing care of AHC patients in years 3, 4 and 5.

Subsequent experiences with the providers of care in the Adult Hypertension Clinic of the Johns Hopkins Hospital and health care providers in a variety of practice settings in a larger statewide high BP control program^{28,29} have indicated the relative ease of implementing components of the program evaluated here. It is not this specific program that should be recommended for a variety of different populations in various care settings. Rather, it is the diagnostic approach to planning and adapting the individual components of such a program to predispose, enable, and reinforce behavior conducive to health that has generalizability to a variety of populations in different organizations of care. Moreover, the principles of developing highly targeted reinforcing interventions, based on an educational diagnosis and assessment of needs, directed at influencing specific health behaviors, should have similar applicability in other aspects of medical care, public health, and health promotion.

REFERENCES

 Cohen CI, Cohen E: Health education: Panacea, pernicious or pointless? N Engl J Med 1978; 299:718–720.

- 2. Hosay PM: The unfulfilled promise of health education. NY Univ Educ Q 1977; 2:16-22.
- Glanz K, Kirsch J, Rosenstock I: Linking research and practice in patient education for hypertension. Med Care 1981; 18:141– 152.
- 4. Haggerty RJ: Changing lifestyles to improve health. Prev Med 1977; 6:276-289.
- 5. Green LW: Determining the impact and effectiveness of health education as it relates to federal policy. Health Educ Monogr 1978; 6:28-66.
- 6. Haynes RB, Taylor DW, Snow JC, et al: Annotated and indexed bibliography on compliance with therapeutic and preventive regimens. In: Haynes RB, Taylor DW, Sackett DL (eds): Compliance in Health Care. Baltimore: Johns Hopkins Press, 1979, 337-423.
- 7. Green LW, Levine DM, Deeds SG: Clinical trials of health education for hypertensive outpatients: design and baseline data. Prev Med 1975; 4:417-425.
- 8. Morisky DE, Levine DM, Green LW, Smith CR: Health education program effects on the management of hypertension in the elderly. Arch Intern Med 1982; 142:1835–1838.
- 9. Chwalow AJ, Green LW, Levine DM, *et al*: Effects of the multiplicity of interventions on the compliance of hypertensive patients with medical regimens in an inner-city population. Prev Med 1978; 7:51.
- 10. Fass MF: The role of health education in hypertension control. Fam Community Health 1981; 4:73-84.
- 11. Bowler MH, Morisky DE, Deeds SG: Needs assessment strategies in working with compliance issues and blood pressure control. Patient Couns Health Educ 1980; 1:22-27.
- 12. Society of Actuaries: Build and Blood Pressure Study. Chicago: the Society, 1959.
- Weight by Height and Age of Adults 18-74 Years. Washington, DC: US Department of Health, Education, and Welfare, DHEW Pub. No. (PHS) 14, 1977.
- Brooks RB, Appel F: Quality of care assessment: Choosing a method for peer review. N Engl J Med 1973; 258:1323-1329.
- 15. Fletcher SW, Appel FA, Bourgeois MA: Management of hypertension: effects of improving patient compliance for follow-up care. JAMA 1975; 233:242-244.
- Inui TS, Yountee EI, Williamson JW: Improved outcomes in hypertension after physician tutorial. Ann Intern Med 1976; 84:646-651.
- 17. Hovland CI, Lumsdaine A, Sheffield FD: Experiments on Mass Communication. New York: John Wiley and Sons, 1949.
- 18. Levine DM, Green LW, Deeds SG, *et al.* Health education for hypertensive patients. JAMA 1979; 241:1700–1703.
- 19. Siegel S: Nonparametric Statistics for the Behavioral Sciences. New York: McGraw-Hill, 1956.
- Kim JO, Kohout FJ: Analysis of variance and covariance. In: Statistical Package for the Social Sciences. New York: McGraw-Hill, 1970.
- Chwalow AJ: Effects of the multiplicity of contacts on compliance with medical regimens for hypertensive outpatients in an inner city clinic population. Doctoral dissertation, Johns Hopkins University School of Hygiene and Public Health, Baltimore, 1978.
- 22. Berkson J, Gage R: Calculation of survival rates for cancer. Proceedings of the Mayo Clinic 1950; 25:270–292.
- 23. Hypertension Detection and Follow-up Program Cooperative Group: Five-Year Findings of the Hypertension Detection and Follow-up Program. I. Reduction in Mortality of Persons with High Blood Pressure, Including Mild Hypertension. JAMA 1979; 242:2562-2571.
- Hypertension Detection and Follow-up Program Cooperative Group: Five-Year Findings of the Hypertension Detection and Follow-up Program. III. Reduction in Stroke Incidence among Persons with High Blood Pressure. JAMA 1982; 247:633-638.
- 25. Bertera RL: The effects of blood pressure self-monitoring in the workplace using automated blood pressure measurement. Doctoral dissertation, Johns Hopkins University School of Hygiene and Public Health, Baltimore, 1981.

- Alderman M, Green LW, Flynn BS: Hypertension control programs in occupational settings. Public Health Rep 1980; 95:158-163.
- 27. Levine DM, Green LW, Russell RP, *et al*: Compliance in hypertension management: what the physician can do. Prac Cardiology 1979; 5:151-160.
- Levine DM, Morisky DE, Bone LR, et al: Data-based planning for educational interventions through hypertension control programs for urban and rural populations in Maryland. Public Health Rep 1982; 7:171-182.

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Appendix A Hypertension-Related and Non-Hypertension Related Causes of Mortality* by Major Subclassifications

Hypertension-Related		Non-Hypertension Related		
Α.	. Cerebrovascular		1.	Cirrhosis
	1.	Atherothrombic Brain Infarction	2.	Malignant Neoplasm- Ileocaecum
	2.	Cerebrovascular accident (CVA)	3.	Malignant Neoplasm- Stomach
	3.	Pontine	4.	Malignant Carcinoma- Esophagus
	4.	CVA-Left Internal Capsule	5.	Dementia, Chronic Brain Syndrome
	5.	Atheroma of Cerebral Artery	6.	Laennec's Cirrhosis
	6. 7	Cerebral Anoxia	7.	Budd-Chiari Syndrome Pancreatitis
B. Ischemic H		ic Heart Disease	9.	Metastatic Small Cell Tumor
	8–13.	MI-Total of 6	10.	Body Burns
	14–17.	ASCVD-Total	11.	Unstable Gastric
		of 4		Carcinoma
	18.	Cardiac Disease	12.	Chronic Brain Syndrome
	19.	HCVD	13.	Metastatic Carcinoma of the Abdomen
	20.	Coronary Atheroma	14.	Metastatic Carcinoma of the Pancreas
	21.	Hypertensive Cardiovascular	15.	Chronic Aggressive Hepatitis with Cirrhosis
	22–23.	Severe Cardiac Disease—Total		
	24.	Transmural Myocardial Infarction		
	25.	Cardiopulmonary Arrest		
C.	Renal			
	26–28.	Kidney Failure— Total of 3		
	29.	Atherosclerotic Nephritis		
D.	Maligna 30–31.	ant Hypertension Malignant Hypertension— Total of 2		

^{*}In those death certificates which listed cardiopulmonary or cardiorespiratory arrest as the leading cause of death, the underlying pathophysiological basis of death was elaborated.